

MPR

HEALTH SYSTEMS DRUG REFERENCE

2014 EDITION



BONUS
Clinical Resource
Section: Page 395

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Dear Healthcare Professional,

Teva Pharmaceuticals, the nation's leading generic manufacturer, markets approximately 400 products from all major therapeutic categories, including cardiovascular, oncology, anti-infective, CNS, anti-inflammatory, antidiabetic, analgesic, and respiratory. Teva's drug forms include tablets and capsules, sterile injectables in vials and bags, ointments, creams, and liquids.

Teva is committed to the continuing professional development of clinicians by offering high-quality educational tools to serve as convenient, authoritative references in daily use. In keeping with this goal, we are proud to sponsor the 2014 edition of the *MPR Health Systems Drug Reference*.

The *MPR Health Systems Drug Reference* contains concise drug monographs derived from FDA-approved labeling and written by a staff of experienced pharmacists. The monographs are organized into therapeutic sections to make it simple to find the information you need quickly.

Unlike other drug reference guides, the *MPR Health Systems Drug Reference* includes a wide variety of drugs your patients may be taking; it is not limited to a single category of drugs. In addition to concise drug monographs, you will also find a Clinical Resource Section containing charts on Common Medical Abbreviations, Oncology Terms, Sugar-free and Alcohol-free Products, and more.

As the *MPR Health Systems Drug Reference* becomes a trusted tool in your clinical armamentarium, please know that we at Teva take enormous pride in and are committed to providing you with valuable educational aids to assist you in caring for your patients.

Sincerely,

A handwritten signature in black ink that reads "Kevin P. Galownia". The signature is written in a cursive, flowing style.

Kevin P. Galownia
Sr. Director, Marketing

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IMPORTANT INFORMATION FOR READERS

The *MPR HEALTH SYSTEMS DRUG REFERENCE* is an up-to-date drug reference to commonly prescribed pharmaceuticals, as well as certain OTC products. It has been produced to provide an easily accessible reminder of basic information useful to review when prescribing medications, such as specific indications for use, dosage, and a checklist of precautions, interactions, and adverse drug reactions. Reference should always be made to each drug being co-administered. The information it contains is intended solely for use by the medical profession. **IT IS NOT INTENDED FOR LAY READERS.** This reference has been assembled and edited by an experienced staff of pharmacists, utilizing information available from FDA-approved labeling. Distinctions have not necessarily been made between those reactions that are well-documented and/or clinically significant, and those that carry only a theoretical risk. A renowned board of consulting medical specialists has also independently reviewed the product references.

However, although every effort is made to assure accuracy, the information in the *MPR HEALTH SYSTEMS DRUG REFERENCE* is not necessarily reviewed by the supplier of a particular drug. If any questions arise about information in the *MPR HEALTH SYSTEMS DRUG REFERENCE*, the clinician should verify it against labeling or by contacting the company marketing the drug. The publisher, sponsor, and editors do not warrant or guarantee any of the products described or the information describing them. **THE PUBLISHER, SPONSOR, AND EDITORS DO NOT ASSUME, AND HEREBY EXPRESSLY DISCLAIM, ANY LIABILITY WHATSOEVER FOR ANY ERRORS OR OMISSIONS IN SUCH INFORMATION OR FOR ANY USE OF ANY OF THE PRODUCTS LISTED.**

No prescription drug should be used except on the advice of, and as directed by, a clinician. The training and experience of a clinician are essential to forming any opinion on the appropriateness of a specific drug for a specific patient. The information in this publication is not by itself sufficient for a lay person – or even a clinician – to evaluate the risks and benefits of taking any particular drug.

In reaching professional judgements on whether to prescribe a pharmaceutical, which to prescribe, and under what regimen, the clinician should thoroughly understand the options available for any clinical application, the potential effectiveness of each product, and the associated risks and side effects. This knowledge should be considered in light of the special circumstances of the patient, for each patient is unique. No single reference can substitute for medical training and experience. The clinician must be familiar with the full product labeling, provided by the manufacturer or distributor of the drug, of every product he or she prescribes, as well as the relevant medical literature.

Certain additional qualifications are important in using this book. First, the *MPR HEALTH SYSTEMS DRUG REFERENCE* has been deliberately kept concise, with a standardized format, so that it could be a convenient reference tool. This means that lengthy and detailed explanations about certain aspects of drugs commonly found in labeling are omitted or condensed.

Second, only the current issue should be used.

The prescribing decision is ultimately the responsibility of the clinician. The *MPR HEALTH SYSTEMS DRUG REFERENCE* is offered to assist clinicians in this area.

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For more drug information and other clinical resources, visit www.eMPR.com.

TYPICAL ENTRY

Key labeling information on the most commonly prescribed products and formulations.
The entries are concise, but they contain information needed when prescribing.

Generic name

Products are arranged in alphabetical order within sections by the generic name(s) of the active ingredient(s). Products with more than one indication appear in each appropriate section.

Brand name*

The manufacturer's trademark-protected name for this product. Products with more than one indication appear in each appropriate section.

Pharmacologic or chemical class

Precedes the generic name and appears in italics.

Indications

Only the use of the product relating to a particular therapeutic section is shown.

Contraindications

The product should generally not be given to patients with any of the conditions listed. Hypersensitivity to the drug, or others in its class, to related drugs, or to any of its excipients is assumed to be a contraindication in all entries.

Interactions

Potential clinically significant drug and some food and lab test interactions are listed.

How supplied

Package sizes for each dosage form and strength. Hospital-only packaging is not listed.

TORSEMIDE

DEMADEX Roche

Diuretic (loop). Torsemide 5mg, 10mg, 20mg, 100mg; scored tabs.

Also: TORSEMIDE INJECTION
DEMADEX INJECTION

Torsemide 10mg/mL; for IV injection.

Indications: Hypertension.

Adults: 5mg once daily, may increase to 10mg once daily. Give IV dose over a period of 2 minutes.

Children: Not recommended.

Contraindications: Anuria.
Sulfonamide allergy.

Precautions: Hepatic disease with cirrhosis and ascites. Monitor electrolytes, BUN, creatinine, uric acid, and fluids. Pregnancy (Cat.B). Nursing mothers.

Interactions: Lithium and salicylate toxicity. Caution with NSAIDs. Antagonized by probenecid and indomethacin. Give oral dose 2 hours before or 4 hours after cholestyramine. Ototoxicity with aminoglycosides and ethacrynic acid.

Adverse reactions: Dizziness, headache, nausea, weakness, vomiting, hyperglycemia, excessive urination, hyperuricemia, hypokalemia, excessive thirst, hypovolemia, impotence, esophageal hemorrhage, dyspepsia.

How supplied: Tabs—100
Ampules—2mL, 5mL

R Legal category

OTC, R, CII, CIII, CIV, or CV indicates federal schedule.

Company

The name of the company to contact for further medical information.

Generic names

The generic name(s) and clinically relevant excipients, followed by quantity of active ingredient and dosage form(s).

Dosage

Manufacturer's recommended doses. Children are defined as persons under 12 years of age unless stated otherwise. Doses for children are presented in ascending age or weight order. Elderly may be considered as adults unless stated otherwise.

Precautions

Clinical conditions requiring caution when using the drug. Recommended clinical tests or monitoring.

Adverse reactions

Common side effects encountered in clinical practice and important but less common adverse reactions. Severe reactions which need to be monitored may appear under "Precautions."

*Occasionally if there is no brand name drug marketed, the generic name may appear here.

SECTION 1: ALLERGIC DISORDERS 1A Allergies

CETIRIZINE

ZYRTEC McNeil Cons & Specialty
Antihistamine. Cetirizine HCl 10mg; tabs.

OTC

Also: Cetirizine
ZYRTEC LIQUID GELS

Cetirizine HCl 10mg; contains gelatin.

OTC

Also: Cetirizine

CHILDREN'S ZYRTEC CHEWABLE

Cetirizine HCl 5mg, 10mg; chew tabs; grape flavor.

OTC

Also: Cetirizine

CHILDREN'S ZYRTEC ALLERGY SYRUP

Cetirizine HCl 1mg/mL; grape flavor, and bubble gum (sugar- and dye-free) flavor.

OTC

Also: Cetirizine

CHILDREN'S ZYRTEC PERFECT MEASURE

Cetirizine HCl 1mg/mL; prefilled single-use spoons; grape flavor; sugar- and dye-free.

OTC

Indications: Allergic rhinitis.

Adults and Children: Chew tabs: may take with or without water. For doses <5mg: use syrup. <2years: not recommended. 2-6years: initially 2.5mg once daily; max 5mg once daily or 2.5mg every 12 hours. ≥6years: initially 5-10mg once daily. ≥65years: use chew tabs or syrup: 5mg once daily. Hepatic or renal impairment: individualize.

Also: Cetirizine

ZYRTEC HIVES RELIEF

Cetirizine HCl 10mg; tabs.

OTC

Also: Cetirizine

CHILDREN'S ZYRTEC HIVES RELIEF SYRUP

Cetirizine HCl 1mg/mL; grape flavor.

OTC

Indications: Itching due to urticaria.

Adults and Children: <6years: not recommended. ≥6years: initially 5-10mg once daily. ≥65years: use syrup: 5mg once daily. Hepatic or renal impairment: individualize.

Contraindications: Hydroxyzine sensitivity.

Warnings/Precautions: Hives Relief: not used for prevention or as a substitute for epinephrine. Hepatic or renal dysfunction. Pregnancy. Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants.

Adverse reactions: Drowsiness, somnolence, fatigue, dry mouth, pharyngitis. Children: headache, pharyngitis, GI upset/pain, cough, somnolence, diarrhea, epistaxis, bronchospasm, fatigue, irritability, insomnia.

How supplied: Tabs-5, 14, 30, 45, 75; Liquid gels-12, 25, 40; Chew tabs 5mg-5, 10mg-12, 24; Prefilled spoons (5mL)-10; Hives Relief tabs-14; Syrups-4oz

DESLOMATADINE

R

CLARINEX Merck

Antihistamine. Desloratadine 5mg; tabs.

Indications: Seasonal allergic rhinitis (for patients ≥2 years old). Perennial allergic rhinitis, chronic idiopathic urticaria (for patients ≥6 months old).

Adults: 5mg once daily. Renal or hepatic impairment: initially 5mg every other day.

Children: Use other forms.

Also: Desloratadine

R

CLARINEX SYRUP

Desloratadine 0.5mg/mL; bubble-gum flavor.

Adults and Children: <6months: not recommended. 6months-11months: 1mg (2mL).

1-5yrs: 1.25mg (2.5mL). 6-11yrs: 2.5mg (5mL). ≥12yrs: 5mg (10mL). All: once daily.

Also: Desloratadine

R

DESLOMATADINE ODT (various)

Desloratadine 2.5mg, 5mg; orally-disintegrating tabs; tutti-frutti flavor; contains phenylalanine.

Adults and Children: Dissolve on tongue; swallow with or without water. <6yrs: use other forms. 6-11yrs: 2.5mg once daily. ≥12yrs: 5mg once daily.

Renal or hepatic impairment: initially 5mg every other day.

Warnings/Precautions: Pregnancy (Cat.C).

Nursing mothers: not recommended.

Adverse reactions: Pharyngitis, dry mouth or throat, somnolence, headache, fatigue, myalgia, nausea, dizziness. Children: fever, diarrhea, upper respiratory infections, irritability, coughing.

How supplied: Tabs-100, 500; Syrup-4oz, 16oz; ODT-contact supplier

DIPHENHYDRAMINE

OTC

BENADRYL ALLERGY McNeil Cons & Specialty

Antihistamine. Diphenhydramine HCl 25mg; caps; tabs; dye-free liq-filled softgels.

Also: Diphenhydramine

OTC

BENADRYL ALLERGY CHEWABLES

Diphenhydramine HCl 12.5mg; chew tabs; contains phenylalanine; grape flavor; contains sodium 2mg/tab.

Also: Diphenhydramine

OTC

BENADRYL ALLERGY LIQUID

Diphenhydramine HCl 12.5mg/5mL; cherry flavor; dye- and sugar-free, bubble-gum flavor; alcohol-free; contains sodium 15mg/5mL.

Also: Diphenhydramine

OTC

BENADRYL PERFECT MEASURE

Diphenhydramine HCl 12.5mg/5mL; pre-filled single use spoons; cherry flavor; alcohol-free; contains sodium 15mg/5mL.

Indications: Symptoms of upper respiratory allergies. Rhinorrhea/sneezing due to common cold.

Adults: 25-50mg every 4-6 hours; max 300mg/day.

Children: <6years: individualize. 6-12years: 12.5-25mg every 4-6 hours; max 150mg/day.

Also: Diphenhydramine**BENADRYL INJECTION** Pfizer

Diphenhydramine HCl 50mg/mL; for IV or IM inj.

Indications: Allergic disorders where oral form is impractical or contraindicated. Adjunct in anaphylaxis. Allergic reactions to blood or plasma.**Adults:** 10–50mg IV or deep IM; max 400mg/day.**Children:** Neonates: not recommended. Others: 5mg/kg per day in 4 divided doses IV or deep IM; max 300mg daily in 4 divided doses.**Contraindications:** Neonates. Premature infants.

Acute asthma. Concomitant diphenhydramine products (including topicals).

Warnings/Precautions: Asthma and lower respiratory disorders. Glaucoma. Hyperthyroidism. Hypertension. Cardiovascular disease. GI or urinary obstruction. Sodium-restricted diet. Children. Pregnancy (Cat.B in 3rd trimester): not recommended. Nursing mothers.**Interactions:** Potentiates CNS depression with alcohol, other CNS depressants. Potentiates anticholinergic effects with MAOIs.**Adverse reactions:** Drowsiness, dizziness, anticholinergic effects, excitability in children.**How supplied:** Caps–24, 48; Tabs–24, 48, 100; Dye-free softgels–24; Chewable–24; Allergy Liq–4oz, 8oz; Dye-free Liq–4oz; Pre-filled spoons (5mL)–10; Inj Vial (10mL)–1; Amp (1mL) or syringe (1mL)–10

R

Warnings/Precautions: Elderly.**Interactions:** Potentiates CNS depression with alcohol, other CNS depressants.**Adverse reactions:** Drowsiness, dry mouth, tremor, convulsions.**How supplied:** Contact supplier.**LEVOCETIRIZINE**

R

XYZAL UCB and Sanofi Aventis

Antihistamine. Levocetirizine dihydrochloride 5mg; scored tabs.

Also: Levocetirizine

R

XYZAL ORAL SOLUTION

Levocetirizine dihydrochloride 0.5mg/mL.

Indications: Seasonal allergic rhinitis (for patients ≥ 2 years old). Perennial allergic rhinitis, chronic idiopathic urticaria (for patients ≥ 6 months old).**Adults:** 2.5mg–5mg once daily in the PM. Renal dysfunction: CrCl 50–80mL/min: 2.5mg once daily; CrCl 30–50mL/min: 2.5mg every other day; CrCl 10–30mL/min: 2.5mg twice per week (every 3–4 days); CrCl <10 mL/min or hemodialysis: contraindicated.**Children:** <6 mos: not recommended. 6mos–5yrs: max 1.25mg once daily in the PM. 6–11yrs: max 2.5mg once daily in the PM. Renal dysfunction: contraindicated.**Contraindications:** End-stage renal disease (CrCl <10 mL/min) or hemodialysis. Impaired renal function (<12 yrs of age).**Warnings/Precautions:** Do not exceed recommended dose. Predisposing factors of urinary retention (eg, spinal cord lesion, prostatic hyperplasia). Discontinue if urinary retention occurs. Pregnancy (Cat.B). Nursing mothers: not recommended.**Interactions:** Avoid alcohol, other CNS depressants. May be potentiated by theophylline. Potentiated by ritonavir.**Adverse reactions:** Adults: somnolence, nasopharyngitis/pharyngitis, fatigue, dry mouth. Children: pyrexia, somnolence, cough, epistaxis, diarrhea, constipation, vomiting, otitis media.**How supplied:** Tabs–90; Soln–150mL**FEXOFENADINE**

OTC

ALLEGRA Sanofi Aventis

Antihistamine. Fexofenadine HCl 60mg, 180mg; tabs.

Indications: Allergic rhinitis (seasonal). Chronic idiopathic urticaria.**Adults:** 180mg once daily or 60mg twice daily. Renal impairment: initially 60mg once daily.**Children:** Use Children's Allegra.**Warnings/Precautions:** Pregnancy (Cat.C).

Nursing mothers.

Interactions: Avoid concomitant aluminum- or magnesium-containing antacids.**Adverse reactions:** Adults: Headache, back pain, viral infection, GI upset, sinusitis, dizziness, drowsiness. Children: cough, fever, pain, otitis media, upper respiratory tract infection.**How supplied:** Tabs 60mg–12, 180mg–5, 30, 45, 70**HYDROXYZINE**

R

HYDROXYZINE HCl (various)

Antihistamine. Hydroxyzine HCl 10mg, 25mg, 50mg, 100mg; tabs.

Also: Hydroxyzine

R

HYDROXYZINE HCl SYRUP

Hydroxyzine HCl 10mg/5mL; contains alcohol 0.5%.

Indications: Allergic pruritus.**Adults:** 25 mg 3–4 times daily.**Children:** <6 yrs: 50mg daily. ≥ 6 yrs: 50–100mg daily. Both in divided doses.**Contraindications:** Early pregnancy. Nursing mothers.**MONTELUKAST**

R

SINGULAIR Merck

Leukotriene receptor antagonist. Montelukast (as sodium) 10mg; tabs.

Also: Montelukast

R

SINGULAIR CHEWABLE

Montelukast (as sodium) 4mg, 5mg; tabs; cherry flavor; contains phenylalanine.

Also: Montelukast

R

SINGULAIR ORAL GRANULES

Montelukast (as sodium) 4mg; per packet.

Indications: Seasonal allergic rhinitis (for patients ≥ 2 years old). Perennial allergic rhinitis (for patients ≥ 6 months old).

Adults and Children: Take granules by mouth within 15 minutes of opening packet; may dissolve in 5mL of cold or room temperature baby formula or breast milk, or mix in spoonful of soft applesauce, carrots, rice, or ice cream. <6months w/perennial allergic rhinitis or <2yrs w/seasonal allergic rhinitis: not established. 6-23months: one 4mg granule packet. 2-5yrs: one 4mg chew tab or granule packet. 6-14yrs: one 5mg chew tab. ≥15yrs: one 10mg tab. For all: take once daily.

Warnings/Precautions: Caution when withdrawing from oral steroids. Pregnancy (Cat.B). Nursing mothers.

Interactions: Monitor with potent CYP450 inducers (eg, phenobarbital, rifampin).

Adverse reactions: Upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis; neuropsychiatric events (monitor).

How supplied: Tabs, chew tabs-30, 90; Oral granules-30

PROMETHAZINE

R

PROMETHAZINE HCl INJECTION (various)
Phenothiazine. Promethazine HCl 25mg/mL, 50mg/mL; sol for IM or IV inj; contains sulfites.

Indications: Allergic reactions to blood or plasma. Uncomplicated allergic conditions of the immediate type where oral therapy is impossible or contraindicated. Adjunct in anaphylaxis.

Adults: 25mg IM or IV, if 2nd dose is needed, may repeat after 2 hours. Switch to oral form as soon as possible

Children: <2yrs: see Contraindications. ≥2yrs: should not exceed half that of suggested adult dose (see literature).

Contraindications: Children <2 years. Coma. Intra-arterial or subcutaneous injection.

Warnings/Precautions: Sulfite sensitivity. CNS depression. Impaired respiratory function (eg, COPD, sleep apnea). Narrow-angle glaucoma. GI or GU obstruction. Cardiovascular or liver disease. Seizure disorders. Peptic ulcer. Bone marrow depression. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Caution with epinephrine, anticholinergics, MAOIs. May alter hCG pregnancy test results and glucose tolerance tests.

Adverse reactions: Inj site reactions, CNS depression/drowsiness, lowered seizure threshold, cholestatic jaundice, anticholinergic and extrapyramidal effects, neuroleptic malignant syndrome, photosensitivity, hypo- or hypertension, rash, blood dyscrasias, nausea, dry mouth, paradoxical reactions; children: respiratory depression (may be fatal).

How supplied: Contact supplier.

1B Anaphylaxis

EPINEPHRINE

R

ADRENALCLICK Amedra
Sympathomimetic. Epinephrine 1mg/mL; 0.15mg/injection, 0.3mg/injection; auto-injection device; contains sulfites.

Indications: Emergency treatment of anaphylaxis.

Adults and Children: IM or SC inj into thigh. <15kg: not recommended. 15-30kg: 0.15mg. ≥30kg: 0.3mg.

Warnings/Precautions: Cardiovascular disease. Hypertension. Hyperthyroidism. Diabetes. Parkinson's disease. Advise patient to seek medical help immediately. Train patient in use of device. Elderly. Pregnancy (Cat.C).

Interactions: Potentiated by tricyclics, MAOIs, levothyroxine, antihistamines. Antagonized by β-blockers, α-blockers. Cardiac arrhythmias possible with concomitant digitalis, diuretics, antiarrhythmics. Pressor effects may be reversed by ergots, phenothiazines.

Adverse reactions: Tachycardia, palpitations, sweating, nausea, vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, restlessness, anxiety, arrhythmia.

How supplied: Auto-injector syringe-1, 2

EPINEPHRINE

R

EPIPEN DEY
Sympathomimetic. Epinephrine 0.3mg (1:1000); auto-injection device; contains sulfites.

Also: Epinephrine

R

EPIPEN JR
Epinephrine 0.15mg (1:2000); auto-injection device; contains sulfites.

Indications: Emergency treatment in anaphylaxis.

Adults: 0.3mg IM in thigh; may repeat if needed.

Children: 0.01mg/kg IM in thigh; may repeat if needed.

Warnings/Precautions: Cardiovascular disease. Hypertension. Hyperthyroidism. Diabetes. Advise patient to seek medical help immediately. Train patient in use of device. Elderly. Children. Pregnancy (Cat.C).

Interactions: Pressor effects may be potentiated by MAOIs, tricyclic antidepressants, furazolidone, antihistamines, levothyroxine, β-blockers, guanethidine. May be antagonized by nitrites, α-blockers, other rapid-acting vasodilators. Arrhythmias possible with digitalis, mercurial diuretics, quinidine, others.

Adverse reactions: Tachycardia, sweating, nausea, vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, nervousness, anxiety, arrhythmia.

How supplied: Packs-2

SECTION 2: CARDIOVASCULAR DISEASE 2A Angina

AMLODIPINE

NORVASC Pfizer

Calcium channel blocker (dihydropyridine). Amlodipine (as besylate) 2.5mg, 5mg, 10mg; tabs.

Indications: Vasospastic and chronic stable angina.

Adults: 10mg once daily. Elderly or hepatic impairment: 5mg once daily.

Children: Not recommended.

Warnings/Precautions: Severe obstructive coronary disease. Severe aortic stenosis. CHF. Hepatic dysfunction. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant simvastatin: limit simvastatin dose to 20mg/day. May potentiate cyclosporine.

Adverse reactions: Edema, fatigue, palpitations, dizziness, nausea, flushing, abdominal pain, drowsiness.

How supplied: Tabs 2.5mg, 10mg-90; 5mg-90, 300

ATENOLOL

TENORMIN AstraZeneca

Cardioselective beta-blocker. Atenolol 25mg, 50mg, 100mg; tabs.

Indications: Long-term management of angina.

Adults: Initially 50mg once daily. May increase after 1 week to 100mg daily; max 200mg/day. Elderly or renal impairment: may need lower dose; monitor trough BP. Coincide a dose for the end of hemodialysis.

Children: Not recommended.

Contraindications: Sinus bradycardia. 2nd or 3rd-degree heart block. Overt heart failure. Cardiogenic shock.

Warnings/Precautions: Bronchospastic disease. Renal dysfunction. Diabetes. Hyperthyroidism. Pheochromocytoma. Surgery. Avoid abrupt cessation. Peripheral circulatory disorders. Ischemic heart disease or failure. Pregnancy (Cat.D): not recommended. Nursing mothers.

Interactions: Additive effect with catecholamine-depleting drugs, prazosin, digoxin. Conduction abnormalities, bradycardia, heart block with calcium channel blockers (esp. verapamil, diltiazem). Increased rebound hypertension with clonidine withdrawal. May block epinephrine.

Adverse reactions: Heart failure, bronchospasm, bradycardia, angina, MI, heart block, dizziness, fatigue, GI upset, depression, orthostatic hypotension, cold extremities.

How supplied: Tabs 25mg, 100mg-100; 50mg-100, 1000

DILTIAZEM

CARDIZEM LA AbbVie

Calcium channel blocker (benzothiazepine). Diltiazem HCl 120mg, 180mg, 240mg, 300mg, 360mg, 420mg; ext-rel tabs.

Indications: Chronic stable angina.

Adults: Swallow whole; take at the same time each day (AM or PM). Initially 180mg once daily; adjust at 1-2 week intervals up to 360mg/day.

Children: Not recommended.

Also: Diltiazem

CARDIZEM CD

Diltiazem HCl 120mg, 180mg, 240mg, 300mg, 360mg; ext-rel caps.

Indications: Vasospastic and chronic stable angina.

Adults: Initially 120-180mg once daily. Titrate over 7-14 days; usual max 480mg once daily.

Children: Not recommended.

Also: Diltiazem

CARDIZEM

Diltiazem HCl 30mg, 60mg +, 90mg +, 120mg +; tabs; + scored.

Adults: 30mg 4 times daily before meals and at bedtime. May increase gradually every 1-2 days; max 360mg/day in divided doses.

Children: Not recommended.

Contraindications: Sick sinus syndrome, 2nd or 3rd-degree AV block unless paced. Hypotension. Acute MI and pulmonary congestion documented by X-ray on admission.

Warnings/Precautions: Heart failure. Impaired renal or hepatic function (monitor). Obstructive hypertrophic cardiomyopathy. Discontinue if persistent rash occurs. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with digoxin, β -blockers, others that may affect cardiac conduction (may lead to AV block). Monitor heart rate with concomitant clonidine. Potentiates propranolol, benzodiazepines, cyclosporine, carbamazepine, lovastatin, simvastatin (consider dose adjustment; monitor). Caution with CYP3A4 substrates, inhibitors (eg, cimetidine), or inducers (eg, rifampin). Anesthetics may potentiate cardiac depression.

Adverse reactions: Edema, headache, fatigue, dizziness, asthenia, 1st-degree AV block, bradycardia, flushing, nausea, rash (may be serious); rare: CHF, hypotension, liver abnormalities.

How supplied: LA tabs-30, 90; CD 120mg, 180mg, 240mg, 300mg-30, 90; CD 360mg-90; Tabs 30mg, 60mg-100, 500; 90mg, 120mg-100

METOPROLOL

LOPRESSOR Validus

beta-blocker. Metoprolol tartrate 50mg, 100mg; scored tabs.

Indications: Long-term management of angina.

Adults: Take with meals. Initially 100mg daily in 2 divided doses. May be increased weekly, if needed. Usual range: 100–400mg/day.

Children: Not recommended.

Contraindications: Sinus bradycardia. 2nd. or 3rd-degree AV block. Overt heart failure. Cardiogenic shock. Sick-sinus syndrome. Severe peripheral arterial circulatory disorders.

Warnings/Precautions: CHF. Ischemic heart disease. Monitor heart rate and rhythm; reduce or stop treatment if severe bradycardia develops. Bronchospastic disease. Hepatic dysfunction. Diabetes. Pheochromocytoma. Hyperthyroidism. Surgery. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Bradycardia with catecholamine-depleting drugs. May be potentiated by potent CYP2D6 inhibitors (eg, fluoxetine, paroxetine, bupropion, thioridazine, quinidine, propafenone, ritonavir, diphenhydramine, hydroxychloroquine, terbinafine, cimetidine), hydralazine, inhalation anesthetics. Increased risk of bradycardia with concomitant digitalis. May block epinephrine. Increased rebound hypertension with clonidine withdrawal. May enhance vasoconstrictive action of ergots. Withhold before diprydamole testing.

Adverse reactions: Fatigue, dizziness, depression, diarrhea, rash, dyspnea, bradycardia, cold extremities, palpitations, CHF, peripheral edema, hypotension, bronchospasm, heart block.

How supplied: Tabs–100

METOPROLOL

TOPROL-XL AstraZeneca

beta-blocker. Metoprolol succinate 25mg, 50mg, 100mg, 200mg; scored ext-rel tabs.

Indications: Long-term management of angina.

Adults: Initially 100mg once daily. May increase at 1-week intervals; max 400mg/day.

Children: Not recommended.

Contraindications: Severe bradycardia. Heart block > 1st degree. Cardiogenic shock. Overt heart failure. Sick sinus syndrome (unless paced).

Warnings/Precautions: Mild or compensated heart failure. Ischemic heart or peripheral vascular disease. Bronchospastic disease. Hepatic dysfunction. Surgery. Diabetes. Hyperthyroidism. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May potentiate hypotension with prazosin, reserpine, hydralazine, cimetidine, antithyroid drugs. May increase cardiac effects of verapamil, lidocaine. Indomethacin, barbiturates, rifampin may decrease effectiveness. Potentiated by flecainide, possibly quinidine, fluoxetine, paroxetine, propafenone. May block epinephrine.

Adverse reactions: Fatigue, dizziness, rash, depression, GI upset, dyspnea, bradycardia, cold extremities, palpitations, CHF, edema, syncope, chest pain, hypotension, bronchospasm, heart block, MI, angina.

How supplied: Tabs–100

NADOLOL

CORGARD King

beta-blocker. Nadolol 20mg, 40mg, 80mg; scored tabs.

Indications: Long-term management of angina.

Adults: Initially 40mg once daily. May increase at 3–7 day intervals. Usual maintenance: 40–80mg once daily; max 240mg daily. Renal impairment: reduce dosage, see literature.

Children: Not recommended.

Contraindications: Asthma. Sinus bradycardia. 2nd. or 3rd-degree AV block. Overt heart failure. Cardiogenic shock. CHF.

Warnings/Precautions: Ischemic heart disease. Bronchospastic disease, COPD. Renal or hepatic dysfunction. Diabetes. Hyperthyroidism. Surgery. SLE. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Hypotension, bradycardia with catecholamine-depleting drugs, general anesthetics. May increase cardiac effects of calcium channel blockers, digitalis. Antagonized by NSAIDs. Adjust antidiabetic medications. May interfere with glaucoma screening tests. May block epinephrine.

Adverse reactions: Bradycardia, dizziness, fatigue, cold extremities, heart failure, heart block, bronchospasm, GI upset, rash, pruritus.

How supplied: Tabs–100

NICARDIPINE

NICARDIPINE (various)

Calcium channel blocker (dihydropyridine). Nicardipine HCl 20mg, 30mg; caps.

Indications: Chronic stable angina.

Adults: Initially 20mg 3 times daily; adjust at intervals of at least 3 days; max 120mg daily. Severe hepatic impairment: initially 20mg twice daily. Renal insufficiency: 20mg 3 times daily and titrate carefully.

Children: <18yrs: not recommended.

Contraindications: Advanced aortic stenosis.

Warnings/Precautions: Cardiac failure. Acute cerebral infarction or hemorrhage. Hepatic or renal impairment. Measure blood pressure 1–2 hrs and 8 hrs after dosing. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by cimetidine. Increases serum levels of cyclosporine, possibly digoxin (monitor).

Adverse reactions: Increased angina, hypotension, flushing, headache, pedal edema, asthenia, dizziness, tachycardia, somnolence, GI upset, insomnia.

How supplied: Contact supplier.

NIFEDIPINE

NIFEDICAL XL Teva US Generics

PROCARDIA XL Pfizer

Calcium channel blocker (dihydropyridine). Nifedipine 30mg, 60mg, 90mg; ext-rel tabs.

Indications: Vasospastic and chronic stable angina.

Adults: Swallow whole. Initially 30–60mg once daily, titrate over 7–14 days; usual max 90mg/day.

Children: Not recommended.

Also: Nifedipine
PROCARDIA

Nifedipine 10mg; caps.

Adults: Initially 10mg three times daily, titrate over 7–14 days (for faster titration: see literature). Usual range 10–20mg three times daily; max 30mg/dose and 180mg/day.

Children: Not recommended.

Warnings/Precautions: Aortic stenosis. Severe obstructive coronary artery disease. Heart failure. GI narrowing (tabs). Monitor blood pressure initially and during titration. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Hypotension, angina, and heart failure possible with β -blockers. Potentiated by cimetidine, grapefruit juice. Potentiates antihypertensives, digoxin. Hypotension possible with fentanyl. Monitor oral anticoagulants, quinidine.

Adverse reactions: Edema, headache, fatigue, dizziness, constipation, nausea, palpitations, muscle cramps; rare: increased angina, acute MI.

How supplied: Tabs 30mg, 60mg–100, 300; Tabs 90mg–100; Caps–100

NITROGLYCERIN

NITRO-BID Fougera

Nitrate. Nitroglycerin 2% (15mg/inch); oint; contains lanolin.

Indications: Prophylaxis of angina. Not for acute attacks.

Adults: Apply, using applicator, usually to the chest and occlude. Initially ½ inch on awakening and then 6 hrs later; may increase to 1 inch, then to 2 inches twice daily.

Children: Not recommended.

Contraindications: Concomitant sildenafil.

Warnings/Precautions: Acute MI. CHF.

Hypotension. Volume depleted. Hypertrophic cardiomyopathy. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Severe hypotension with sildenafil. Vasodilating effects potentiated with alcohol, other vasodilators. Orthostatic hypotension with calcium channel blockers.

Adverse reactions: Headache, dizziness, flushing, orthostatic hypotension, rash; syncope, methemoglobinemia (rare).

How supplied: Oint–30g, 60g (w. applicator); Oint–48 × 1g packets

NITROGLYCERIN

NITROLINGUAL Shionogi

Nitrate. Nitroglycerin 0.4mg/spray; lingual pump spray.

Indications: Acute attacks and prophylaxis of angina.

Adults: 1–2 sprays at onset of attack, onto or under tongue while sitting; max 3 sprays/15 minutes. May use prophylactically 5–10 minutes before exertion.

Do not inhale spray. Do not rinse mouth for 5–10 minutes after use.

Children: Not recommended.

Contraindications: Concomitant sildenafil.

Warnings/Precautions: Acute or recent MI.

Hypotension. Monitor for tolerance. Hypertrophic cardiomyopathy. Avoid abrupt cessation. Volume depletion. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Hypotension potentiated with sildenafil, alcohol, vasodilators, calcium channel blockers, other vasoactive drugs. Do not use epinephrine to treat hypotension from nitrate overdose.

Adverse reactions: Headache, dizziness, flushing, orthostatic hypotension, paresthesia, tachycardia, nausea, rash.

How supplied: Spray–12g (200 metered sprays); 4.9g (60 metered sprays)

NITROGLYCERIN

NITROSTAT Pfizer

Nitrate. Nitroglycerin 0.3mg, 0.4mg, 0.6mg; sublingual tabs.

Indications: Acute relief of angina attack.

Prophylaxis of angina pectoris.

Adults: Treatment: 1 tab sublingually or in buccal pouch at onset, may repeat in 5 minutes; max 3 tabs in 15 minutes. Prophylaxis: 5–10 minutes before activity.

Children: Not recommended.

Contraindications: Early MI. Severe anemia.

Increased intracranial pressure. Concomitant sildenafil.

Warnings/Precautions: Acute MI, heart

failure: monitor. Hypotensive or volume depleted.

Hypertrophic cardiomyopathy. Avoid abrupt cessation. Discontinue if blurred vision or dry mouth occur.

Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Hypotension potentiated by sildenafil, calcium channel blockers,

alcohol, vasodilators, antihypertensives, β -blockers, phenothiazines, aspirin. May antagonize alteplase,

heparin. Drugs that cause dry mouth (eg, tricyclics, anticholinergics) may interfere with sublingual

dissolution. Avoid ergotamine and related drugs.

Tolerance to other forms of nitrates may blunt effects. May interfere with cholesterol tests.

Adverse reactions: Headache, vertigo, weakness, palpitation, orthostatic hypotension, tachycardia, syncope, flushing, rash, exfoliative dermatitis.

How supplied: Tabs 0.4mg–4 × 25, 100; 0.3mg, 0.6mg–100

PROPRANOLOL

INDERAL Akrimax

beta-blocker. Propranolol HCl 10mg, 20mg, 40mg, 60mg, 80mg; scored tabs.

Indications: Long-term management of angina.

Hypertrophic subaortic stenosis.

Adults: Angina: 80–320mg/day divided into 2, 3, or 4 doses. Stenosis: 20–40mg 3–4 times a day before meals and at bedtime.

Children: Not recommended.

Also: Propranolol

INDERAL LA

Propranolol HCl 60mg, 80mg, 120mg, 160mg; sust-rel caps.

Adults: Angina: Initially 80mg once daily. May increase at 3–7 day intervals; max 320mg daily. Stenosis: 80–160mg once daily.

Children: Not recommended.

Contraindications: Asthma. Sinus bradycardia. 2nd or 3rd-degree AV block. Overt heart failure. Cardiogenic shock.

Warnings/Precautions: CHF. Wolff-Parkinson-White syndrome. Renal or hepatic dysfunction. Bronchospastic disease, COPD. Diabetes. Hyperthyroidism. Surgery. SLE. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiated by alcohol, CNS depressants, other antihypertensives, antithyroid drugs, haloperidol, chlorpromazine, cimetidine. Bradycardia with catecholamine-depleting drugs. Antagonized by NSAIDs, barbiturates, rifampin, phenytoin. May increase cardiac effects of calcium channel blockers, digitalis, lidocaine. Potentiates theophylline, antipyrine, lidocaine. May block epinephrine. May interfere with glaucoma screening tests.

Adverse reactions: Heart failure, hypotension, bronchospasm, bradycardia, heart block, fatigue, dizziness, depression, GI upset, skin reactions (eg, rash, Stevens-Johnson syndrome, urticaria), pharyngitis, agranulocytosis.

How supplied: Tabs 60mg–100; 10mg, 20mg, 40mg, 80mg–100, 5000; LA–100

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Contraindications: Sinus bradycardia. 2nd or 3rd-degree AV block, sick sinus syndrome, unless paced.

Warnings/Precautions: Attempt vagal maneuvers, when clinically advisable, before administration. Discontinue if high-level heart block occurs. Avoid in asthma. Obstructive lung disease (eg, emphysema, bronchitis). Discontinue if severe respiratory difficulties occur. Elderly. Pregnancy (Cat.C).

Interactions: Concomitant digoxin +/–verapamil may cause ventricular fibrillation. Potentiated by dipyridamole. Antagonized by methylxanthines (eg, caffeine, theophylline). Carbamazepine may increase degree of heart block.

Adverse reactions: Facial flushing, dyspnea, chest pressure, nausea, headache, lightheadedness, numbness, arrhythmias at time of conversion; rare: ventricular fibrillation.

How supplied: Prefilled syringes (2mL, 4mL)–10

ADENOSINE

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ADENOSCAN Hospira

Nucleoside. Adenosine 3mg/mL; soln for IV infusion; preservative-free.

Indications: Adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to undergo adequate exercise stress.

Adults: Give peripherally as a continuous IV infusion. ≥ 18 ys: 140microgram/kg/min over 6 minutes for a total dose of 0.84mg/kg. Infusion rate (mL/min) = 0.140 (mg/kg/min) $\times$ total body weight (kg)/adenosine conc. (3mg/mL). See literature.

Children: <18ys: not recommended.

Contraindications: Sinus bradycardia. 2nd or 3rd-degree AV block, sick sinus syndrome, unless paced. Bronchospastic disease (eg, asthma).

Warnings/Precautions: Unstable angina; increased risk of fatal cardiac arrest, ventricular tachycardia, nonfatal MI. Pre-existing 1st-degree AV block. Avoid in high-grade AV block or sinus node dysfunction. Discontinue if persistent or symptomatic high-grade AV block or hypotension occurs. Autonomic dysfunction. Stenotic valvular heart disease. Pericarditis or pericardial effusions. Stenotic carotid artery disease with cerebrovascular insufficiency. Uncorrected hypovolemia. Obstructive lung disease (eg, emphysema, bronchitis). Discontinue if severe respiratory difficulties occur. Elderly. Pregnancy (Cat.C).

Interactions: May be potentiated by β -blockers, cardiac glycosides, calcium channel blockers; use caution. Antagonized by methylxanthines (eg, caffeine, theophylline). Potentiated by dipyridamole.

Adverse reactions: Flushing, chest discomfort, dyspnea, headache, throat/neck/jaw discomfort, GI discomfort, lightheadedness/dizziness, ST segment depression, 1st or 2nd-degree AV block, paresthesia, hypo- or hypertension, bronchoconstriction.

How supplied: Single-use vials (20mL, 30mL)–10

2B CHF and arrhythmias

ADENOSINE

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ADENOCARD Astellas

Nucleoside. Adenosine 3mg/mL; soln for IV inj; preservative-free.

Indications: Paroxysmal supraventricular tachycardia (PSVT), including that associated with accessory bypass tracts (Wolff-Parkinson-White Syndrome).

Adults: Give peripherally by rapid bolus either directly into vein or through IV line (followed by saline flush) over 1–2 seconds. Initially 6mg; if no result within 1–2 mins, may give 12mg; may repeat a second 12mg dose if needed. Max 12mg/dose.

Children: <50kg: Give centrally or peripherally by rapid IV bolus, followed by saline flush. Initially 0.05–0.1mg/kg; if no conversion of PSVT within 1–2 mins, may give incrementally higher doses, increasing the amount by 0.05–0.1mg/kg. Continue until sinus rhythm is established, or max single dose of 0.3mg/kg is used. ≥ 50 kg: as adult.

ALPROSTADIL**PROSTIN VR PEDIATRIC** Pfizer*Prostaglandin E1.* Alprostadil 500mcg/mL; soln for IV infusion after dilution; contains dehydrated alcohol.**Indications:** Palliative therapy to maintain ductus arteriosus patency until corrective or palliative surgery can be performed in neonates with congenital heart defects and who depend on patent ductus for survival.**Adults: Not applicable.****Children:** Give by continuous IV infusion into large vein (preferred) or through an umbilical artery catheter placed at the ductal opening. Initially 0.05–0.1mcg/kg/min. Reduce dose from 0.1 to 0.05 to 0.025 to 0.01mcg/kg/min after therapeutic response is achieved to provide lowest dose that maintains response. If inadequate response to 0.05mcg/kg/min; may increase up to 0.4mcg/kg/min.**Warnings/Precautions:** Respiratory distress syndrome: not recommended. Bleeding disorders. Prolonged therapy (>120hrs): monitor for antral hyperplasia and gastric outlet obstruction. Monitor respiratory status, arterial pressure, blood oxygenation, BP, blood pH; decrease infusion rate if arterial pressure falls significantly. Neonates <2kg at birth.**Interactions:** Caution with anticoagulants.**Adverse reactions:** Apnea, fever, flushing, bradycardia, hypotension, tachycardia, seizures, diarrhea, sepsis, cortical proliferation of the long bones (long-term infusion).**How supplied:** Ampules (1mL)–5

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(eg, quinidine, procainamide; reduce their doses by ½ to ⅓), cyclosporine, digoxin (reduce digoxin dose by ½ or discontinue), oral anticoagulants (reduce anticoagulant dose by ½ to ⅓ and monitor PT), phenytoin, lidocaine. Myopathy with statins metabolized by CYP3A4. Potentiated by protease inhibitors, loratadine, cimetidine, trazodone, grapefruit juice. Exacerbation of arrhythmias with antiarrhythmics. Additive bradycardia, AV block with β-blockers, calcium channel blockers, fentanyl. QTc prolongation with quinolones, macrolides, azole antifungals, disopyramide. Antagonized by rifampin, St. John's wort, cholestyramine. May affect thyroid function tests. See literature.

Adverse reactions: Alveolitis, pulmonary inflammation or fibrosis, post-op adult respiratory distress syndrome, exacerbation of arrhythmias, heart block or failure, sinus bradycardia, hepatotoxicity, corneal deposits, optic neuropathy/neuritis (reevaluate if occurs), photosensitivity, skin pigmentation, thyroid disorders, malaise, peripheral neuropathy, GI upset, blood dyscrasias, pancreatitis.**How supplied:** Tabs–60**CANDESARTAN****ATACAND** AstraZeneca*Angiotensin II receptor blocker.* Candesartan cilexetil 4mg, 8mg, 16mg, 32mg; tabs.**Indications:** Heart failure (NYHA class II–IV and ejection fraction ≤40%), to reduce risk of death and hospitalization; alone or with an ACE inhibitor.**Adults:** ≥18yrs: Initially 4mg once daily; double daily dose at 2-week intervals as tolerated to target 32mg once daily. Salt/volume depleted or moderate hepatic impairment: consider lower initial dose.**Children:** <18yrs: not recommended.**Contraindications:** Concomitant aliskiren in patients with diabetes.**Warnings/Precautions:** Fetal toxicity may develop; discontinue if pregnancy is detected. Correct hypovolemia before starting or monitor closely. Hepatic or renal impairment. Severe CHF. Renal artery stenosis. Surgery. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.**Interactions:** Monitor lithium and for hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.**Adverse reactions:** Back pain, dizziness, upper respiratory tract infection, pharyngitis, rhinitis, rhabdomyolysis (rare).**How supplied:** Tabs 4mg, 8mg–30; 16mg, 32mg–30, 90

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AMIODARONE**CORDARONE** Pfizer*Class III antiarrhythmic.* Amiodarone HCl 200mg; scored tabs.**Indications:** Documented, life-threatening recurrent refractory ventricular fibrillation or hemodynamically unstable ventricular tachycardia.**Adults:** Give consistently with regard to meals.

Initiate in hospital with cardiac monitoring: 800–1600mg/day in divided doses with meals for 1–3 weeks. After control achieved, 600–800mg/day for 1 month then reduce to maintenance dose, usually 400mg/day.

Children: Not recommended.**Contraindications:** Severe sinus node dysfunction. 2nd or 3rd-degree AV block. Bradycardia with syncope unless paced. Cardiogenic shock.**Warnings/Precautions:** Be experienced with the treatment and monitoring of life-threatening arrhythmias before prescribing this medication. Before use, correct potassium and magnesium deficiencies. Surgery. Monitor thyroid function. Monitor for pulmonary and liver toxicity; reduce dose or discontinue if either occurs. Do regular ophthalmic exams. Withdraw cautiously. Pregnancy (Cat.D). Nursing mothers: not recommended.**Interactions:** Interactions may persist months after discontinuing. Potentiates antiarrhythmics

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CAPTOPRIL**CAPOTEN** Par

ACE inhibitor. Captopril 12.5mg, 25mg, 50mg, 100mg; scored tabs.

Indications: Heart failure inadequately controlled by digitalis and diuretics. To reduce mortality in stable post-MI patients with left ventricular dysfunction (ejection fraction $\leq 40\%$).**Adults:** Take 1 hr before meals. Heart failure: Initially 25mg 3 times daily (generally with diuretic and digitalis regimen). Increase, if needed, to 50mg 3 times daily. After 2 wks, may increase; max 450mg/day. Salt/volume depleted, or if systolic BP < 100 mmHg: Initially 6.25mg–12.5mg 3 times daily. Titrate to usual dose after several days. Post-MI: First dose 6.25mg 3 days post-MI, then increase to 12.5mg 3 times daily. Increase to 25mg 3 times daily over several days; maintenance 50mg 3 times daily. Renal impairment: see literature.**Children: Not recommended.****Contraindications:** History of ACE-associated or other angioedema.**Warnings/Precautions:** Fetal toxicity may develop: discontinue if pregnancy is detected. Renal impairment. Salt/volume depletion. Dialysis (esp. high-flux membrane). CHF. Aortic stenosis. Monitor WBCs and renal function in renal and collagen vascular disease. Monitor for hyperkalemia in diabetics, blood pressure and renal insufficiency. Surgery. Discontinue if neutropenia, agranulocytosis, angioedema or laryngeal edema occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.**Interactions:** Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or alkaliuretics may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant alkaliuretics in diabetics or renal impairment (CrCl < 60 mL/min): not recommended. Caution with K^+ -sparing diuretics, K^+ -containing supplements and K^+ -containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors); monitor renal function in elderly and/or volume depleted. Potentiated by diuretics, β -blockers, adrenergic antagonists. Discontinue nitroglycerin, other nitrates, or other vasodilators before starting therapy; if resumed, reduce dose and give cautiously. May increase lithium levels. May produce false (+) urinary acetone. Nitrodermal reactions with injectable gold (sodium aurothiomalate).**Adverse reactions:** Headache, dysgeusia, rash, pruritus, dizziness, fatigue, cough, proteinuria, nephritis, GI upset, hyperkalemia, hyponatremia, tachycardia, excessive hypotension, dry mouth, jaundice, somnolence, impotence, angioedema.**How supplied:** Tabs 25mg, 50mg–100, 1000; 12.5mg, 100mg–100

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CARVEDILOL**COREG CR** GlaxoSmithKlineNoncardioselective beta-blocker/ α -1 blocker.

Carvedilol (as phosphate) 10mg, 20mg, 40mg, 80mg; ext-rel caps.

Indications: Mild to severe heart failure (HF), to increase survival and reduce hospitalization risk. To reduce cardiovascular mortality post-MI with left ventricular ejection fraction $\leq 40\%$.**Adults:** Take with food in the AM. Swallow whole or may open caps and sprinkle beads on a spoonful of applesauce and take immediately. ≥ 18 ys: HF: initially 10mg once daily for 2 weeks, may double dose every 2 weeks if tolerated; max 80mg once daily. Reduce dose if pulse < 55 . Post-MI: initially 20mg once daily; increase to 40mg once daily after 3–10 days if tolerated; then to target dose of 80mg once daily. Low BP or heart rate, or fluid retention: may start at 10mg once daily. Switching from immediate-release carvedilol: see literature. ≥ 65 ys: switching from highest dose of immediate-release carvedilol (25mg twice daily) to Coreg CR: initially Coreg CR 40mg; if tolerated for ≥ 2 weeks, may increase to 80mg.**Children: < 18 ys: not recommended.****Also: Carvedilol****COREG**

Carvedilol 3.125mg, 6.25mg, 12.5mg, 25mg; tabs.

Adults: Take with food. Monitor dose increases closely. ≥ 18 ys: CHF: initially 3.125mg twice daily for 2 weeks, may double dose every 2 weeks if tolerated; mild to moderate HF (> 85 kg): usual max 50mg twice daily. Reduce dose if pulse < 55 . Post-MI: initially 6.25mg twice daily; increase to 12.5mg twice daily after 3–10 days if tolerated; then to target dose 25mg twice daily. Low BP or heart rate, or fluid retention: may start at 3.125mg twice daily.**Children: < 18 ys: not recommended.****Contraindications:** Cardiogenic shock or decompensated HF requiring intravenous inotropic therapy. Asthma, related bronchospastic conditions. 2nd or 3rd-degree AV block, sick sinus syndrome, or severe bradycardia, unless paced. Severe hepatic impairment.**Warnings/Precautions:** Peripheral vascular disease. Nonallergic bronchospasm. Diabetes (monitor blood glucose). Hyperthyroidism. Monitor renal function in ischemic heart disease, diffuse vascular disease, underlying renal insufficiency, and/or if systolic BP < 100 mmHg. Initiation of therapy may temporarily worsen signs and symptoms; benefits may be delayed for several weeks; may need increased diuretic dose at first. Avoid abrupt cessation. Prinzmetal's angina. Pheochromocytoma. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** May be potentiated by CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine, propafenone), alcohol (separate by 2 hours). Bradycardia, hypotension with catecholamine depletors (eg, reserpine, MAOIs). Carvedilol levels

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reduced by rifampin. Increased absorption with cimetidine. Caution with drugs that affect cardiac conduction (esp. diltiazem, verapamil). May potentiate antidiabetic agents. Monitor digoxin, cyclosporine when changing carvedilol dose. Anesthesia.

Adverse reactions: Dizziness, edema, hypotension, syncope, bradycardia, AV block, GI upset, hyperglycemia, weight gain, abnormal vision.

How supplied: CR caps-30, 90; Tabs-100

DIGOXIN

LANOXIN Covis

Cardiac glycoside. Digoxin 0.125mg, 0.25mg; scored tabs.

Also: Digoxin

LANOXIN INJECTION

Digoxin 0.25mg/mL; soln for IV or IM inj.

Also: Digoxin

LANOXIN INJECTION PEDIATRIC

Digoxin 0.1mg/mL; soln for IV or IM inj.

Indications: Mild-to-moderate heart failure (with a diuretic and an ACE inhibitor when possible). Control of ventricular response rate in chronic atrial fibrillation.

Adults and Children: Individualize: see literature. Reduce dose in premature and immature infants. Children usually need proportionally larger doses (based on body weight or surface area) than adults. Use divided doses for children <10 yrs. Retitrate when changing formulations (esp. oral tabs to or from other dose forms).

Contraindications: Ventricular fibrillation.

Warnings/Precautions: Renal dysfunction: reduce dose. Sinus node disease. Incomplete AV block. Accessory AV pathway (Wolff-Parkinson-White syndrome). Heart failure with preserved LV ejection fraction (eg, restrictive cardiomyopathy, constrictive pericarditis, amyloid heart disease, acute cor pulmonale, idiopathic hypertrophic subaortic stenosis). Electrical cardioversion. Acute MI. Toxicity risk increased by hypokalemia, hypomagnesemia, hypercalcemia. Hypocalcemia may nullify effects.

Thyroid disease. Hypermetabolic states. Monitor digoxin levels, electrolytes, renal function. Premature infants. Neonates. Pregnancy (Cat.C). Nursing mothers.

Interactions: Toxicity risk increased by potassium-depleting drugs (eg, diuretics, amphotericin B, corticosteroids). Digoxin levels increased by antibiotics (eg, macrolides, tetracyclines), amiodarone, propafenone, quinidine, verapamil, indomethacin, itraconazole, alprazolam, spironolactone, drugs that reduce GI motility (eg, propantheline, diphenoxylate), thyroid antagonists, drugs that reduce renal function. Digoxin levels decreased by thyroid hormones, antacids, kaolin-pectin, cholestyramine, rifampin, sulfasalazine, neomycin, drugs that increase GI motility (eg, metoclopramide), some antineoplastics. Digoxin levels possibly affected by quinine, penicillamine, felodipine, others. Arrhythmias with sympathomimetics, succinylcholine, or rapid calcium infusion. Heart block with drugs that affect cardiac conduction (eg, calcium channel blockers, β -blockers).

Adverse reactions: GI upset, anorexia, CNS effects (eg, blurred or yellow vision, or mental disturbances, confusion, headache, weakness, dizziness, apathy), gynecomastia, rash, heart block, arrhythmias (esp. children).

How supplied: Tabs-100, 1000; Inj 0.25mg/mL (2mL amps)-10, 50; Inj Pediatric (1mL amp)-10

DILTIAZEM

DILTIAZEM HCl INJECTION (various)

Calcium channel blocker. Diltiazem HCl 5mg/mL; soln for IV inj or infusion after dilution.

Indications: Temporary control of rapid ventricular rate in atrial fibrillation or flutter. Rapid conversion of paroxysmal supraventricular tachycardias (PSVT) to sinus rhythm.

Adults: Direct IV single injections (bolus): initially 0.25mg/kg over 2 minutes; if needed, may give second dose (0.35mg/kg) after 15 minutes; subsequent bolus doses should be individualized. If continuous IV infusion is needed, begin immediately after bolus administration. Initial infusion rate: 10mg/h; may increase in 5mg/h increments up to 15mg/h. May be maintained for up to 24 hours.

Children: Not recommended.

Contraindications: Sick sinus syndrome or 2nd or 3rd degree AV block (unless paced). Severe hypotension. Cardiogenic shock. Concomitant IV β -blockers. Atrial fibrillation or flutter associated with an accessory bypass tract such as in Wolff-Parkinson-White syndrome or short PR syndrome. Ventricular tachycardia.

Warnings/Precautions: Have resuscitative equipment readily available. CHF. Renal or hepatic impairment. Hemodynamically compromised. Continuously monitor ECG and blood pressure. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Possible bradycardia, AV block, and/or depression of contractility with concomitant oral β -blockers. Additive effects with agents known to affect cardiac conduction. Avoid concomitant CYP3A4 inducers (eg, rifampin). Potentiated by cimetidine; may need to adjust diltiazem dose. May potentiate anesthetics, benzodiazepines, buspirone, carbamazepine, cyclosporine, quinidine; monitor.

Adverse reactions: Hypotension, inj site reactions (eg, itching, burning), vasodilation, arrhythmia; dermatological events (eg, erythema multiforme, exfoliative dermatitis; discontinue if occurs), hepatotoxicity, ventricular premature beats.

How supplied: Contact supplier.

DISOPYRAMIDE

NORPACE Pfizer

Class I antiarrhythmic. Disopyramide (as phosphate) 100mg, 150mg; caps.

Indications: Documented life-threatening ventricular arrhythmias.

Adults: 400-800mg daily in 4 divided doses every 6 hours. For rapid control of ventricular arrhythmias,

consider loading dose of 300mg (200mg if body weight <110 lbs). Renal dysfunction, cardiac decompensation, or body wt <110 lbs: see literature.

Children: Initiate in hospital. Give as divided doses every 6 hours: <1 year: 10–30mg/kg per day; 1–4 years: 10–20mg/kg per day. 4–12 years: 10–15mg/kg per day. 12–18 years: 6–15mg/kg per day.

Also: **Disopyramide**

NORPACE-CR

Disopyramide (as phosphate) 100mg, 150mg; controlled-release caps.

Adults: 200–400mg every 12 hours.

Children: Use immediate-release caps.

Contraindications: Cardiogenic shock. 2nd- or 3rd-degree AV block, unless paced. Congenital QT prolongation. Severe renal insufficiency (CrCl ≤40mL/min); CR form not recommended.

Warnings/Precautions: Correct potassium imbalance before starting. Discontinue if hypotension or CHF worsening occurs; if needed, restart at lower dose after cardiac compensation established. Reduce dose in 1st-degree AV block, consider discontinuing if persistent. Monitor closely or discontinue if QT prolongation or QRS widening occurs. Atrial tachyarrhythmias: digitalize first. Conduction defects. Cardiomyopathy. Renal or hepatic dysfunction. Urinary retention. BPH. Glaucoma. Myasthenia gravis. Chronic malnutrition. Elderly. Labor & delivery. Pregnancy (Cat.C): may stimulate uterine contractions. Nursing mothers: not recommended.

Interactions: Avoid other antiarrhythmics except in unresponsive, life-threatening arrhythmias. Avoid CYP3A4 inhibitors (eg, erythromycin, clarithromycin); may result in fatal interactions. Hypoglycemia with β -blockers, alcohol. Antagonized by hepatic enzyme inducers (eg, phenytoin). Do not give within 48 hours before or 24 hours after verapamil.

Adverse reactions: Anticholinergic effects (eg, dry mouth, urinary retention, constipation, blurred vision), GI upset, dizziness, fatigue, impotence, hypotension, heart failure, AV block, edema, rash, hypoglycemia, hypokalemia, jaundice, blood dyscrasias, lupus-like syndrome, psychosis.

How supplied: Caps-100; CR-100, 500

DRONEDARONE

MULTAQ Sanofi Aventis

Antiarrhythmic. Dronedarone 400mg; tabs.

Indications: To reduce the risk of hospitalization for atrial fibrillation (AF) in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

Adults: ≥18yrs: 400mg twice daily (AM & PM) with meals.

Children: <18yrs: not established.

Contraindications: Permanent AF (normal sinus rhythm will not or cannot be restored). Symptomatic heart failure (HF) with recent decompensation requiring hospitalization or NYHA Class IV HF. 2nd- or 3rd-degree AV block or sick sinus syndrome,

unless paced. Bradycardia (<50bpm). Concomitant strong CYP3A inhibitors (eg, ketoconazole, itraconazole, voriconazole, cyclosporine, telithromycin, clarithromycin, nefazodone, ritonavir). Concomitant agents that can cause QTc prolongation (eg, phenothiazines, tricyclics, certain oral macrolide antibiotics, Class I and III antiarrhythmics). Liver or lung toxicity related to previous amiodarone use. QTc Bazett interval ≥500ms. PR interval >280ms. Severe hepatic impairment. Pregnancy (Cat.X) (use effective contraception). Nursing mothers.

Warnings/Precautions: Increased risk of death, stroke, or HF in decompensated HF or permanent AF. Monitor cardiac rhythm every 3 months during therapy. Ensure appropriate antithrombotic therapy before starting. Discontinue if worsening HF develops and requires hospitalization or if pulmonary toxicity is confirmed. Monitor hepatic enzymes during 1st 6 months of therapy; discontinue if hepatic injury develops. Maintain normal serum K⁺ and Mg²⁺ levels. Monitor renal function periodically.

Interactions: See Contraindications. Avoid concomitant antiarrhythmics, rifampin, other CYP3A inducers (eg phenobarbital, carbamazepine, phenytoin, St. John's wort), grapefruit juice. Consider discontinuing digoxin; if continued, reduce digoxin dose by ½, and monitor. Avoid doses >10mg once daily of simvastatin. Reduce dose and monitor Ca²⁺ channel blockers, β -blockers (bradycardia), other CYP2D6 substrates. Verapamil, diltiazem increase dronedarone levels. Dronedarone increases verapamil, diltiazem, nifedipine levels. May potentiate dabigatran and other P-gP substrates, some statins, sirolimus, tacrolimus, other narrow-therapeutic range CYP3A substrates: adjust dose and monitor. Monitor other CYP3A or CYP2D6 substrates (eg, SSRIs, tricyclics). Monitor INR with warfarin.

Adverse reactions: Diarrhea, nausea, abdominal pain, vomiting, asthenia; increased serum creatinine, liver injury, QT prolongation, interstitial lung disease.

How supplied: Tabs-60, 180, 500

ENALAPRIL

VASOTEC Valeant

ACE inhibitor. Enalapril maleate 2.5mg, 5mg, 10mg, 20mg; scored tabs.

Indications: Symptomatic CHF, usually with digitalis and diuretics. Asymptomatic left ventricular dysfunction (ejection fraction ≤35%).

Adults: Initially 2.5mg 1–2 times daily. May increase to 5–20mg daily in 1–2 divided doses; max 40mg/day. Reduce diuretic dosage before 1st dose, if possible; observe patient for at least 2 hrs after 1st dose, until BP has stabilized for at least 1 hr. CHF with hyponatremia or renal dysfunction: see literature. Left ventricular dysfunction: Initially 2.5mg twice daily; max 20mg daily in divided doses.

Children: Not established.

Contraindications: History of ACEI-associated or other angioedema. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment: monitor for worsening renal function. Salt/volume depletion. CHF. Dialysis (esp. high-flux membrane). Renal artery stenosis. Surgery. Monitor for hyperkalemia in diabetics. Monitor WBCs in renal or collagen vascular disease. Discontinue if neutropenia, angioedema, laryngeal edema, jaundice or marked elevations of hepatic enzymes develop. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. Potentiated by, and hypotension with, diuretics. Hyperkalemia with K⁺-sparing diuretics or K⁺ supplements. May increase lithium levels. May be antagonized by, and renal toxicity potentiated by NSAIDs, including COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate).

Adverse reactions: Cough, headache, dizziness, fatigue, diarrhea, rash, orthostatic hypotension, asthenia, hyperkalemia, renal impairment, nausea; rare: hepatic failure.

How supplied: Tabs 2.5mg–30, 90; 5mg, 10mg, 20mg–30, 90, 1000

FLECAINIDE

R

TAMBOCOR Medicis

Class IC antiarrhythmic. Flecainide acetate 50mg, 100mg +, 150mg +; tabs; + scored.

Indications: Documented, life-threatening ventricular arrhythmias. Paroxysmal supraventricular tachycardias (PSVT), paroxysmal atrial fibrillation/d flutter (PAF) in patients without structural heart disease.

Adults: Sustained ventricular tachycardia: Initiate in hospital; initially 100mg every 12 hrs; may increase by 50mg twice daily at 4 day intervals; max 400mg/day. PSVT or PAF: 50mg every 12 hrs; may increase by 50mg twice daily at 4 day intervals; max 300mg daily. CrCl ≤35mL/min per 1.73m²: Initially 100mg once daily or 50mg every 12hrs.

Children: <18yrs: not recommended.

Contraindications: 2nd or 3rd-degree AV block or right bundle branch block associated with left hemiblock, unless paced. Chronic atrial fibrillation. Cardiogenic shock. Recent MI.

Warnings/Precautions: Verify benefits outweigh risks; see literature. Heart failure or myocardial dysfunction. Sick sinus syndrome. Pacemaker patients. Correct potassium imbalances before use. Severe renal or hepatic impairment, concomitant amiodarone or reduced myocardial function: monitor plasma level. Discontinue if heart block occurs

unless paced. Discontinue if liver dysfunction, blood dyscrasias occur. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Increased digoxin toxicity. May potentiate negative inotropic effects of β-blockers. Potentiated by cimetidine. Antagonized by phenytoin, phenobarbital, carbamazepine. Avoid disopyramide, verapamil, nifedipine, diltiazem, other negative inotropics. ½ dose when given with amiodarone.

Adverse reactions: Dizziness, visual disturbances, dyspnea, headache, fatigue, palpitations, chest pain, asthenia, tremor, edema, GI upset, new or exacerbated arrhythmias, heart failure, cardiac arrest, conduction defects.

How supplied: Tabs–100

FOSINOPRIL

R

FOSINOPRIL (various)

ACE inhibitor. Fosinopril sodium 10mg +, 20mg, 40mg; tabs; + scored.

Indications: Adjunct to diuretics in heart failure, with or without digitalis.

Adults: Initially 10mg once daily. Moderate to severe renal failure or volume depleted: initially 5mg once daily. Maintenance: 20–40mg once daily.

Children: Contact manufacturer.

Contraindications: History of ACEI-associated or other angioedema. Pregnancy (Cat.D in 2nd and 3rd trimesters).

Warnings/Precautions: Salt/volume depletion. Renal or hepatic impairment. Monitor WBCs in renal or collagen vascular disease. CHF. Dialysis (esp. high-flux membrane). Renal artery stenosis. Monitor for hyperkalemia in diabetics. Discontinue if angioedema, laryngeal edema, jaundice, or markedly elevated liver enzymes occurs. Surgery. Pregnancy (Cat.C in 1st trimester). Nursing mothers: not recommended.

Interactions: Potentiated by diuretics. Potassium or K⁺-sparing diuretics may cause hyperkalemia. May increase lithium levels. Separate acid dosing by 2hrs. May cause false low serum digoxin measurements.

Adverse reactions: Angina, orthostatic hypotension, dizziness, cough, GI upset, pain, hyperkalemia, upper respiratory infection, arrhythmias, asthenia; angioneurotic edema (discontinue if occurs).

How supplied: Contact supplier.

LISINOPRIL

R

ZESTRIL AstraZeneca

ACE inhibitor. Lisinopril 2.5mg, 5mg, 10mg, 20mg, 30mg, 40mg; tabs.

Indications: Heart failure inadequately controlled by diuretics +/or digitalis. Adjunct to other therapies within 24 hrs post-MI in hemodynamically stable patients, to reduce mortality.

Adults: CHF: initially 5mg once daily; range 5–40mg once daily; increase by 10mg at 2 week intervals; max 40mg once daily; hyponatremia or moderate to

severe renal impairment: initially 2.5mg once daily; supervise closely. Reduce diuretic dosage before 1st dose (if possible) and observe until BP is stabilized. Post-MI: 5mg within 24 hrs of onset of symptoms, then 5mg after 24 hrs, then 10mg after 48 hrs, then 10mg once daily for up to 6 weeks; if systolic BP ≤ 120 mmHg at onset, start with 2.5mg daily for 3 days; or if systolic BP ≤ 100 mmHg, start with 5mg daily, then reduce to 2.5mg daily as needed; discontinue if prolonged hypotension (systolic BP ≤ 90 mmHg for >1 hr) occurs.

Children: Not recommended.

Contraindications: History of ACE-associated or other angioedema.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment. Dialysis (esp. high-flux membrane). Salt/volume depletion. Hypertrophic cardiomyopathy. CHF. Ischemic heart disease. Cerebrovascular disease. Renal artery stenosis. Surgery. Monitor BP, electrolytes, renal and liver function. Monitor serum potassium in diabetics. Monitor WBC count in renal and collagen vascular disease. Discontinue if angioedema or laryngeal edema (have SC epinephrine available), jaundice or elevated liver enzymes occur. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: May cause hypotension or increased BUN with diuretics, hyperkalemia with K^+ sparing diuretics or K^+ supplements. Risk of hypoglycemia with concomitant antidiabetic agents; adjust doses. May increase lithium levels; monitor frequently. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in diabetics or renal impairment (GFR <60 mL/min): not recommended. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare.

Adverse reactions: Dizziness, headache, fatigue, diarrhea, upper respiratory symptoms, cough, nausea, orthostatic hypotension, hyperkalemia, renal impairment, angioedema; liver dysfunction, blood dyscrasias (rare).

How supplied: Tabs-100

METOPROLOL

LOPRESSOR Validus
beta-blocker. Metoprolol tartrate 50mg, 100mg; scored tabs.

Also: Metoprolol

LOPRESSOR INJECTION Novartis

Metoprolol tartrate 5mg; soln for IV inj.

Indications: In stabilized patients after MI, to reduce mortality.

Adults: See literature. Early treatment: initially administer three 5mg IV bolus inj given at approximately 2-minute intervals; monitor BP, HR,

ECG. If full IV dose (15mg) tolerable, give 50mg (tab) every 6 hours starting 15 mins after the last IV dose and continue for 48 hours, thereafter, give maintenance dose of 100mg (tab) twice daily; if full IV dose not tolerable, give 25-50mg (tab) every 6 hours starting 15 mins after the last IV dose or as soon as clinical condition allows; if severe intolerance: discontinue treatment. Late treatment: if early phase treatment is contraindicated, intolerable or delayed therapy needed, start with 100mg (tab) twice daily for at least three months.

Children: Not recommended.

Contraindications: Significant 1st degree heart block. 2nd, or 3rd-degree AV block. Systolic pressure <100 mmHg or heart rate <45 beats/min. Moderate-to-severe cardiac failure.

Warnings/Precautions: CHF. Monitor heart rate and rhythm; reduce or stop treatment if severe bradycardia develops. Bronchospastic disease. Hepatic dysfunction. Diabetes. Pheochromocytoma. Hyperthyroidism. Surgery. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Bradycardia with catecholamine-depleting drugs. May be potentiated by potent CYP2D6 inhibitors (eg, fluoxetine, paroxetine, bupropion, thioridazine, quinidine, propafenone, ritonavir, diphenhydramine, hydroxychloroquine, terbinafine, cimetidine), hydralazine, inhalation anesthetics. Increased risk of bradycardia with concomitant digitalis. May block epinephrine. Increased rebound hypertension with clonidine withdrawal. May enhance vasoconstrictive action of ergots. Withhold before dipyridamole testing.

Adverse reactions: Fatigue, dizziness, depression, hypotension (discontinue if occurs), diarrhea, rash, dyspnea, bradycardia, cold extremities, palpitations, CHF, peripheral edema, bronchospasm, heart block.

How supplied: Tabs-100; Ampuls (5mL)-10

METOPROLOL

R

TOPROL-XL AstraZeneca
beta-blocker. Metoprolol succinate 25mg, 50mg, 100mg, 200mg; scored ext-rel tabs.

Indications: Stable, symptomatic (NYHA Class II or III) ischemic, hypertensive, or cardiomyopathic heart failure.

Adults: Class II: initially 25mg once daily; more severe: 12.5mg once daily. May double dose as tolerated every 2 weeks; reduce if symptomatic bradycardia occurs; max 200mg/day.

Children: Not recommended.

Contraindications: Severe bradycardia. Heart block $>1^{\text{st}}$ degree. Cardiogenic shock. Overt heart failure. Sick sinus syndrome (unless paced).

Warnings/Precautions: Mild or compensated heart failure. Ischemic heart or peripheral vascular disease. Bronchospastic disease. Hepatic dysfunction. Surgery. Diabetes. Hyperthyroidism. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May potentiate hypotension with prazosin, reserpine, hydralazine, cimetidine, antithyroid drugs. May increase cardiac effects of verapamil, lidocaine. Indomethacin, barbiturates, rifampin may decrease effectiveness. Potentiated by felodipine, possibly quinidine, flouxetine, paroxetine, propafenone. May block epinephrine.

Adverse reactions: Fatigue, dizziness, rash, depression, GI upset, dyspnea, bradycardia, cold extremities, palpitations, CHF, edema, syncope, chest pain, hypotension, bronchospasm, heart block, MI, angina.

How supplied: Tabs-100

MEXILETINE

MEXILETINE (various)

Class IB antiarrhythmic. Mexiletine HCl 150mg, 200mg, 250mg; caps.

Indications: Documented life-threatening ventricular arrhythmias.

Adults: Take with food or antacid. Initially 200mg every 8hrs. Adjust dose if needed at not less than 2-3 day intervals in 50-100mg increments. Usual dose: 200-300mg every 8hrs; max 1.2g/day. If arrhythmia is controlled by ≤ 300 mg every 8hrs, may try dividing same daily dose every 12hrs; max 450mg every 12hrs. See literature for information on rapid induction and changing from other antiarrhythmics.

Children: Not recommended.

Contraindications: Cardiogenic shock. 2nd or 3rd-degree AV block unless paced.

Warnings/Precautions: Hepatic impairment. Severe heart failure. Sinus node dysfunction or intraventricular conduction defects. Hypotension. Epilepsy. Monitor ECG, blood and liver function. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May potentiate other antiarrhythmics, theophylline. Monitor control if used with hepatic enzyme-inducing drugs. Avoid drugs or diets that alter urinary pH.

Adverse reactions: GI upset, dizziness, tremor, nervousness, ataxia, chest pain, blurred vision, exacerbated arrhythmias, hepatotoxicity.

How supplied: Contact supplier.

NESIRITIDE

NATRECOR Scios

Vasodilator (human B-type natriuretic peptide).

Nesiritide 1.5mg/vial; pwd for IV inj after reconstitution and dilution; contains mannitol.

Indications: Acutely decompensated CHF with dyspnea at rest or with minimal activity.

Adults: 2mcg/kg IV bolus once, then 0.01mcg/kg per minute by continuous IV infusion; limited experience with therapy >96 hours. Doses up to 0.03mcg/kg per minute have been used; see full labeling. Reduce dose or discontinue if symptomatic hypotension occurs.

Children: Not established.

Contraindications: Persistent systolic BP <100mmHg. Cardiogenic shock.

Warnings/Precautions: Not recommended in significant valvular stenosis, restrictive or obstructive cardiomyopathy, constrictive pericarditis, pericardial tamponade, other conditions where vasodilators are inappropriate, or when cardiac output is dependent on venous return, or in patients with low cardiac filling pressures. Impaired renal function (esp if severe heart failure); monitor serum creatinine during and after therapy until stabilized. Monitor BP closely. Pregnancy (Cat.C). Nursing mothers.

Interactions: Hypotension potentiated by ARBs and/or ACE inhibitors.

Adverse reactions: Hypotension, headache, nausea, back pain, dizziness; hypersensitivity.

How supplied: Single-use vials-1

NOREPINEPHRINE

LEVOPHED Hospira

Sympathomimetic. Norepinephrine bitartrate 1mg/mL (equivalent of 1mg base of norepinephrine); soln for IV infusion after dilution; contains sulfites.

Indications: Adjunctive treatment in cardiac arrest and profound hypotension.

Adults: Correct blood volume depletion before administration. Give by IV infusion after dilution (contains 4mcg of base/mL) into a large vein. Initially 2mL to 3mL (or 8-12mcg of base) per minute; adjust flow rate until adequate low normal BP (usually 80-100 mmHg systolic) and maintain tissue perfusion. Usual maintenance: 0.5mL to 1mL (or 2-4mcg of base) per minute. Withdraw gradually. Titrate dose based on response; see literature.

Children: Not recommended.

Contraindications: Hypotension due to blood volume deficits except as an emergency measure. Mesenteric or peripheral vascular thrombosis. Profound hypoxia or hypercapnia. Concomitant cyclopropane and halothane anesthesia.

Warnings/Precautions: Hypertension. Monitor BP every 2 minutes initially until desirable level is obtained, then every 5 minutes if administration is continued. Avoid extravasation. Asthma. Sulfite sensitivity. Elderly (avoid infusion into leg veins). Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Risk of ventricular tachycardia or fibrillation with cyclopropane, halothane anesthesia. Caution with MAOIs, triptiline or imipramine antidepressants; may cause prolonged hypertension.

Adverse reactions: Ischemic injury, reflex bradycardia, arrhythmias, anxiety, transient headache, respiratory difficulties, extravasation necrosis, volume depletion (esp. long-term use).

How supplied: Ampuls (4mL)-10

PHENYLEPHRINE

PHENYLEPHRINE HCl INJECTION (various)

Sympathomimetic. Phenylephrine HCl 10mg/mL; soln for IV, IM, or SC inj; contains sulfites.

Indications: Paroxysmal supraventricular tachycardia.

Adults: Give by rapid IV inj within 20–30secs. Initial max dose: 0.5mg, subsequent doses not to exceed preceding dose by 0.1–0.2mg; max: 1mg.

Children: Not recommended.

Contraindications: Severe hypertension. Ventricular tachycardia.

Warnings/Precautions: Cardiovascular disease. Hypertension. Thyroid disease. Asthma. Sulfite sensitivity. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers.

Interactions: Potentiated by oxytocic drugs, tricyclic antidepressants, or MAOIs. Caution with halothane anesthesia.

Adverse reactions: Headache, reflex bradycardia, excitability, restlessness: rare: arrhythmias.

How supplied: Vial 10mg/mL (1mL, 5mL)–25

PROPAFENONE

RYTHMOL GlaxoSmithKline

Class IC antiarrhythmic. Propafenone HCl 150mg, 225mg, 300mg; scored tabs.

Indications: Documented life-threatening sustained ventricular arrhythmias. To prolong recurrence of disabling paroxysmal atrial fibrillation/flutter or paroxysmal supraventricular tachycardia in patients without structural heart disease.

Adults: Individualize. Initially 150mg every 8hrs. May increase at intervals of at least 3–4 days (longer for elderly or marked myocardial damage) to 225mg every 8hrs; max 300mg every 8hrs. Hepatic impairment: reduce dose by 20–30%.

Children: Not recommended.

Also: Propafenone

RYTHMOL SR

Propafenone HCl 225mg, 325mg, 425mg; ext-rel caps.

Indications: To prolong recurrence of symptomatic atrial fibrillation in patients without structural heart disease.

Adults: Individualize. Not interchangeable on a mg-to-mg basis with immediate-release form (see literature). Swallow whole. Initially 225mg every 12hrs. May increase at 5-day intervals to 325mg every 12hrs; max 425mg every 12hrs. When switching from 150mg three times daily of the immediate-release form, start Rhythmol SR at 325mg twice daily. QRS widening, 2nd or 3rd degree heart block, or hepatic impairment: reduce dose.

Children: Not recommended.

Contraindications: Heart failure. Cardiogenic shock. SA, AV and intraventricular disorders of impulse generation or conduction (eg, sick sinus syndrome, AV block), unless paced. Known Brugada Syndrome. Bradycardia. Marked hypotension. Bronchospastic disorders. Marked electrolyte imbalance.

Warnings/Precautions: Significant proarrhythmic risk in structural heart disease. Avoid in patients with non-life-threatening ventricular arrhythmias. Monitor ECG, pacemakers before and during therapy. Discontinue if ECG changes are suggestive of Brugada Syndrome or if CHF worsens; reduce

dose if 2nd or 3rd degree AV block or QRS widening occurs. Monitor for agranulocytosis. Hepatic or renal dysfunction. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Local anesthetics may increase CNS effects. Avoid drugs that may prolong the QT interval (eg, antiarrhythmics, phenothiazines, cisapride, bepridil, tricyclic antidepressants, macrolides). Avoid concomitant quinidine, amiodarone. Potentiates β -blockers, warfarin, digoxin (consider reducing their doses when starting propafenone), desipramine, cyclosporine, theophylline. Antagonized by rifampin. Monitor and adjust dose with CYP2D6, CYP1A2, and CYP3A4 inhibitors.

Adverse reactions: Dizziness, palpitations, chest pain, dyspnea, taste disturbance, nausea, fatigue, anxiety, constipation, upper respiratory tract infection, edema, influenza, angina pectoris, atrial flutter, 1st degree AV block, heart failure, bradycardia, headache, blurred vision; new or exacerbated arrhythmias, conduction defects, elevated ANA titer, exacerbation of myasthenia gravis.

How supplied: Tabs, caps–100

PROPRANOLOL

INDERAL Akrimax

beta-blocker. Propranolol HCl 10mg, 20mg, 40mg, 60mg, 80mg; scored tabs.

Indications: Atrial and ventricular arrhythmias (see literature). Tachyarrhythmia due to digitalis intoxication. In stabilized patients after MI, to reduce mortality and risk of reinfarction.

Adults: Arrhythmias: 10–30mg 3–4 times a day before meals and at bedtime. Post-MI: 180–240mg daily in divided doses.

Children: Not recommended.

Contraindications: Asthma. Sinus bradycardia. 2nd or 3rd degree AV block. Overt heart failure. Cardiogenic shock.

Warnings/Precautions: CHF. Wolff-Parkinson-White syndrome. Renal or hepatic dysfunction. Bronchospastic disease, COPD. Diabetes. Hyperthyroidism. Surgery. SLE. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiated by alcohol, CNS depressants, other antihypertensives, antithyroid drugs, haloperidol, chlorpromazine, cimetidine. Bradycardia with catecholamine-depleting drugs. Antagonized by NSAIDs, barbiturates, rifampin, phenytoin. May increase cardiac effects of calcium channel blockers, digitalis, lidocaine. Potentiates theophylline, antipyrine, lidocaine. May block epinephrine. May interfere with glaucoma screening tests.

Adverse reactions: Heart failure, hypotension, bronchospasm, bradycardia, heart block, fatigue, dizziness, depression, GI upset, skin reactions (eg, rash, Stevens-Johnson syndrome, urticaria), pharyngitis, agranulocytosis.

How supplied: Tabs 60mg–100; 10mg, 20mg, 40mg, 80mg–100, 5000

QUINAPRIL**ACCUPRIL** Pfizer*ACE inhibitor.* Quinapril (as HCl) 5mg+, 10mg, 20mg, 40mg; tabs; + scored.**Indications:** Heart failure inadequately controlled by diuretics and/or digitalis.**Adults:** Initially 5mg twice daily, if needed increase weekly to 20–40mg daily in 2 equally divided doses. In CHF with hyponatremia or renal impairment: initially 2.5–5mg once daily based on CrCl (see literature), if needed titrate dose under supervision.**Children: Not established.****Contraindications:** History of ACE-associated or other angioedema. Concomitant aliskiren in patients with diabetes.**Warnings/Precautions:** Fetal toxicity may develop; discontinue if pregnancy is detected. Salt/volume depletion. Renal or hepatic impairment. CHF. Dialysis (esp. high-flux membrane). Monitor renal function in severe CHF, hypertension, or renal artery stenosis. Monitor WBCs in renal or collagen vascular disease. Monitor for hyperkalemia in diabetics. Surgery. Discontinue if angioedema, laryngeal edema, jaundice or marked elevation in liver enzymes occurs. Black patients: increased risk of angioedema, possibly less effective. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers.**Interactions:** See Contraindications. K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes may cause hyperkalemia. May increase lithium levels; monitor frequently. Antagonizes tetracycline. Potentiated by diuretics. May be antagonized by NSAIDs including COX-2 inhibitors. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.**Adverse reactions:** Headache, dizziness, fatigue, cough, GI upset, hypotension, hyperkalemia, back pain, tachycardia, dry mouth, somnolence, sweating; rare: angioedema, anaphylactoid reactions, excessive hypotension, hepatic failure, neutropenia, agranulocytosis.**How supplied:** Tabs–90**QUINIDINE SULFATE****QUINIDINE SULFATE** (various)*Class I antiarrhythmic.* Quinidine sulfate 300mg; ext-rel tabs.**Indications:** Atrial and ventricular arrhythmias (see literature).**Adults:** Take with food and in an upright position. 300–600mg every 8–12 hrs.**Children: Not recommended.****Contraindications:** Complete AV or bundle branch block or other severe intraventricular conduction

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defects. Myasthenia gravis. Arrhythmias due to digitalis intoxication. Aberrant impulses, abnormal rhythms due to escape mechanisms.

Warnings/Precautions: Atrial flutter; digitalize first. Incomplete AV block. Marginally compensated cardiovascular disease. Heart failure. Hypotension. Renal or hepatic dysfunction. Monitor blood, liver and kidney function in long-term use. Monitor ECG and serum levels if dose is over 2.5g/day. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Toxicity increased by amiodarone, cimetidine, ranitidine, diuretics, carbonic anhydrase inhibitors, sodium bicarbonate, verapamil, diltiazem. Potentiates anticoagulants, anticholinergics, neuromuscular blocking agents, phenothiazines, reserpine, timolol. Increases digitalis serum levels. Plasma levels decreased by barbiturates, hydantoins, rifampin, nifedipine.**Adverse reactions:** Nausea, vomiting, abdominal pain, diarrhea, new or exacerbated arrhythmias, heart block, syncope, cinchonism, headache, blood dyscrasias, hypotension, flushing, impaired hearing and vision, allergic reactions, hepatic dysfunction.**How supplied:** Contact supplier.**RAMIPRIL****ALTACE** King*ACE inhibitor.* Ramipril 1.25mg, 2.5mg, 5mg, 10mg; gel caps.**Indications:** Treatment of CHF in stabilized patients after MI, to reduce mortality, hospitalizations, and progression to severe/resistant heart failure.**Adults:** Swallow whole. Adjust at 3-week intervals. Initially 2.5mg twice daily, if hypotension occurs may reduce to 1.25mg twice daily; usual maintenance: 5mg twice daily. CrCl <40mL/min: initially 1.25mg once daily; may increase up to max 2.5mg twice daily.**Children: Not recommended.****Contraindications:** History of ACE-associated or other angioedema.**Warnings/Precautions:** Fetal toxicity may develop; discontinue if pregnancy is detected. Salt/volume depletion. Renal or hepatic impairment (discontinue if jaundice or marked increases in hepatic enzymes occur). Severe CHF. Dialysis (esp. high-flux membrane). Monitor WBCs in collagen vascular disease. Monitor renal function in severe CHF, hypertension, or renal artery stenosis. Monitor for hyperkalemia in diabetes or renal insufficiency. Surgery. Discontinue if angioedema or laryngeal stridor occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.**Interactions:** Concomitant telmisartan: not recommended. K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes may cause hyperkalemia. May increase lithium levels. Excessive hypotension with diuretics (reduce diuretic dose if possible). May be antagonized by NSAIDs, including COX-2 inhibitors. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare.

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Adverse reactions: Hypotension, cough, dizziness, angina, GI upset, postural hypotension, syncope, vertigo, hyperkalemia.

How supplied: Caps—100

SOTALOL

R

BETAPACE Bayer

Class II and III antiarrhythmic. Sotalol HCl 80mg, 120mg, 160mg, 240mg; scored tabs.

Indications: Documented life-threatening ventricular arrhythmias.

Adults: Initiate and titrate up in hospital with appropriate monitoring. Initially 80mg twice daily. Increase at 3-day intervals to usual maintenance 120–160mg twice daily; usual range 160–320mg/day divided in 2 or 3 doses (refractory patients may need 480–640mg/day). Renal impairment (CrCl <60mL/min): prolong dosing interval (see literature).

Children: Not recommended.

Contraindications: Sinus bradycardia. 2nd or 3rd degree AV block unless paced. Long QT syndromes. Cardiogenic shock. Uncontrolled CHF (patients with NYHA Class IV may not tolerate beta-blockade; titrate slowly and give full support if attempting to use sotalol in these patients). Asthma.

Warnings/Precautions: Do not substitute for Betapace AF. Hemodialysis. Sick sinus syndrome. Bronchospastic disease. CHF. Left ventricular dysfunction. Correct electrolyte imbalances and withdraw other antiarrhythmics before starting. Baseline QTc interval >500msec; consider lowering dose or discontinuing if QTc interval exceeds 550msec. Recent acute MI. Diabetes. Acid-base imbalance. Increased arrhythmia risk in females, sustained ventricular tachycardia, electrolyte disorders (esp. hypokalemia, hypomagnesemia), excessive QT prolongation, history of cardiomegaly, CHF, renal impairment, and high doses. Hyperthyroidism. History of anaphylaxis. Surgery. Avoid abrupt cessation (withdraw over 1–2 weeks if possible, monitor for angina and acute coronary insufficiency). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Class IA antiarrhythmics (eg, disopyramide, quinidine, procainamide), Class III antiarrhythmics (eg, amiodarone), or other drugs that prolong QT interval (eg, some phenothiazines, cisapride, bepridil, tricyclic antidepressants, macrolides): not recommended. Caution with Class IB and IC antiarrhythmics. Additive conduction abnormalities and hypotension with digitalis, β -blockers, calcium channel blockers. Hypotension, bradycardia with reserpine, guanethidine, other catecholamine-depleting drugs. Increased rebound hypertension when withdrawing clonidine. Diuretics (monitor electrolytes). Antagonizes albuterol, other β -agonists. Monitor antidiabetic agents. May block epinephrine. Avoid within 2 hours of aluminum- or magnesium-containing antacids.

Adverse reactions: Dyspnea, fatigue, nervousness, bradycardia, chest pain, palpitation, asthenia, light-

headedness, GI disturbances; sleep, respiratory, vascular or visual disorders; edema, headache, ECG abnormalities, hypotension, new or exacerbated arrhythmias (eg, torsade de pointes), syncope.

How supplied: Tabs—100

TELMISARTAN

R

MICARDIS Boehringer Ingelheim

Angiotensin II receptor blocker. Telmisartan 20mg, 40mg, 80mg; tabs.

Indications: Cardiovascular (CV) risk reduction in patients ≥ 55 years of age at high risk of developing major CV events who are unable to take ACE inhibitors.

Adults: 80mg once daily. Monitor BP; adjustments to meds that lower BP may be needed.

Children: Not recommended.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct hypovolemia before starting therapy or monitor closely. Severe CHF. Biliary obstruction. Hepatic or renal impairment. Renal artery stenosis. Dialysis (monitor for orthostatic hypotension). Neonates. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant ACE inhibitors (eg, ramipril): not recommended. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. Hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. May potentiate digoxin. Monitor lithium levels. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted.

Adverse reactions: Back pain, upper respiratory tract infection, sinusitis, diarrhea, pharyngitis, angioedema; intermittent claudication, skin ulcer; rare: rhabdomyolysis.

How supplied: Tabs—3 $\times$ 10 (blister cards)

TRANDOLAPRIL

R

MAVIK AbbVie

ACE inhibitor. Trandolapril 1mg+, 2mg, 4mg; tabs; +scored.

Indications: In stabilized patients after MI, who have LV systolic dysfunction or CHF symptoms.

Adults: Initially 1mg once daily; titrate to 4mg once daily as tolerated. Renal dysfunction (CrCl <30mL/min) or hepatic cirrhosis: initially 0.5mg once daily.

Children: Not established.

Contraindications: History of ACEI-associated or other angioedema.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment: monitor for worsening renal function. Salt/volume depletion. Renal artery stenosis. Monitor

for neutropenia in collagen vascular and/or renal disease. Monitor for hyperkalemia in diabetics. Dialysis (esp. high-flux membrane). Surgery. Discontinue if laryngeal edema, angioedema, or jaundice occurs. Avoid hypotension in CHF, aortic stenosis, ischemic heart disease, or cerebrovascular disease. Black patients may have higher risk of angioedema than non-black patients. Neonates. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: Concomitant aliskiren in patients with diabetes, renal impairment (CrCl <60mL/min): not recommended. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Excessive hypotension with diuretics, inhalation anesthetics. Hyperkalemia with K⁺ supplements, K⁺-sparing diuretics, or salt substitutes. May increase lithium levels. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted. Potentiates antidiabetic medicines (insulin or oral hypoglycemic agents). Nitritoid reactions with injectable gold (sodium aurothiomalate): rare.

Adverse reactions: Cough, dizziness, hypotension, syncope, hyperkalemia, myalgia; rare: hepatic failure.

How supplied: Tabs-100

VALSARTAN

DIOVAN Novartis

Angiotensin II receptor blocker. Valsartan 40mg+, 80mg, 160mg, 320mg; + scored; tabs.

Indications: Heart failure (NYHA Class II-IV). To reduce cardiovascular mortality in stable post-MI patients with left ventricular failure or dysfunction.

Adults: Heart failure: initially 40mg twice daily, increase to 80mg twice daily, then to 160mg twice daily as tolerated. Post-MI: may start 12hrs post-MI; initially 20mg twice daily, increase within 1 wk to 40mg twice daily; target maintenance: 160mg twice daily as tolerated. Low BP or renal dysfunction: reduce dose.

Children: Not recommended.

Contraindications: Concomitant aliskiren in diabetics.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct hypovolemia before beginning therapy (may need to reduce diuretic) or monitor closely for hypotension. Hepatic or renal impairment (monitor). Renal artery stenosis. Severe CHF (if renal function depends on renin-angiotensin-aldosterone system). Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Concomitant K⁺ supplements, K⁺-sparing diuretics, K⁺ containing salt substitutes may lead to hyperkalemia and, in heart failure patients, increased serum creatinine. May be antagonized by, and renal toxicity potentiated by,

NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume depleted). May be potentiated by inhibitors of OATP1B1 (eg, rifampin, cyclosporine) or MPR2 (eg, ritonavir). Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Dizziness, hypotension, diarrhea, arthralgia, back pain, fatigue, hyperkalemia, increased BUN, neutropenia, rhabdomyolysis (rare).

How supplied: Tabs 40mg-30; 80mg, 160mg, 320mg-90

2C Edema

ACETAZOLAMIDE

ACETAZOLAMIDE INJECTION (various)

Carbonic anhydrase inhibitor. Acetazolamide 500mg/vial; pld for inj after reconstitution; preservative-free.

Indications: Edema.

Adults: Give by IV inj. Edema: give 1-2 days on, 1 day off. 250mg-375mg once daily. CHF: 250-375mg once daily in the AM. Acute high altitude sickness: see literature.

Children: Not recommended.

Contraindications: Hypokalemia. Hyponatremia. Severe renal, hepatic, or adrenocortical impairment. Hyperchloremic acidosis. Cirrhosis. Chronic noncongestive angle-closure glaucoma. Sulfonamide allergy.

Warnings/Precautions: Respiratory impairment. Renal calcium calculi. Diabetes. Gout. Monitor blood and electrolytes. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Inhibits renal excretion of basic drugs and promotes excretion of acidic drugs. May increase toxicity of salicylates (acidosis), folic acid antagonists. Hypokalemia with corticosteroids, potassium wasting diuretics. Monitor phenytoin, primidone, antihyperglycemics, quinidine, lithium, cyclosporine. Antagonizes methenamine.

Adverse reactions: Anorexia, drowsiness, confusion, malaise, depression, GI distress, paresthesias, tinnitus, acidosis, initial hypokalemia, hyperuricemia, transient myopia; renal calculi, nephrotoxicity, hepatic dysfunction, blood dyscrasias, rash, fever, photosensitivity (rare).

How supplied: Contact supplier.

AMILORIDE + HYDROCHLOROTHIAZIDE

AMILORIDE/HCTZ (various)

K⁺-sparing + thiazide. Amiloride HCl 5mg, hydrochlorothiazide 50mg; scored tabs.

Indications: Edema when normokalemia is important.

Adults: Initially 1 tab daily with food; may increase to 2 tabs daily in single or divided doses. After initial diuresis, reassess therapy; may be given intermittently for maintenance.

Children: Not recommended.

Contraindications: Concomitant triamterene, spironolactone, salt substitutes, K⁺ supplements (unless hypokalemia is severe). Hyperkalemia. Anuria. Diabetic nephropathy. Renal impairment. Sulfonamide allergy.

Warnings/Precautions: Acidosis predisposition. Electrolyte imbalance. Hepatic impairment. Monitor electrolytes, renal function (esp. in diabetics). Discontinue if serum potassium >5.5mEq/L or renal values progress. Gout. SLE. Severely ill. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid lithium, spironolactone, triamterene, other K⁺-sparing diuretics, K⁺ supplements. Hyperkalemia with ACE inhibitors, NSAIDs. Hypokalemia with amphotericin B, corticosteroids, ACTH. Potentiated by CNS depressants. May potentiate nondepolarizing muscle relaxants. Antagonized by NSAIDs. May interfere with glucose tolerance or parathyroid test.

Adverse reactions: Headache, weakness, GI upset, rash, dizziness, hyperkalemia, fatigue, arrhythmia, pruritus, leg ache, dyspnea, syncope, orthostatic hypotension, electrolyte imbalances, insomnia, depression, nasal congestion, impotence, photosensitivity, cough, hyperglycemia, hyperuricemia, adverse lipid values.

How supplied: Contact supplier.

BUMETANIDE

R

BUMETANIDE INJECTION (various)

Diuretic (loop). Bumetanide 0.25mg/mL; contains benzyl alcohol.

Indications: Edema.

Adults: Initially 0.5–1mg IM or IV. May give 1–2 more doses at 2–3 hour intervals; max 10mg/day.

Children: <18yrs: not recommended.

Contraindications: Anuria. Infants. Hepatic coma. Severe electrolyte depletion.

Warnings/Precautions: Hepatic cirrhosis. Ascites. Progressive renal disease. Gout. Diabetes. Postsympathectomy. Monitor electrolytes, blood, liver function. May need K⁺ supplementation. K⁺ losing nephropathy. Discontinue if renal dysfunction progresses. Aldosterone excess. Ventricular arrhythmias. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May increase digitalis, lithium toxicity. Hypokalemia with digitalis, diuretics in CHF. Alcohol, CNS depressants increase orthostatic hypotension. Avoid probenecid, indomethacin. Ototoxicity may be potentiated with aminoglycosides.

Adverse reactions: Muscle cramps, dizziness, hypotension, headache, nausea, encephalopathy, ototoxicity, rash, fluid or electrolyte imbalance, hyperglycemia, hyperuricemia, blood dyscrasias.

How supplied: Contact supplier.

BUMETANIDE

R

BUMETANIDE TABLETS (various)

Diuretic (loop). Bumetanide 1mg; scored tabs.

Indications: Edema.

Adults: 0.5mg–2mg daily; max 10mg daily. Intermittent dosing optimal.

Children: <18yrs: not recommended.

Contraindications: Anuria. Hepatic coma. Severe electrolyte depletion.

Warnings/Precautions: Hepatic cirrhosis. Ascites. Sulfonamide allergy. Progressive renal disease. Gout. Diabetes. Postsympathectomy. Monitor electrolytes, blood, liver function. Potassium supplementation may be needed. Potassium-losing nephropathy. Aldosterone excess. Discontinue if renal dysfunction progresses. Ventricular arrhythmias. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May increase digitalis, lithium toxicity. Hypokalemia with digitalis, diuretics in CHF. Alcohol, CNS depressants may increase orthostatic hypotension. Avoid probenecid, indomethacin. Ototoxicity may be potentiated with aminoglycosides.

Adverse reactions: Muscle cramps, dizziness, hypotension, headache, nausea, encephalopathy, ototoxicity, rash, fluid or electrolyte imbalance, hyperglycemia, hyperuricemia, blood dyscrasias.

How supplied: Contact supplier.

FUROSEMIDE

R

LASIX Sanofi Aventis

Loop. Furosemide 20mg, 40mg+, 80mg; tabs; +scored.

Indications: Edema.

Adults: Initially 20–80mg daily. May repeat or increase after 6–8 hours; max 600mg/day. Maintenance: intermittent dosing optimal.

Children: Initially 2mg/kg. Increase if needed by 1–2mg/kg after 6–8 hours; max 6mg/kg per day. Maintenance: lowest effective dose.

Contraindications: Anuria.

Warnings/Precautions: Hepatic cirrhosis: do not initiate during hepatic coma or electrolyte depletion. Discontinue if increasing azotemia and oliguria occur during treatment of severe progressive renal disease. Renal or hepatic dysfunction. Diabetes.

Gout. SLE. Sulfonamide sensitivity. Bladder emptying disorders. Prostatic hyperplasia. Urethral narrowing. Hypoproteinemia. Monitor BP, electrolytes, fluids, blood, BUN. Potassium supplementation may be needed. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant chloral hydrate: not recommended. Concomitant acetylsalicylic acid may reduce creatinine clearance. Digitalis, lithium toxicity. Alcohol, CNS depressants may increase orthostatic hypotension. Antagonized by indomethacin, phenytoin. May alter excretion of salicylates, lithium. Hypokalemia with corticosteroids, ACTH, large amounts of licorice, prolonged laxatives. Increased risk of cephalosporin-

induced nephrotoxicity and radiocontrast nephropathy. Increased risk of gouty arthritis with cyclosporine. Antagonizes tubocurarine, norepinephrine. Potentiates antihypertensives, succinylcholine, ganglionic or peripheral adrenergic blocking drugs. Ototoxicity with aminoglycosides, ethacrynic acid. Ototoxicity, nephrotoxicity with cisplatin (give lower doses of furosemide with positive fluid balance). Separate sucralate dosing by at least two hours. Antagonized by, and potentiates, methotrexate.

Adverse reactions: Excessive diuresis, fluid or electrolyte imbalance, GI upset, dizziness, vertigo, paresthesias, or thostatic hypotension, hyperglycemia, jaundice, hyperuricemia, rash, photosensitivity, tinnitus, hearing loss, blood dyscrasias, renal calcification, persistence of patent ductus arteriosus in premature infants.

How supplied: Tabs 20mg-100, 1000; 40mg-100, 500, 1000; 80mg-50, 500

HYDROCHLOROTHIAZIDE

HYDROCHLOROTHIAZIDE (various)

Thiazide. Hydrochlorothiazide 25mg, 50mg; scored tabs.

Indications: Edema.

Adults: 25-100mg daily in single or divided doses; may give on intermittent schedule (every other day or 3-5 days/wk).

Children: See literature. 1-2mg/kg per day in 1 or 2 divided doses. <6months: up to 3mg/kg per day in 2 divided doses. ≤2years: max 37.5mg/day. 2-12years: up to 100mg/day.

Contraindications: Anuria. Sulfonamide allergy.

Warnings/Precautions: Renal or hepatic impairment. Arrhythmia. Diabetes. Gout. Asthma. SLE. Postsympathectomy. Excessive fluid loss. Monitor electrolytes, BUN (if high). K⁺ supplements or K⁺ sparing diuretics may be needed. Discontinue if electrolyte disorders develop rapidly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Digitalis, lithium toxicity. Adjust antidiabetic, antihypertensive medications. NSAIDs may cause renal failure. ACTH, corticosteroids, amphotericin B increase hypokalemia risk. Orthostatic hypotension with alcohol, CNS depressants. Hyperglycemia, hyperuricemia more likely with diazoxide. Antagonized by NSAIDs. May potentiate nondepolarizing muscle relaxants. May antagonize norepinephrine. May interfere with parathyroid tests.

Adverse reactions: Electrolyte disorders (esp. hypokalemia), hyperglycemia, hyperuricemia, photosensitivity, orthostatic hypotension, GI disturbances, adverse lipid values.

How supplied: Contact supplier.

SPIRONOLACTONE

ALDACTONE Pfizer

K⁺-sparing. Spironolactone 25mg, 50mg+, 100mg+; tabs; + scored.

Indications: Edema.

Adults: Initially 25-200mg daily. Usual starting dosage: 100mg/day in single or divided doses. Maintain for 5 days, then retitrate.

Children: Initially 3.3mg/kg per day in single or divided doses.

Contraindications: Hyperkalemia. Renal impairment.

Warnings/Precautions: Hepatic cirrhosis.

Hyponatremia. Surgery. Monitor electrolytes.

Pregnancy. Nursing mothers: not recommended.

Interactions: Avoid K⁺ sparing diuretics, K⁺ supplements, K⁺ containing salt substitutes, lithium. Hyperkalemia more likely with ACE inhibitors, NSAIDs. Hypokalemia with corticosteroids, ACTH. Antagonized by NSAIDs. Potentiates ganglionic blockers, alcohol, barbiturates, narcotics, skeletal muscle relaxants. Digitalis toxicity.

Adverse reactions: Hyperkalemia, hyponatremia, gynecomastia, GI disturbances, drowsiness, headache, rash, confusion, drug fever, ataxia, impotence, hirsutism, voice deepening, menstrual changes, gastric ulcers, agranulocytosis.

How supplied: Tabs 25mg-100, 500, 2500; 50mg, 100mg-100

TORSEMIDE

DEMADEX Roche

Diuretic (loop). Torsemide 5mg, 10mg, 20mg, 100mg; scored tabs.

Also: Torsemide

TORSEMIDE INJECTION (various)

Torsemide 10mg/mL; for IV injection.

Indications: Edema.

Adults: Give IV dose over a period of 2 minutes.

Edema due to CHF: 10-20mg once daily oral or IV, if needed titrate upwards by doubling dose until desired response; max 200mg daily. Edema due to renal disease: 20mg once daily oral or IV, if needed titrate upwards by doubling dose until desired response; max 200mg daily. Edema due to hepatic disease: 5-10mg once daily oral or IV, give with aldosterone antagonist or potassium-sparing diuretic, may titrate upwards by doubling dose until desired response is achieved; max 40mg daily.

Children: Not recommended.

Contraindications: Anuria. Sulfonamide allergy.

Warnings/Precautions: Hepatic disease with cirrhosis and ascites. Monitor electrolytes, BUN, creatinine, uric acid, and fluids. Pregnancy (Cat.B). Nursing mothers.

Interactions: Lithium and salicylate toxicity.

Cautious with NSAIDs. Antagonized by probenecid and indomethacin. Give oral dose 2 hours before or 4 hours after cholestyramine. Ototoxicity with aminoglycosides and ethacrynic acid.

Adverse reactions: Dizziness, headache, nausea, weakness, vomiting, hyperglycemia, hyperuricemia, hypokalemia, excessive thirst, hypovolemia, impotence, esophageal hemorrhage, dyspepsia.

How supplied: Tabs-100; Ampules-Contact supplier

TRIAMTERENE + HYDROCHLOROTHIAZIDE

DYAZIDE GlaxoSmithKline
K⁺-sparing + thiazide. Triamterene 37.5mg, hydrochlorothiazide 25mg; caps.

Indications: Edema.

Adults: 1–2 caps once daily.

Children: Not recommended.

Contraindications: Hyperkalemia. Renal impairment. Anuria. Sulfonamide allergy. Concomitant potassium or K⁺-sparing diuretics.

Warnings/Precautions: Diabetes. Acidosis predisposition. Electrolyte imbalance. Hypochloremia with metabolic alkalosis. Excess diuresis. History of renal stones. Gout. Surgery. SLE. Monitor electrolytes, renal function. Discontinue if serum potassium >5.5mEq/L or <3mEq/L. Hepatic impairment: monitor for hepatic coma, if confusion increases, discontinue for a few days. Severely ill. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Digoxin, lithium toxicity. Hyperkalemia more likely with ACE inhibitors, parenteral penicillin G. Hypokalemia with ACTH, corticosteroids, amphotericin B. Hyponatremia with sulfonylureas. NSAIDs may cause renal failure. Adjust antidiabetic, antitumor medications. May potentiate nondepolarizing muscle relaxants, antihypertensives. Antagonizes oral anticoagulants, methenamine. May interfere with parathyroid tests.

Adverse reactions: Drowsiness, muscle cramps, weakness, headache, GI disturbances, dizziness, impotence, arrhythmias, hypotension, dry mouth, urine discoloration.

How supplied: Caps–100, 1000

2D Electrolyte disturbances**CONIVAPTAN**

VAPRISOL Astellas

Dual arginine vasopressin (V_{1A} and V₂) receptors antagonist. Conivaptan HCl 20mg/100mL in 5% dextrose; soln for IV infusion.

Indications: Euvolemic and hypervolemic hyponatremia in hospitalized patients.

Adults: Administer via large veins; rotate infusion site every 24hrs. Loading dose: 20mg IV over 30mins, followed by 20mg continuous IV infusion over 24hrs. After initial day of treatment, give 20mg/day continuous IV infusion for an additional 1–3 days; may titrate up to max 40mg/day if serum sodium is not rising at desired rate. Max duration after loading dose: 4 days. Moderate hepatic impairment: Loading dose: 10mg IV over 30mins, followed by 10mg/day as continuous IV infusion for 2–4 days; may titrate up to max 20mg/day if serum sodium is not rising at desired rate.

Children: Not recommended.

Contraindications: Hypovolemic hyponatremia. Concomitant potent CYP3A4 inhibitors (eg,

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ketoconazole, itraconazole, clarithromycin, ritonavir, indinavir). Anuric patients. Corn or corn product allergy.

Warnings/Precautions: Not for treating CHF. Renal or hepatic impairment. Monitor serum sodium concentration, volume status, neurologic status. Discontinue if serum sodium rises too rapidly (>12mEq/L per 24hrs); may resume at reduced dose if hyponatremia persists or recurs and no evidence of neurologic sequelae. Discontinue if hypovolemia or hypotension develops; may resume at reduced dose if euvolemic and not hypotensive. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Potentiated by CYP3A4 inhibitors. Potentiates CYP3A4 substrates (eg, midazolam, simvastatin, amlodipine); avoid; allow at least 1 week after end of conivaptan administration before resuming these drugs. May potentiate digoxin; monitor.

Adverse reactions: Infusion site reactions (eg, phlebitis, erythema, pain), GI upset, headache, hypokalemia, hyponatremia, orthostatic hypotension, hyper- or hypotension, peripheral edema, thirst.

How supplied: Single-use premixed soln–1

POTASSIUM CHLORIDE

R

KLOR-CON M Upsher-Smith

Potassium (as chloride) 10mEq, 15mEq +, 20mEq +; ext-rel tabs (+ scored).

Also: Potassium chloride

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KLOR-CON

Potassium (as chloride) 8mEq, 10mEq; ext-rel tabs.

Also: Potassium chloride

R

KLOR-CON POWDER

Potassium (as chloride) 20mEq/packet, 25mEq/packet; pwd for oral soln; fruit flavor.

Also: Potassium chloride

R

KLOR-CON/EF

Potassium (as bicarbonate) 25mEq; effervescent tabs; fruit flavor.

Indications: Hypokalemia, including that caused by diuretics. Digitalis intoxication without AV block.

Adults: Take with meals and fluids. Swallow tabs whole; may break Klor-Con M tabs in half, or mix in 4oz water. Effervescent tabs, pwd: dissolve in beverage. Prophylaxis: 20mEq daily. Treatment: 40–100mEq daily in divided doses; max 20mEq/dose.

Children: Not recommended.

Contraindications: Hyperkalemia. Chronic renal disease. Acute dehydration. Heat cramps. Severe tissue destruction. Adrenal insufficiency. Familial periodic paralysis. Acidosis (potassium chloride products). Alkalosis (potassium bicarbonate products). Tablets: Esophageal compression due to enlarged left atrium. Decreased GI motility.

Warnings/Precautions: Discontinue if GI bleed, ulceration, or other disturbances occur. Renal or cardiac disease. Monitor potassium level, clinical

status, acid-base balance, and ECG. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Hyperkalemia with ACE inhibitors, spirinolactone, triamterene, amiloride, and potassium-containing salt substitutes. Anticholinergics, other agents that decrease GI motility increase risk of serious GI reactions with tablets.

Adverse reactions: Hyperkalemia, GI discomfort and irritation, diarrhea, rash (rare). Tablets: Esophageal and GI ulceration, bleeding, obstruction, perforation.

How supplied: M10–90, 100, 1000; M15–100, 1000; M20–90, 100, 500, 1000; Klor-Con 8, 10–100, 500; Pwd (20mEq packets)–30, 100; Pwd (25mEq packets)–30, 100, 250; Klor-Con/EF–30, 100

TOLVAPTAN

R

SAMSCA Otsuka

Selective vasopressin V₂-receptor antagonist.

Tolvaptan 15mg, 30mg; tabs.

Indications: Clinically significant euvolemic and hypervolemic hyponatremia (serum sodium <125mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, cirrhosis, and syndrome of inappropriate antidiuretic hormone (SIADH).

Adults: Initiate and re-initiate only in a hospital. Initially 15mg once daily, may increase dose after ≥24hrs to 30mg once daily, then to max 60mg once daily as needed to raise serum sodium. Avoid fluid restriction during the first 24hrs of therapy; resume fluid restriction after drug discontinuation.

Children: Not recommended.

Contraindications: Urgent need to raise serum sodium acutely. Inability of patient to sense or appropriately respond to thirst. Hypovolemic hyponatremia. Concomitant strong CYP3A inhibitors (eg, clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, telithromycin. Anuric patients.

Warnings/Precautions: Discontinue or interrupt therapy if too rapid a rise in serum sodium occurs (eg, >12mEq/L/24hrs) or if significant signs/symptoms of hypovolemia develop. Severe renal impairment. Monitor frequently for changes in serum electrolytes, volume, and neurologic status during initiation and titration. Severe malnutrition, alcoholism, advanced liver disease: slower rates of correction advisable. Monitor serum potassium in patients with potassium >5mEq/L or on drugs known to increase potassium. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Potentiated by CYP3A inhibitors, grapefruit juice; avoid moderate CYP3A inhibitors (eg, erythromycin, fluconazole, aprepitant, diltiazem, verapamil). Antagonized by CYP3A inducers (eg, rifampin, rifabutin, rifapentin, barbiturates, phenytoin, carbamazepine, St. John's wort); avoid. Concomitant P-gp inhibitors (eg,

cyclosporine); consider reducing tolvaptan dose. Monitor digoxin. Concomitant hypertonic saline or V₂ agonist (desmopressin): not recommended.

Adverse reactions: Thirst, dry mouth, asthenia, constipation, pollakiuria, polyuria, hyperglycemia; GI bleeding (in cirrhotic patients; use only if need outweighs risk), osmotic demyelination syndrome.

How supplied: Tabs–10

2E Hyperlipoproteinemias

ATORVASTATIN

R

LIPITOR Pfizer

HMG-CoA reductase inhibitor. Atorvastatin (as calcium) 10mg, 20mg, 40mg, 80mg; tabs.

Indications: Adjunct to diet in primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Types IIa and IIb) to reduce total-C, LDL-C, apo B and TG, and to increase HDL-C. Adjunct to diet in treating elevated serum TG (Type IV). Treatment of primary dysbetalipoproteinemia (Type III) not adequately responsive to diet. Adjunct to diet to lower lipid-lowering treatments (or when these are unavailable), in homozygous familial hypercholesterolemia to reduce total-C and LDL-C. Adjunct to diet to reduce total-C, LDL-C and apo B in patients 10–17 years of age (≥1 year post-menarche) with heterozygous familial hypercholesterolemia if LDL-C remains ≥190mg/dL, or if LDL-C remains ≥160mg/dL with either family history of premature cardiovascular disease (CVD) or if patient has at least 2 other CVD risk factors. To reduce risk of MI, stroke, and risk of revascularization procedures in adults at risk (see full labeling). To reduce risk of MI and stroke in patients with type 2 diabetes and at risk (see full labeling). To reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization, hospitalization for CHF, and angina in patients with clinically evident coronary heart disease. Limitations of use: not studied where major abnormality is elevation of chylomicrons (Fredrickson Types I and V).

Adults: ≥17yrs: Heterozygous and Types IIa and IIb: initially 10 or 20mg once daily; if more than a 45% reduction in LDL-C is needed, may start at 40mg once daily; range 10–80mg once daily. Homozygous: 10–80mg daily. Concomitant clarithromycin, itraconazole, saquinavir + ritonavir, darunavir + ritonavir, fosamprenavir or fosamprenavir + ritonavir: max 20mg/day. Concomitant nelfinavir or boceprevir: max 40mg/day.

Children: Heterozygous: <10yrs: not recommended. 10–17yrs: initially 10mg/day, may increase to 20mg/day after at least 4 weeks. Homozygous: 80mg/day has been used; see literature.

Contraindications: Active liver disease. Unexplained persistent elevated serum transaminases. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Discontinue if myopathy, elevated CPK levels occur; suspend if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Monitor liver function before starting therapy and repeat as clinically indicated. History of liver disease. Substantial alcohol ingestion. Hemorrhagic stroke. Elderly.

Interactions: See Adult dose. Avoid with concomitant cyclosporine, gemfibrozil, tipranavir + ritonavir, telaprevir. Potentiated by strong CYP3A4 inhibitors, grapefruit juice (>1.2L/day). Caution with lopinavir + ritonavir, other fibrates, niacin ($\geq 1\text{g/day}$), colchicine; consider dose reduction of atorvastatin. May increase serum levels of digoxin, oral contraceptives (norethindrone, ethinyl estradiol); monitor digoxin. Caution with drugs that decrease levels or activity of steroid hormones (eg, ketoconazole, spironolactone, cimetidine).

Adverse reactions: GI upset, headache, myalgia, arthralgia, rash, elevated serum transaminases, myopathy, rhabdomyolysis with renal dysfunction; increased HbA1c and fasting serum glucose, cognitive impairment; rare: immune-mediated necrotizing myopathy.

How supplied: Tabs 10mg, 20mg-90, 5000; 40mg, 80mg-90, 500, 2500

COLESEVELAM

WELCHOL Daiichi Sankyo

Bile acid sequestrant. Colesevelam HCl 625mg; tabs.

Also: Colesevelam

WELCHOL FOR ORAL SUSPENSION

Colesevelam HCl 3.75g; pwd pkts; citrus flavored; contains phenylalanine 48mg/3.75g pkt.

Indications: Adjunct to diet and exercise: to reduce elevated LDL-C in adults with primary hypercholesterolemia (Type IIa), alone or with a statin, when response to nondrug therapy is inadequate; to reduce LDL-C in boys and postmenarchal girls 10-17yrs of age with heterozygous familial hypercholesterolemia, alone or with a statin after failing an adequate trial of diet therapy.

Adults and Children: <10yrs: not recommended. Take with a meal and liquid. $\geq 10\text{yrs}$: Susp: one 3.75g pkt once daily. Empty contents into a glass or cup, add 4-8oz of water, fruit juice, or diet soft drinks; stir and drink. Do not take susp in its dry form. $>17\text{yrs}$: 3 tabs twice daily or 6 tabs once daily. With a statin: may be dosed at the same time or dosed apart.

Contraindications: History of bowel obstruction. Serum TG >500mg/dL. History of hypertriglyceridemia-induced pancreatitis.

Warnings/Precautions: TG levels >300mg/dL. Monitor lipids, TG, and non-HDL-C levels prior to therapy and periodically thereafter. Susceptibility to Vit. A, D, E, or K deficiencies. Risk of bowel obstruction (eg, gastroparesis, other GI motility

disorders, or a history of major GI surgery). Dysphagia or swallowing disorders (esp. w/tab form). Pregnancy (Cat.B). Nursing mothers.

Interactions: Monitor drugs with a narrow therapeutic index, glyburide, levothyroxine, oral contraceptives containing ethinyl estradiol and norethindrone, phenytoin, warfarin; give at least 4 hours prior to colestevam. May potentiate metformin extended-release.

Adverse reactions: Constipation, dyspepsia, nausea, dysphagia.

How supplied: Tabs-180; Susp 3.75g-30 (single-dose pkt)

EZETIMIBE

ZETIA Merck

Cholesterol absorption inhibitor. Ezetimibe 10mg; tabs.

Indications: Adjunct to diet, alone or in combination with an HMG-CoA reductase inhibitor (statin), in primary hyperlipidemia (heterozygous familial and non-familial) to reduce elevated total-C, LDL-C, Apo B, and non-HDL-C. Adjunct to diet and in combination with fenofibrate to reduce elevated total-C, LDL-C, Apo B, and non-HDL-C in mixed hyperlipidemia.

Adjunct to other lipid-lowering treatments, or if these treatments are unavailable, with atorvastatin or simvastatin to reduce elevated total-C and LDL-C in homozygous familial hypercholesterolemia. Adjunct to diet in homozygous familial sitosterolemia to reduce elevated sitosterol and campesterol.

Adults: $\geq 10\text{yrs}$: 10mg once daily. Concomitant bile acid sequestrants: give ezetimibe either $\geq 2\text{hrs}$ before or $\geq 4\text{hrs}$ after. Concomitant simvastatin doses $>20\text{mg}$ in moderate-to-severe renal impairment: use caution and monitor closely.

Children: <10yrs: not recommended. **Contraindications:** The use of ezetimibe with a statin is contraindicated in active liver disease or unexplained persistent elevations in serum transaminases. Statins are contraindicated in pregnancy and nursing.

Warnings/Precautions: Moderate to severe hepatic insufficiency: not recommended. If given with a statin: monitor liver function initially and then as recommended for the statin. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant fibrates (except fenofibrate): not recommended. Potentiates cyclosporine. Potentiated by fenofibrate, gemfibrozil, cyclosporine. Monitor warfarin, cyclosporine. Antagonized by cholestyramine.

Adverse reactions: Upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, dizziness, headache, fatigue; rare: myopathy/rhabdomyolysis; w. statin: nasopharyngitis, myalgia, back pain, increased serum transaminases.

Note: For more information on statins, see their entries.

How supplied: Tabs-30, 90, 500, 5000

EZETIMIBE + ATORVASTATIN

R

LIPTRUZET Merck

Cholesterol absorption inhibitor + HMG-CoA reductase inhibitor. Ezetimibe/atorvastatin; 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg; tabs.

Indications: To reduce elevated total-C, LDL-C, Apo B, TG, and non-HDL-C, and to increase HDL-C in primary (heterozygous familial and non-familial) or mixed hyperlipidemia. To reduce elevated total-C and LDL-C in homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments (eg, LDL apheresis) or if such treatments are unavailable. Limitations of use: No incremental benefit on cardiovascular morbidity/mortality over and above that demonstrated for atorvastatin has been established. Not studied in Fredrickson type I, III, IV, and V dyslipidemias.

Adults: Swallow whole. Usual range: 10mg/10mg to 10mg/80mg. Initially 10mg/10mg or 10mg/20mg; for LDL-C reduction >55%: may start at 10mg/40mg; monitor lipids within ≥ 2 wks and adjust dose as needed. HoFH: 10mg/40mg or 10mg/80mg. Concomitant bile acid sequestrants: give Liptruzet dose either ≥ 2 hrs before or ≥ 4 hrs after bile acid sequestrant administration. Concomitant lopinavir/ritonavir: use lowest dose. Concomitant clarithromycin, itraconazole, saquinavir/ritonavir, darunavir/ritonavir, fosamprenavir, or fosamprenavir/ritonavir: max 10mg/20mg. Concomitant nelfinavir or boceprevir: max 10mg/40mg.

Children: Not established.

Contraindications: Active liver disease. Unexplained persistent elevated hepatic transaminases. Pregnancy (Category X). Nursing mothers.

Warnings/Precautions: Increased risk of myopathy/rhabdomyolysis (with high doses). Discontinue if elevated CPK ($>10 \times$ ULN) levels occur or myopathy is diagnosed or suspected; withhold if a predisposition in renal failure secondary to rhabdomyolysis develops. Monitor liver function prior to starting therapy and repeat as clinically indicated. History of liver disease or renal impairment; monitor closely. Substantial alcohol consumption. Elderly.

Interactions: See Adult dose. Avoid with concomitant cyclosporine, tipranavir/ritonavir, telaprevir, gemfibrozil. Potentiated by strong CYP3A4 inhibitors, grapefruit juice (>1.2 L/day). Caution with lopinavir/ritonavir, colchicine, fenofibrates, niacin ≥ 1 g/day; consider dose reduction of Liptruzet. May increase serum levels of digoxin (monitor), oral contraceptives. May be antagonized by cholestyramine, CYP3A4 inducers (eg, efavirenz, rifampin); coadminister rifampin simultaneously. Monitor oral anticoagulants. Caution with drugs that decrease levels or activity of endogenous steroid hormones (eg, ketoconazole, spironolactone, cimetidine).

Adverse reactions: Increased ALT/AST, musculoskeletal pain, arthralgia, abdominal pain,

nausea; increased in HbA1c or fasting serum glucose; myopathy, rhabdomyolysis; rare: immune-mediated necrotizing myopathy.

How supplied: Tabs-30, 90

FENOFIBRATE

R

LOFIBRA TABLETS Teva US Generics

Fibrate. Fenofibrate 54mg, 160mg; tabs.

Indications: Adjunct to diet in hypertriglyceridemia (Types IV and V), and to reduce elevated total-C, LDL-C, apo B, and TG, and to increase HDL-C, in primary hypercholesterolemia and mixed dyslipidemia (Types IIa and IIb).

Adults: Take with food. Hypertriglyceridemia: 54mg-160mg/day; adjust in 4-8 week intervals. Hypercholesterolemia, dyslipidemia: 160mg/day. Renal impairment (CrCl <50 mL/min): initially 54mg/day. Discontinue if inadequate response after 2 months on max dose.

Children: Not recommended.

Elderly: Initially 54mg/day.

Also: Fenofibrate

R

LOFIBRA CAPSULES

Fenofibrate 67mg, 134mg, 200mg; caps (micronized).

Adults: Take with food. Hypertriglyceridemia: 67-200mg/day; adjust in 4-8 week intervals; max 200mg/day. Hypercholesterolemia, dyslipidemia: 200mg/day. Renal impairment (CrCl <50 mL/min): initially 67mg/day. Discontinue if inadequate response after 2 months on max dose.

Children: Not recommended.

Elderly: Initially 67mg/day.

Contraindications: Hepatic dysfunction. Primary biliary cirrhosis. Severe renal dysfunction. Gallbladder disease.

Warnings/Precautions: Renal impairment. Monitor CBCs for first year; monitor liver function, discontinue if ALT (SGPT) levels $>3 \times$ ULN persist. Discontinue if markedly elevated CPK levels, myopathy, or gallstones occur. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid statins. Potentiates oral anticoagulants (monitor). Allow at least 1 hour before or 4-6 hours after bile acid sequestrants. Caution with immunosuppressants (eg, cyclosporine), other nephrotoxic drugs.

Adverse reactions: Abnormal liver function tests, elevated CPK, respiratory or GI effects, myopathy, cholelithiasis, pancreatitis, increased creatinine, rash; rare: rhabdomyolysis, transient hematologic changes, blood dyscrasias.

How supplied: Tabs-90

Caps-100

FENOFIBRATE

R

TRICOR AbbVie

Fibrate. Fenofibrate 48mg, 145mg; tabs.

Indications: Adjunct to diet in hypertriglyceridemia (Types IV and V), and to reduce elevated total-C, LDL-C, apo B, and TG, and to increase HDL-C, in

primary hypercholesterolemia and mixed dyslipidemia (Types IIa and IIb). Limitations of use: not shown to reduce coronary heart disease morbidity and mortality in a controlled trial of patients with type 2 diabetes mellitus.

Adults: Hypertriglyceridemia: 48–145mg/day, adjust at 4–8 week intervals. Hypercholesterolemia, dyslipidemia: 145mg/day. Renal impairment or elderly: initially 48mg/day. Discontinue if inadequate response after 2 months on max dose.

Children: Not recommended.

Contraindications: Hepatic dysfunction. Primary biliary cirrhosis. Severe renal dysfunction. Gallbladder disease.

Warnings/Precautions: Renal impairment. Monitor CBCs for first year; monitor liver function; discontinue if ALT (SGPT) levels $>3 \times$ ULN persist. Discontinue if markedly elevated CPK levels, myopathy, gallstones or severely depressed HDL-C levels occur (do not reinitiate). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid statins. Potentiates oral anticoagulants (monitor). Allow at least 1 hour before or 4–6 hours after bile acid sequestrants. Caution with immunosuppressants (eg, cyclosporine), colchicine, other nephrotoxic drugs.

Adverse reactions: Abnormal liver function tests, elevated CPK, rhinitis, myopathy, cholelithiasis, pancreatitis, increased BUN or creatinine, rash; rare: rhabdomyolysis, transient hematologic changes, blood dyscrasias.

Note: Formerly marketed in 54mg and 160mg strengths.

How supplied: Tabs–90

FLUVASTATIN

LESCOL Novartis

HMG-CoA reductase inhibitor. Fluvastatin sodium 20mg, 40mg; caps.

Indications: Adjunct to diet in primary hypercholesterolemia and mixed dyslipidemia (Types IIa and IIb) to reduce elevated total-C, LDL-C, TG, and apo B, and to increase HDL-C when response to nondrug therapy is inadequate. Adjunct to diet to reduce total-C, LDL-C and apo B in patients 10–16 years of age (≥ 1 year post-menarche) with heterozygous familial hypercholesterolemia if LDL-C remains ≥ 190 mg/dL, or if LDL-C remains ≥ 160 mg/dL with either family history of premature cardiovascular disease (CVD) or if patient has at least 2 other CVD risk factors. In patients with coronary heart disease: To slow the progression of coronary atherosclerosis to lower total-C and LDL-C, and to reduce the risk of undergoing coronary revascularization procedures. Limitations of Use: not studied in conditions where major abnormality is elevation of chylomicrons, VLDL, or IDL.

Adults: Swallow whole. ≥ 18 ys: LDL-C reduction of $<25\%$: initially Lescol 20mg capsule once daily in the PM. LDL-C reduction of $\geq 25\%$: Lescol XL 80mg

tab once daily, or Lescol 40mg capsule once daily in the PM or twice daily. Usual range: 20–80mg/day. Concomitant cyclosporine, fluconazole: max Lescol 20mg capsule twice daily.

Children: <10 ys: not recommended. 10–16ys: Initially Lescol 20mg capsule once daily; may increase dose at 6-week intervals to max daily dose of either Lescol 40mg capsule twice daily or Lescol XL 80mg tablet once daily.

Contraindications: Active liver disease.

Unexplained, persistent elevated serum transaminases. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Discontinue if myopathy, elevated CPK levels occur; suspend if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Monitor liver function before starting therapy and repeat as clinically indicated. Interrupt therapy if serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs; do not restart if alternate etiology not found. History of liver disease. Substantial alcohol consumption. Monitor for endocrine dysfunction. Homozygous familial hypercholesterolemia. Severe renal insufficiency.

Interactions: See Adult dose. Avoid concomitant gemfibrozil. Caution with other fibrates, niacin (≥ 1 g/day), colchicine; consider reducing dose of fluvastatin. Monitor oral anticoagulants, glyburide, phenytoin. Inhibition of endogenous steroid production with spironolactone, ketoconazole, cimetidine.

Adverse reactions: Headache, dyspepsia, myalgia, abdominal pain, nausea, elevated serum transaminases, myopathy, rhabdomyolysis with renal dysfunction; increased HbA1c and fasting serum glucose, rare: cognitive impairment, non-fatal hepatic failure, immune-mediated necrotizing myopathy.

How supplied: Tabs, caps–30, 100

GEMFIBROZIL

LOPID Pfizer

Isobutyric acid derivative. Gemfibrozil 600mg; scored tabs.

Indications: Type IV and V hyperlipidemias resistant to dietary management, when TG levels are >1000 mg/dL and pancreatitis is likely. Reduction in risk of coronary artery disease in certain Type IIb patients with HDL-C levels <35 mg/dL, when response to 1st line agents and nondrug management is inadequate.

Adults: 1.2g daily in 2 divided doses 30 minutes before AM and PM meals.

Children: Not recommended.

Contraindications: Hepatic or renal dysfunction. Primary biliary cirrhosis. Gallbladder disease.

Warnings/Precautions: Monitor serum lipids and liver function. Discontinue if lipid response is inadequate after 3 months, or if persistent liver abnormalities or gallstones develop. Obtain blood

counts periodically during first 12 months. Investigate muscle complaints; discontinue if myositis is suspected. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Anticoagulants potentiated; reduce anticoagulant dosage and monitor prothrombin time. Rhabdomyolysis and renal failure with lovastatin. Avoid use with HMG-CoA reductase inhibitors. Hypoglycemia with repaglinide.

Adverse reactions: Dyspepsia, abdominal pain, acute appendicitis, atrial fibrillation, gallbladder disease, cholestatic jaundice, blurred vision, paresthesias, hypesthesia, altered taste, dizziness, somnolence, peripheral neuritis, headache, depression, impotence, decreased libido, myopathy, arthralgia, synovitis, abnormal liver function tests, blood dyscrasias, angioedema, rash.

How supplied: Tabs-60, 500

LOVASTATIN

R

LOVASTATIN TABLETS (various)
HMG-CoA reductase inhibitor. Lovastatin 10mg, 20mg, 40mg; tabs.

Indications: To reduce risk of MI, unstable angina, and coronary revascularization procedures in patients without symptomatic cardiovascular disease (CVD), average to moderately elevated total-C and LDL-C, and below average HDL-C. Primary hypercholesterolemia (Types IIa and IIb) to reduce elevated total-C and LDL-C when response to nondrug therapy is inadequate. To slow progression of coronary atherosclerosis in patients with coronary heart disease to lower total-C and LDL-C. Adjunct to nondrug therapy to reduce total-C, LDL-C and apo B in patients 10-17yrs of age (≥ 1 yr post-menarche) with heterozygous familial hypercholesterolemia if LDL-C remains >189 mg/dL, or if LDL-C remains >160 mg/dL with either family history of premature cardiovascular disease (CVD) or if patient has at least 2 other CVD risk factors.

Adults: Give with evening meal. ≥ 17 yrs: initially 10-20mg once daily, may increase at 4 week intervals; max 80mg/day in single or divided doses. Concomitant danazol, diltiazem, dronedarone, verapamil: initially 10mg/day; max 20mg/day. Concomitant amiodarone: max 40mg/day. Severe renal insufficiency (CrCl <30 mL/min): 20mg/day; caution with dose increases.

Children: <10 yrs: not recommended. 10-17yrs: initially 10-20mg once daily, may increase at 4 week intervals. Usual range: 10-40mg/day; max 40mg/day.

Contraindications: Active liver disease. Unexplained, persistent elevated serum transaminases. Concomitant strong CYP3A4 inhibitors (eg, itraconazole, ketoconazole, posaconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone). Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Discontinue if myopathy, elevated CPK levels occur; suspend

if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Monitor liver function before starting therapy and repeat as clinically indicated. History of liver disease. Alcoholism. Homozygous familial hypercholesterolemia.

Interactions: See Contraindications. Increased risk of myopathy with strong CYP3A4 inhibitors, danazol, diltiazem, dronedarone, verapamil, amiodarone. May be potentiated by voriconazole, ranolazine; consider dose adjustment of lovastatin. Avoid gemfibrozil, cyclosporine, grapefruit juice >1 quart daily. Caution with, other fibrates, macrolides, niacin (≥ 1 g/day), colchicine. Monitor oral anticoagulants. Inhibition of endogenous steroid production with spironolactone, ketoconazole, cimetidine.

Adverse reactions: GI upset, headache, rash, pruritus, myalgia, dizziness, blurred vision, elevated serum transaminases, myopathy, rhabdomyolysis with renal dysfunction; increased HbA1c and fasting serum glucose, cognitive impairment; rare: immune-mediated necrotizing myopathy.

How supplied: Contact supplier.

NIACIN

R

NIASPAN AbbVie

Nicotinic acid deriv. Niacin 500mg, 750mg, 1g; ext-rel tabs.

Indications: Adjunct to diet in primary hyperlipidemia and mixed dyslipidemia to reduce elevated total-C, LDL-C, apo B, TG and to increase HDL-C; or combined with lovastatin or simvastatin when further reductions in TG or LDL-C or increases in HDL-C are needed, and monotherapy is inadequate. To reduce risk of recurrent nonfatal MI in patients with a history of MI and hyperlipidemia. Combined with a bile acid sequestrant to slow progression or promote regression of atherosclerosis in patients with coronary artery disease and hyperlipidemia. Combined with a bile acid sequestrant to reduce elevated total-C and LDL-C in primary hyperlipidemia when diet or diet + monotherapy has been inadequate. Adjunct in patients with severe hypertriglyceridemia who are at risk for pancreatitis, when determined dietary measures are inadequate. Limitations of use: no incremental benefit on cardiovascular morbidity/mortality over and above that demonstrated for niacin, simvastatin and lovastatin monotherapy, has been established. Niacin ext-rel at doses of 1500-2000mg/day, in combination with simvastatin, did not reduce incidence of cardiovascular events more than simvastatin in a randomized controlled trial of patients with cardiovascular disease and mean baseline LDL-C levels of 74mg/dL.

Adults: Swallow whole. Take at bedtime with low-fat snack. Avoid concomitant alcohol, hot beverages, or spicy foods; may pre-treat with aspirin (up to 325mg) $\frac{1}{2}$ hour before dosing. >16 yrs: initially 500mg once daily for 4 weeks, then 1g once daily for weeks 5-8.

May increase by up to 500mg every 4 weeks to usual range of 1–2g daily; max 2g/day. Combined with lovastatin or simvastatin: max 2g niacin and 40mg lovastatin or simvastatin per day. Retitrate if restarting after an extended time. Women may respond at lower doses than men.

Children: ≤16yrs: not recommended.

Contraindications: Active liver disease. Unexplained elevations of serum transaminases. Active peptic ulcer disease. Arterial bleeding.

Warnings/Precautions: Do not substitute for equivalent doses of immediate-release or sustained-release niacin (hepatotoxicity may occur). History of jaundice, hepatobiliary disease, peptic ulcer. Substantial alcohol consumption. Monitor serum transaminase levels (before treatment then every 6–12 weeks for 1 year then periodically); discontinue if transaminase levels $\geq 3 \times \text{ULN}$ persist or if signs of liver disease occur. Renal dysfunction. Cardiovascular disease (eg, unstable angina, acute MI). Gout. Monitor blood glucose and for hypophosphatemia. Surgery. Diabetes or patients at risk for diabetes. Uncontrolled hypothyroidism. Elderly. Pregnancy (Cat.C), nursing mothers: not recommended (consider discontinuing drug).

Interactions: Avoid other products with high amounts of niacin or nicotinamide, alcohol. Monitor for myopathy/rhabdomyolysis with HMG-CoA reductase inhibitors. May potentiate antihypertensives, other vasoactive drugs (eg, ganglionic or adrenergic blockers, nitrates, calcium channel blockers). Caution with anticoagulants (monitor PT and platelet counts). Antidiabetic agents may need adjustment. Separate dosing of bile acid sequestrants by at least 4–6 hours. May cause false (+) Benedict's test.

Adverse reactions: Flushing, diarrhea, nausea, vomiting, cough, pruritus, dizziness, tachycardia, palpitations, shortness of breath, sweating, chills, edema, pain, rhinitis, rash, glucose intolerance, peptic ulcer, abnormal liver function tests, jaundice.

How supplied: Tabs–30, 90

PITAVASTATIN

R

LIVALO Kowa

HMG-CoA reductase inhibitor. Pitavastatin 1mg, 2mg, 4mg; tabs.

Indications: Adjunct to diet: To reduce elevated total-C, LDL-C, ApoB, and TG, and to increase HDL-C in primary hyperlipidemia and mixed dyslipidemia. Limitations of use: effect on cardiovascular morbidity and mortality has not been determined. Not studied in Fredrickson Type I, III, and V dyslipidemias.

Adults: Initially 2mg once daily; may increase after 4 weeks to max 4mg once daily. Moderate to severe renal impairment (CrCl $< 60 \text{ mL/min}$, or ESRD with hemodialysis): 1mg once daily; max 2mg once daily. Concomitant erythromycin: max 1mg daily. Concomitant rifampin: max 2mg daily.

Children: Not recommended.

Contraindications: Active liver disease.

Unexplained, persistent elevated serum transaminases. Concomitant cyclosporine. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Discontinue if myopathy or markedly elevated CK levels occur; suspend if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Risk factors for myopathy (eg, renal impairment, inadequately treated hypothyroidism, age > 65 years, concomitant fibrates, lipid-modifying niacin). Monitor liver function before starting therapy and repeat as clinically indicated. Interrupt therapy if serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs; do not restart if alternate etiology not found. Substantial alcohol ingestion.

Interactions: Potentiated by cyclosporine (see Contraindications). Avoid gemfibrozil. Fibrates, niacin increase myopathy risk (consider reducing pitavastatin dose). Potentiated by erythromycin, rifampin (see Adult dose). Monitor warfarin.

Adverse reactions: Myalgia, back/extremity pain, GI upset, constipation, elevated creatine phosphokinase, transaminases, alkaline phosphatase, bilirubin, glucose; myopathy, rhabdomyolysis with renal dysfunction, hypersensitivity reactions; rare: cognitive impairment, non-fatal hepatic failure, immune-mediated necrotizing myopathy.

How supplied: Tabs–90

PRAVASTATIN

R

PRAVACHOL Bristol-Myers Squibb

HMG-CoA reductase inhibitor. Pravastatin sodium 10mg, 20mg, 40mg, 80mg; tabs.

Indications: As adjunct to diet when response to nondrug therapy is inadequate: To reduce risk of MI, reduce risk of undergoing myocardial revascularization procedures, and reduce risk of cardiovascular mortality with no increase in death from non-cardiovascular causes in hypercholesterolemic patients without clinically evident coronary heart disease; To reduce mortality risk by reducing coronary death, to reduce risk of MI, to reduce risk of undergoing myocardial revascularization procedures, to reduce risk of stroke or transient ischemic attack (TIA), and to slow progression of coronary atherosclerosis in patients with clinically evident coronary artery disease; To reduce elevated total-C, LDL-C, apo B, and TG, and to increase HDL-C in primary hypercholesterolemia and mixed dyslipidemia (Types IIa and IIb); To treat elevated serum TG (Type IV); To treat primary dysbetalipoproteinemia (Type III). Adjunct to diet in patients 8–18 years of age with heterozygous familial hypercholesterolemia if LDL-C remains $\geq 190 \text{ mg/dL}$, or if LDL-C remains $\geq 160 \text{ mg/dL}$ with either family history of premature cardiovascular disease (CVD) or if patient has at least 2 other CVD risk factors. Limitations of use: not studied in conditions where major lipoprotein

abnormality is elevation of chylomicrons (Fredrickson Types I and V).

Adults: ≥ 18 yrs: initially 40mg once daily; may increase to 80mg once daily after 4 weeks. Renal dysfunction: initially 10mg daily. Concomitant immunosuppressants (eg, cyclosporine): initially 10mg once daily at bedtime; usual max 20mg/day. Concomitant clarithromycin: max 40mg/day.

Children: < 8 yrs: not recommended. 8–13 yrs: 20mg once daily. 14–18 yrs: 40mg once daily.

Contraindications: Active liver disease.

Unexplained, persistent elevated serum transaminases. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Discontinue if myopathy or markedly elevated CPK levels occur; suspend if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Monitor liver function before starting therapy and when clinically indicated. Interrupt therapy if serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs; do not restart if alternate etiology not found. History or symptoms of liver disease or heavy alcohol ingestion. Reevaluate if endocrine dysfunction occurs. Homozygous familial hypercholesterolemia. Renal impairment.

Interactions: See Adult dose. Increased risk of myopathy with cyclosporine, clarithromycin, colchicine. Avoid gemfibrozil. Caution with other fibrates, niacin; may need to reduce pravastatin dose. Enhanced effects with cholestyramine, colestipol (give pravastatin 1hr before or 4hrs after). Caution with drugs that decrease levels or activity of steroid hormones (eg, ketoconazole, spironolactone, cimetidine).

Adverse reactions: Musculoskeletal pain, GI upset, upper respiratory infection, headache; elevated serum transaminases, myopathy, rhabdomyolysis with renal dysfunction; increased HbA1c and fasting serum glucose, rare: cognitive impairment, non-fatal hepatic failure, immune-mediated necrotizing myopathy.

How supplied: Tabs–90

ROSUVASTATIN

CRESTOR AstraZeneca

HMG-CoA reductase inhibitor. Rosuvastatin (as calcium) 5mg, 10mg, 20mg, 40mg; tabs.

Indications: As an adjunct to diet in primary hyperlipidemia and mixed dyslipidemia (Types IIa and IIb) to reduce elevated total-C, LDL-C, ApoB, non-HDL-C, and TG, and to increase HDL-C. Adjunct to diet in hypertriglyceridemia. Adjunct to diet in primary dysbetalipoproteinemia (Type III hyperlipoproteinemia). Adjunct to other lipid-lowering treatments (or if these treatments are unavailable), in homozygous familial hypercholesterolemia to reduce LDL-C, total-C, and ApoB. Adjunct to diet to slow the progression of atherosclerosis as part of a treatment strategy to lower total-C and LDL-C to target levels. To reduce risk of MI, stroke, or arterial revascularization

procedures in patients without clinically evident CHD but with an increased risk of CVD based on age (men ≥ 50 years, women ≥ 60 years), hs-CRP ≥ 2 mg/L, and at least one additional risk factor. Pediatric patients 10–17 yrs of age with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated total-C, LDL-C and ApoB after failing an adequate trial of diet therapy. Limitations of use: not studied in Fredrickson Type I and V dyslipidemias.

Adults: Take once daily. Primary hyperlipidemia, mixed dyslipidemia, hypertriglyceridemia, primary dysbetalipoproteinemia, slowing progression of atherosclerosis, prevention of CVD: Dose range 5–40mg; usual starting dose 10–20mg; 40mg (if 20mg is insufficient); consider 5mg initially for Asian patients (see literature). Homozygous: initially 20mg. Concomitant cyclosporine: max 5mg. Concomitant lopinavir/ritonavir or atazanavir/ritonavir: max 10mg. Concomitant niacin or fenofibrate: consider dose reduction. Concomitant gemfibrozil: avoid; if needed, max 10mg. Severe renal impairment (CrCl ≤ 30 mL/min) not on hemodialysis: initially 5mg; max 10mg.

Children: < 10 yrs: not recommended. HeFH: 10–17 yrs: usual range 5–20mg/day. Max 20mg/day. May adjust dose at ≥ 4 week intervals.

Contraindications: Active liver disease.

Unexplained persistent elevated serum transaminases. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Discontinue if myopathy or elevated CK levels occur; suspend if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Monitor liver function before starting therapy and as clinically indicated. Interrupt therapy if serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs; do not restart if alternate etiology not found. History of liver disease or heavy alcohol ingestion. Severe renal insufficiency. Hypothyroidism (if undertreated). Elderly.

Interactions: Avoid gemfibrozil. Increased risk of myopathy with niacin, fibrates, inhibitors of certain transporter proteins including OATP1B1 and BCRP (eg, cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir). Monitor anticoagulants. Caution with drugs that decrease levels or activity of steroid hormones. Separate dosing of antacids (give ≥ 2 hours after rosuvastatin).

Adverse reactions: Headache, myalgia, abdominal pain, asthenia, nausea; lab abnormalities (eg, thyroid function, alkaline phosphatase, hyperglycemia), proteinuria and hematuria (consider dose reduction if persistent), elevated serum transaminases, myopathy, rhabdomyolysis with renal dysfunction, increased HbA1c and fasting serum glucose, rare: cognitive impairment, non-fatal hepatic failure, immune-mediated necrotizing myopathy.

How supplied: Tabs 5mg, 10mg, 20mg–90; 40mg–30

SIMVASTATIN**ZOCOR** Merck*HMG-CoA reductase inhibitor.* Simvastatin 5mg, 10mg, 20mg, 40mg, 80mg; tabs.

Indications: Adjunct to diet when response to nondrug therapy is inadequate: primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Types IIa and IIb) to reduce elevated total-C, LDL-C, apo B and TG, and to increase HDL-C; hypertriglyceridemia (Type IV) or primary dysbetalipoproteinemia (Type III); adjunct to or when other lipid-lowering treatments for homozygous familial hypercholesterolemia are not available, to reduce total-C and LDL-C. In patients with coronary heart disease (CHD), diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease to reduce: risk of total mortality by reducing CHD death, risk of non-fatal MI and stroke, risk for undergoing myocardial revascularization procedures. Adjunct to diet to reduce total-C, LDL-C, and apo B in patients 10–17 years of age (≥ 1 yr post-menarche) with heterozygous familial hypercholesterolemia if LDL-C remains ≥ 190 mg/dL, or if LDL-C remains ≥ 160 mg/dL with either family history of premature cardiovascular disease (CVD) or if patient has at least 2 other CVD risk factors. Limitations of use: not studied in conditions where major abnormality is elevation of chylomicrons (eg, hyperlipidemia Fredrickson types I and V).

Adults: ≥ 17 yrs: Initially 10–20mg once daily in the PM; if patient is high risk of CHD event: initially 40mg/day; range 5–40mg/day; monitor lipids after 4 weeks and periodically thereafter. Concomitant verapamil, diltiazem, dronedarone: max simvastatin 10mg/day. Concomitant amiodarone, amlodipine, ranolazine: max simvastatin 20mg/day. Severe renal insufficiency: initially 5mg/day, monitor closely. Homozygous familial hypercholesterolemia: 40mg once daily in the PM. Chinese patients taking niacin ≥ 1 g/day or niacin-containing products: use caution with simvastatin doses > 20 mg/day. Restrict 80mg/day dose to chronic users (≥ 12 mos) without evidence of muscle toxicity; if currently tolerating simvastatin 80mg and need to start a contraindicated drug or is associated with a simvastatin dose cap: switch to an alternative statin with less potential drug interaction. If patients unable to achieve their LDL-C goal using simvastatin 40mg: do not titrate to 80mg dose, switch to alternative regimen that provides greater LDL-C lowering. See literature.

Children: < 10 yrs: not recommended. 10–17 yrs: initially 10mg once daily in the PM, may increase at 4 week intervals; range 10–40mg/day; max 40mg/day.

Contraindications: Concomitant strong CYP3A4 inhibitors (eg, itraconazole, ketoconazole, posaconazole, voriconazole, HIV protease inhibitors, boceprevir, telaprevir, erythromycin, clarithromycin, telithromycin, nefazodone), gemfibrozil, cyclosporine, danazol. Active liver disease. Unexplained, persistent

R

elevated serum transaminases. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Increased risk of myopathy/rhabdomyolysis with simvastatin 80mg doses. Discontinue if myopathy, elevated CPK levels occur; suspend if a predisposition to development of renal failure secondary to rhabdomyolysis develops. Monitor liver function before starting therapy and repeat as clinically indicated. Interrupt therapy if serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs; do not restart if alternate etiology not found. History of liver disease. Substantial alcohol consumption. Severe renal insufficiency.

Interactions: See Contraindications. Avoid concomitant grapefruit juice > 1 quart daily. Caution with fibrates, niacin ≥ 1 g/day or niacin-containing products (esp. Chinese patients). Reduce max simvastatin dose if amiodarone, dronedarone, verapamil, diltiazem, amlodipine, ranolazine must be used. Caution with colchicine. Monitor digoxin, oral anticoagulants.

Adverse reactions: Upper respiratory infection, headache, abdominal pain, constipation, nausea, elevated serum transaminases, myopathy, rhabdomyolysis; increased HbA1c and fasting serum glucose, rare: cognitive impairment, non-fatal hepatic failure, immune-mediated necrotizing myopathy.

How supplied: Tabs–30, 90

2F Hypertension**ALISKIREN**

R

TEKTURA Novartis*Direct renin inhibitor.* Aliskiren 150mg, 300mg; tabs.**Indications:** Hypertension.

Adults: ≥ 18 yrs: initially 150mg once daily, may increase to 300mg once daily if BP not adequately controlled. May be given with other antihypertensives (see literature).

Children: < 18 yrs: not recommended.

Contraindications: Concomitant ARBs or ACEIs in diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before starting therapy or start under close supervision. Moderate renal impairment (CrCl < 60 mL/min): avoid concomitant with ARBs or ACEIs. Impaired renal function: monitor serum creatinine periodically. Renal artery stenosis. Severe CHF. Monitor for hyperkalemia. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Concomitant cyclosporine, itraconazole: not recommended. Caution with ACEIs, ARBs, NSAIDs, K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes; may cause hyperkalemia. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or

volume-depleted. Decreased absorption with high fat meals.

Adverse reactions: Diarrhea, hypotension, cough, rash, edema, elevated uric acid, gout, renal stones; rare: angioedema (discontinue if occurs; do not restart).

How supplied: Tabs-30, 90

ALISKIREN + AMLODIPINE + HYDROCHLOROTHIAZIDE R

AMTURNIDE Novartis

Renin inhibitor + dihydropyridine calcium channel blocker (CCB) + thiazide diuretic.

Aliskiren hemifumarate/amlopidine besylate/hydrochlorothiazide (HCTZ): 150/5/12.5mg; 300/5/12.5mg; 300/5/25mg; 300/10/12.5mg; 300/10/25mg; tablets.

Indications: Hypertension. Not for initial therapy.

Adults: Take once daily. Titrate at 2-week intervals; max one 300/10/25mg tablet daily. Replacement: may substitute for individually titrated components. Add-on/switch: if not adequately controlled on any two of the following: aliskiren, dihydropyridine CCB, thiazide diuretics. May switch with a lower dose of any component that causes dose-limiting ADRs. ≥ 75 years or severe hepatic impairment: initially amlodipine 2.5mg/day (not available). Concomitant simvastatin: see Interactions.

Children: Not recommended.

Contraindications: Concomitant ARBs or ACEIs in diabetes. Anuria. Sulfonamide allergy.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before starting or start under close supervision. Severe obstructive coronary disease: increased risk of angina or MI with CCB dose change. Moderate renal dysfunction (CrCl < 60 mL/min): avoid concomitant with ARBs or ACEIs. Impaired renal function: monitor serum creatinine periodically. Renal artery stenosis. Heart failure. Monitor for electrolyte disturbances. Hepatic dysfunction. Asthma. SLE. Gout. Acute myopia. Secondary angle-closure glaucoma. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Aliskiren: concomitant cyclosporine, itraconazole: not recommended. Caution with ACEIs, ARBs, NSAIDs, K^+ sparing diuretics, K^+ containing salt substitutes; may cause hyperkalemia. Decreased absorption with high fat meals. HCTZ: concomitant lithium (risk of toxicity): monitor; potentiates antihypertensives, possibly non-depolarizing muscle relaxants; orthostatic hypotension with alcohol, other CNS depressants; may need to adjust antidiabetic agents; decreased absorption by cholestyramine, colestipol resins (separate dosing by at least 4 hours). Both Aliskiren + HCTZ: may be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted. Amlodipine potentiates

simvastatin; limit simvastatin dose to max 20mg daily.

Adverse reactions: Peripheral edema, dizziness, headache, nasopharyngitis; rare: angioedema (discontinue if occurs, do not restart).

How supplied: Tabs-30, 90, 100

AMILORIDE + HYDROCHLOROTHIAZIDE R

AMILORIDE/HCTZ (various)

Diuretic combination. Amloride HCl 5mg, hydrochlorothiazide 50mg; scored tabs.

Indications: Hypertension when normokalemia is important.

Adults: Initially 1 tab daily with food. May increase to 2 tabs daily in single or divided doses.

Children: Not recommended.

Contraindications: Concomitant triamterene, spironolactone, salt substitutes, K^+ supplements (unless hypokalemia is severe). Hyperkalemia. Anuria. Diabetic nephropathy. Renal impairment. Sulfonamide allergy.

Warnings/Precautions: Acidosis predisposition. Electrolyte imbalance. Hepatic impairment. Monitor electrolytes, renal function (esp. in diabetics). Discontinue if serum potassium > 5.5 mEq/L or renal values progress. Gout. SLE. Severely ill. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid lithium, spironolactone, triamterene, other K^+ -sparing diuretics, K^+ supplements. Hyperkalemia with ACE inhibitors, NSAIDs. Hypokalemia with amphotericin B, corticosteroids, ACTH. Potentiated by CNS depressants. May potentiate nondepolarizing muscle relaxants. Antagonized by NSAIDs. May interfere with glucose tolerance or parathyroid test.

Adverse reactions: Headache, weakness, GI upset, rash, dizziness, hyperkalemia, fatigue, arrhythmia, pruritus, leg ache, dyspnea, syncope, orthostatic hypotension, electrolyte imbalances, insomnia, depression, nasal congestion, impotence, photosensitivity, cough, hyperglycemia, hyperuricemia, adverse lipid values.

How supplied: Contact supplier.

AMLODIPINE R

NORVASC Pfizer

Calcium channel blocker (dihydropyridine). Amlodipine (as besylate) 2.5mg, 5mg, 10mg; tabs.

Indications: Hypertension.

Adults: 5mg daily. Adjust at 7-14 day intervals; usual max 10mg daily. Small, fragile, elderly, hepatic impaired, patients on other antihypertensives: 2.5mg daily.

Children: < 6 yrs: not established. 6-17 yrs: 2.5-5mg daily.

Warnings/Precautions: Severe obstructive coronary disease. Severe aortic stenosis. CHF. Hepatic dysfunction. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant simvastatin: limit simvastatin dose to 20mg/day. May potentiate cyclosporine.

Adverse reactions: Edema, fatigue, palpitations, dizziness, nausea, flushing, abdominal pain, drowsiness.

How supplied: Tabs 2.5mg, 10mg-90; 5mg-90, 300

AMLODIPINE + BENAZEPRIL

LOTREL Novartis

Calcium channel blocker (dihydropyridine) + ACE inhibitor. Amlodipine (as besylate), benazepril (as HCl); 2.5mg/10mg, 5mg/10mg, 5mg/20mg, 5mg/40mg, 10mg/20mg, 10mg/40mg; caps.

Indications: Hypertension (not for initial therapy).

Adults: For patients not adequately controlled with either a dihydropyridine calcium channel blocker or an ACE inhibitor or in those who show inability to achieve BP control with amlodipine without developing edema: Initially 2.5mg/10mg once daily; may titrate up to 10mg/40mg once daily if BP remains uncontrolled. Replacement therapy: may be substituted for titrated components. CrCl ≤ 30 mL/min: not recommended. Hepatic impairment, elderly: consider lower doses.

Children: Not recommended.

Contraindications: History of ACEI-associated or other angioedema. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Discontinue if angioedema, laryngeal edema, jaundice or marked elevation in liver enzymes occurs. Salt/volume depletion. Renal impairment: monitor for worsening renal function. Dialysis. Renal artery stenosis. Hepatic impairment. Monitor WBCs in renal or collagen vascular disease. CHF. Severe obstructive coronary artery disease. Severe aortic stenosis. Monitor for hyperkalemia. Surgery. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl < 60 mL/min): not recommended. Hyperkalemia with K⁺ supplements or K⁺ sparing diuretics. May increase lithium levels. Potentiated by diuretics. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare. Potentiates simvastatin; limit simvastatin dose to 20mg daily. May be antagonized by, and renal toxicity potentiated by, NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume depleted).

Adverse reactions: Cough, edema, fatigue, dizziness, GI upset, angioedema, orthostatic hypotension, hyperkalemia, palpitations, flushing; rare: hepatic failure.

How supplied: Caps-100

ATENOLOL

TENORMIN AstraZeneca

Cardioselective beta-blocker. Atenolol 25mg, 50mg, 100mg; tabs.

Indications: Hypertension.

Adults: Initially 50mg daily. May increase after 1-2 weeks to 100mg once daily; max 100mg/day. Elderly: Initially 25-50mg daily; monitor trough BP. CrCl 15-35 mL/minute: max 50mg/day; CrCl < 15 mL/minute: max 25mg/day; monitor trough BP. Coincide a dose for the end of hemodialysis.

Children: Not recommended.

Contraindications: Sinus bradycardia, 2nd or 3rd-degree heart block. Overt heart failure. Cardiogenic shock.

Warnings/Precautions: Bronchospastic disease. Renal dysfunction. Diabetes. Hyperthyroidism. Pheochromocytoma. Surgery. Avoid abrupt cessation. Peripheral circulatory disorders. Ischemic heart disease or failure. Pregnancy (Cat.D): not recommended. Nursing mothers.

Interactions: Additive effect with catecholamine-depleting drugs, prazosin, digoxin. Conduction abnormalities, bradycardia, heart block with calcium channel blockers (esp. verapamil, diltiazem). Increased rebound hypertension with clonidine withdrawal. May block epinephrine.

Adverse reactions: Heart failure, bronchospasm, bradycardia, angina, MI, heart block, dizziness, fatigue, GI upset, depression, orthostatic hypotension, cold extremities.

How supplied: Tabs 25mg, 100mg-100; 50mg-100, 1000

AZILSARTAN MEDOXOMIL

EDARBI Takeda

Angiotensin II receptor blocker. Azilsartan medoxomil 40mg, 80mg; tabs.

Indications: Hypertension. May be used alone or in combination with other antihypertensive agents.

Adults: ≥ 18 yrs: Monotherapy, not volume-depleted: 80mg once daily. Volume-depleted (eg, concomitant high-dose diuretics): initially 40mg once daily.

Children: < 18 yrs: not established.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before starting therapy, or reduce initial dose; monitor for hypotension. Severe CHF. Renal artery stenosis. Renal impairment: monitor for worsening renal function. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment

(CrCl <60mL/min): not recommended. May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted).

Adverse reactions: Diarrhea; rare: orthostatic hypotension, dizziness, nausea, asthenia, fatigue, muscle spasm, cough.

How supplied: Tabs-30, 90

AZILSARTAN MEDOXOMIL + CHLORTHALIDONE

R

EDARBYCLOR Takeda

Angiotensin II receptor blocker (ARB) + diuretic. Azilsartan medoxomil, chlorthalidone; 40/12.5mg, 40/25mg; tablets.

Indications: Hypertension in patients not adequately controlled with monotherapy. As initial therapy in patients likely to need multiple drugs to achieve blood pressure goals.

Adults: ≥18yrs: initially 40/12.5mg once daily. May increase to 40/25mg after 2–4 weeks as needed. Max: 40/25mg. Patients titrated to the individual components: may give corresponding dose of Edarbyclor. See full labeling.

Children: <18yrs: not established.

Contraindications: Anuria. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before starting therapy; monitor for hypotension. Severe CHF. Renal artery stenosis. Hepatic impairment. Renal impairment: monitor; consider discontinuing if impairment progresses. Gout. Hypokalemia. Hyperuricemia. Pregnancy (Cat.D; avoid). Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). May increase toxicity of lithium. Digitalis may exacerbate hypokalemia.

Adverse reactions: Dizziness, fatigue, hypotension, syncope, serum creatinine increased.

How supplied: Tabs-30, 90

BENAZEPRIL

R

LOTENSIN Validus

ACE inhibitor. Benazepril (as HCl) 5mg, 10mg, 20mg, 40mg; tabs.

Indications: Hypertension.

Adults: If not on diuretic: initially 10mg daily. Usual maintenance: 20–40mg daily in 1 or 2 divided doses; usual max 80mg/day. If on diuretic: discontinue

diuretic, if possible, 2–3 days before starting; resume diuretic if pressure not controlled with benazepril alone. If diuretic cannot be discontinued: initially 5mg daily. Creatinine clearance <30mL/min/1.73m²: initially 5mg daily; max 40mg/day.

Children: <6yrs or CrCl <30mL/min/1.73m²:

not recommended. ≥6yrs: Initially 0.2mg/kg daily; usual max 0.6mg/kg/day (or 40mg/day).

Prepare suspension if unable to swallow tablets or if calculated mg/kg dosage does not correspond to available tablet strengths (see full labeling).

Contraindications: History of ACEI-associated or other angioedema. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Salt/volume depletion. Renal or hepatic impairment. Discontinue if jaundice or marked elevations of hepatic enzymes develop. Monitor for worsening renal function in patients with renal impairment. Monitor WBCs in renal or collagen vascular disease. CHF. Dialysis (esp. high-flux membrane). Renal artery stenosis. Monitor for hyperkalemia in diabetics. Surgery. Discontinue if angioedema or laryngeal edema occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers.

Interactions: See Contraindications. Potassium or potassium-sparing diuretics may cause hyperkalemia. May increase lithium levels. Potentiated by diuretics. May be antagonized by, and renal toxicity potentiated by, NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare. Hypoglycemia with insulin and oral antidiabetics; rare.

Adverse reactions: Headache, dizziness, fatigue, GI upset, cough, angioedema, orthostatic hypotension, hyperkalemia; rare: hepatic failure.

How supplied: Tabs-100

BISOPROLOL

R

ZEBETA Teva US Generics

Cardioselective beta-blocker. Bisoprolol (as fumarate) 5mg +, 10mg; tabs; + scored.

Indications: Hypertension.

Adults: 5mg once daily; max 20mg once daily. Renal or hepatic dysfunction, or bronchospastic disease: initially 2.5mg once daily.

Children: Not recommended.

Contraindications: Cardiogenic shock. Overt heart failure. 2nd or 3rd-degree AV block. Marked sinus bradycardia.

Warnings/Precautions: CHF. Angina. Peripheral vascular disease. Asthma. COPD. Surgery. Diabetes. Thyroid disease. Hepatic or renal impairment. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Additive effects with reserpine, guanethidine, other catecholamine depleting drugs, calcium channel blockers, antiarrhythmics, myocardial depressants. Increased rebound hypertension with clonidine withdrawal. Antagonized by rifampin. May block epinephrine.

Adverse reactions: Headache, fatigue, GI upset, upper respiratory symptoms (eg, cough, dyspnea, rhinitis), chest pain.

How supplied: Tabs-30

BISOPROLOL + HYDROCHLOROTHIAZIDE

ZIAC Teva US Generics

Cardioselective beta-blocker + diuretic. Bisoprolol (as fumarate), hydrochlorothiazide; 2.5mg/6.25mg, 5mg/6.25mg, 10mg/6.25mg; tabs.

Indications: Hypertension.

Adults: Initially one 2.5mg/6.25mg tab once daily. Adjust at 14-day intervals; max two 10mg/6.25mg tabs (20mg bisoprolol + 12.5mg HCTZ) once daily.

Children: Not recommended.

Note: See **Bisoprolol** and **Hydrochlorothiazide** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions.

How supplied: Tabs 2.5mg/6.25mg, 5mg/6.25mg-100; 10mg/6.25mg-30

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periodically in elderly and/or volume-depleted). Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Back pain, dizziness, upper respiratory tract infection, pharyngitis, rhinitis, rhabdomyolysis (rare).

How supplied: Tabs 4mg, 8mg-30; 16mg, 32mg-30, 90

CAPTAPRIL

CAPOTEN Par

ACE inhibitor. Captopril 12.5mg, 25mg, 50mg, 100mg; scored tabs.

Indications: Hypertension.

Adults: Take 1 hr before meals. Initially 25mg 2-3 times daily. After 1-2 wks may increase to 50mg 2-3 times daily. If control unsatisfactory, see literature.

Titrate to usual dose after several days. Monitor closely for 1st 2 wks and if dose increased; max 450mg/day. Renal impairment: see literature.

Children: See literature.

Contraindications: History of ACEI-associated or other angioedema.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment. Salt/volume depletion. Dialysis (esp. high-flux membrane). CHF. Aortic stenosis. Monitor WBCs and renal function in renal and collagen vascular disease. Monitor for hyperkalemia in diabetics, blood pressure and renal insufficiency. Surgery. Discontinue if neutropenia, agranulocytosis, angioedema, or laryngeal edema occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in diabetics or renal impairment (CrCl <60mL/min): not recommended. Caution with K⁺-sparing diuretics, K⁺-containing supplements and K⁺-containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors); monitor renal function in elderly and/or volume depleted. Potentiated by diuretics, β -blockers, adrenergic antagonists. Discontinue nitroglycerin, other nitrates, or other vasodilators before starting therapy; if resumed, reduce dose and give cautiously. May increase lithium levels. May produce false (+) urinary acetone. Nitroind reactions with injectable gold (sodium aurothiomalate).

Adverse reactions: Headache, dysgeusia, rash, pruritus, dizziness, fatigue, cough, proteinuria, nephritis, GI upset, hyperkalemia, hyponatremia, tachycardia, dry mouth, jaundice, somnolence, impotence, angioedema.

How supplied: Tabs 25mg, 50mg-100, 1000; 12.5mg, 100mg-100

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CANDESARTAN

ATACAND AstraZeneca

Angiotensin II receptor blocker. Candesartan cilexetil 4mg, 8mg, 16mg, 32mg; tabs.

Indications: Hypertension.

Adults: Individualize. ≥ 18 yrs: Monotherapy and not volume-depleted: initially 16mg once daily; usual range: 8-32mg per day once daily or in 2 divided doses. Salt/volume depleted or moderate hepatic impairment: consider lower initial dose. May add diuretic if needed.

Children: <1yr or CrCl <30mL/min: not recommended. Give once daily or in 2 divided doses. 1-<6yrs (may give oral susp if unable to swallow tabs): initially 0.2mg/kg/day; usual range: 0.05-0.4mg/kg/day. 6-<17yrs (<50kg): initially 4-8mg/day; usual range: 2-16mg/day; (>50kg): initially 8-16mg/day; usual range: 4-32mg/day. Salt/volume depletion: consider lower initial dose.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct hypovolemia before starting or monitor closely. Hepatic or renal impairment. Severe CHF. Renal artery stenosis. Surgery. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Monitor lithium and for hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function

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CARVEDILOL**COREG CR** GlaxoSmithKline*Noncardioselective beta-blocker/alpha-1 blocker.*

Carvedilol (as phosphate) 10mg, 20mg, 40mg, 80mg; ext-rel caps.

Indications: Hypertension.**Adults:** Take with food in the AM. Swallow whole or may open capsules and sprinkle beads on a spoonful of applesauce and take immediately. ≥ 18 yrs: initially 20mg once daily, may double dose every 1–2 weeks if tolerated and needed. Max daily dose of 80mg. Switching from immediate-release carvedilol: see literature. ≥ 65 yrs: switching from highest dose of immediate-release carvedilol (25mg twice daily) to Coreg CR: initially Coreg CR 40mg; if tolerated for ≥ 2 weeks, may increase to 80mg.**Children:** < 18 yrs: not recommended.**Also:** **Carvedilol****COREG**

Carvedilol 3.125mg, 6.25mg, 12.5mg, 25mg; tabs.

Adults: Take with food. ≥ 18 years: initially 6.25mg twice daily; may increase as tolerated at 1–2 week intervals to 12.5mg twice daily. Max 25mg twice daily.**Children:** < 18 yrs: not recommended.**Contraindications:** Cardiogenic shock or decompensated HF requiring intravenous inotropic therapy. Asthma, related bronchospastic conditions. 2nd or 3rd-degree AV block, sick sinus syndrome, or severe bradycardia, unless paced. Severe hepatic impairment.**Warnings/Precautions:** Peripheral vascular disease. Nonallergic bronchospasm. Diabetes (monitor blood glucose). Hyperthyroidism. Monitor renal function in ischemic heart disease, diffuse vascular disease, underlying renal insufficiency, and/or if systolic BP < 100 mmHg. Avoid abrupt cessation. Prinzmetal's angina. Pheochromocytoma. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** May be potentiated by CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine, propafenone), alcohol (separate by 2 hours). Bradycardia, hypotension with catecholamine depleters (eg, reserpine, MAOIs). Carvedilol levels reduced by rifampin. Increased absorption with cimetidine. Caution with drugs that affect cardiac conduction (esp. diltiazem, verapamil). May potentiate antidiabetic agents. Monitor digoxin, cyclosporine when changing carvedilol dose. Anesthesia.**Adverse reactions:** Bradycardia, orthostatic hypotension, dizziness, nasopharyngitis, GI upset, edema.**How supplied:** CR caps—30, 90; Tabs—100**CLEVIDIPINE****CLEVIPREX** The Medicines Company*Calcium channel blocker (dihydropyridine).*

Clevidipine butyrate emulsion 0.5mg/mL; soln for IV infusion; contains lipids 0.2g/mL (soybean oil, egg phospholipids).

Rx

Indications: To reduce blood pressure when oral therapy is not feasible or desirable.**Adults:** ≥ 18 yrs: Individualize; titrate. Give by IV infusion. Initially 1–2mg/hr; double dose at 90sec intervals until BP approaches goal, then titrate slower (adjust at 5–10min intervals). Dose increases of 1–2mg/hr results in systolic BP lowering of about 2–4mmHg. Maintenance: 4–6mg/hr; usual max 16–32mg/hr. Do not exceed 1000mL (21mg/hr for 24hrs) due to lipid load. Switch to oral therapy when indicated.**Children:** < 18 yrs: not recommended.**Contraindications:** Egg or soy allergy. Defective lipid metabolism (eg, pathologic hyperlipemia, lipid nephrosis, acute pancreatitis with hyperlipidemia). Severe aortic stenosis.**Warnings/Precautions:** Maintain aseptic technique. Monitor BP and pulse during infusion and until stabilized. Heart failure (monitor). Monitor for rebound hypertension for at least 8hrs after stopping infusion (if not given other antihypertensives after prolonged infusion). Avoid abrupt cessation of any β -blocker treatment. Pheochromocytoma. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.**Adverse reactions:** Headache, nausea, vomiting; hypotension, reflex tachycardia (slow infusion if occurs, do not use beta-blocker); rare: myocardial infarction, cardiac arrest, syncope, dyspnea.**How supplied:** Single-use vials—50mL, 100mL**CLONIDINE****CATAPRES** Boehringer Ingelheim*Central alpha-agonist.* Clonidine HCl 0.1mg, 0.2mg, 0.3mg; tabs.**Indications:** Hypertension.**Adults:** Initially 0.1mg twice daily. Usual range 0.2–0.6mg daily in divided doses; max 2.4mg/day.**Children:** Not established.**Also:** **Clonidine****CATAPRES-TTS**

Clonidine 0.1mg/day, 0.2mg/day, 0.3mg/day; each transdermal patch delivers dose for 1 week.

Adults: Apply to intact, hairless area of upper arm or anterior torso; rotate application sites. Taper withdrawal of other antihypertensives. Initially one 0.1mg/day patch weekly; may increase after 1–2 weeks; max 0.6mg/day.**Children:** Not established.**Warnings/Precautions:** Sinus node dysfunction. AV block. Pheochromocytoma: not effective. Conduction disturbances. Renal dysfunction. Avoid abrupt cessation. If local reaction occurs from patch, using tabs may cause generalized rash. Discontinue 4hrs before surgery; resume as soon as possible after surgery. Patch: remove before defibrillation, cardioversion, or MRI. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Antagonized by tricyclic antidepressants. Potentiates CNS depressants. Orthostatic regulation disturbances (eg, orthostatic hypotension, dizziness, fatigue) possible with

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neuroleptics. Monitor heart rate in patients receiving agents known to affect sinus node function or AV nodal conduction (eg, digitalis, calcium channel blockers, β -blockers).

Adverse reactions: Dry mouth, dry eye, drowsiness, dizziness, weakness, constipation, sedation, rash, myalgia, urticaria, nausea, insomnia, agitation, orthostatic hypotension, impotence, arrhythmias.

How supplied: Tabs-100; Patch-4

DILTIAZEM

CARDIZEM LA AbbVie

Calcium channel blocker (benzothiazepine). Diltiazem HCl 120mg, 180mg, 240mg, 300mg, 360mg, 420mg; ext-rel tabs.

Indications: Hypertension.

Adults: Swallow whole; take at the same time each day (AM or PM). Initially 180-240mg once daily; adjust at 2-week intervals up to max 540mg/day.

Children: Not recommended.

Also: Diltiazem

CARDIZEM CD

Diltiazem HCl 120mg, 180mg, 240mg, 300mg, 360mg; ext-rel caps.

Adults: Initially 180-240mg once daily; adjust at 2-week intervals. Usual range: 240-360mg once daily; usual max 480mg once daily.

Children: Not recommended.

Contraindications: Sick sinus syndrome, 2nd or 3rd-degree AV block unless paced. Hypotension. Acute MI and pulmonary congestion documented by X-ray on admission.

Warnings/Precautions: Heart failure. Impaired renal or hepatic function (monitor). Obstructive hypertrophic cardiomyopathy. Discontinue if persistent rash occurs. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with digoxin, β -blockers, others that may affect cardiac conduction (may lead to AV block). Monitor heart rate with concomitant clonidine. Potentiates propranolol, benzodiazepines, cyclosporine, carbamazepine, lovastatin, simvastatin (consider dose adjustment; monitor). Caution with CYP3A4 substrates, inhibitors (eg, cimetidine), or inducers (eg, rifampin). Anesthetics may potentiate cardiac depression.

Adverse reactions: Edema, headache, fatigue, dizziness, asthenia, 1st-degree AV block, bradycardia, flushing, nausea, rash (may be serious); rare: CHF, hypotension, liver abnormalities.

How supplied: LA tabs-30, 90; CD 120mg, 180mg, 240mg, 300mg-30, 90; CD 360mg-90

DILTIAZEM

DILACOR XR Actavis

Calcium channel blocker (benzothiazepine). Diltiazem HCl 120mg, 180mg, 240mg; ext-rel caps.

Indications: Hypertension.

Adults: Do not crush or chew. Take in AM on empty stomach. Initially 180mg or 240mg once daily. Usual

range: 180-480mg/day; max 540mg/day. Over 60 yrs: may start with 120mg daily.

Children: Not recommended.

Contraindications: Sick sinus syndrome, 2nd or 3rd-degree AV block unless paced. Hypotension. Acute MI and pulmonary congestion documented by X-ray on admission.

Warnings/Precautions: Impaired ventricular, renal or hepatic function. Monitor hepatic function. Discontinue if persistent rash occurs. Preexisting severe gastric stricture. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Digoxin and β -blockers may lead to AV block. Monitor digoxin levels. Serum propranolol, carbamazepine levels may be increased. Potentiation with cimetidine, cyclosporine. Anesthetics may potentiate cardiac depression. Additive hypotensive effects with antihypertensives.

Adverse reactions: Pharyngitis, cough, flu syndrome, edema, myalgia, GI upset, sinusitis, asthenia, vasodilatation, pain, arthrosis, insomnia, tinnitus, rash; liver abnormalities (rare).

How supplied: Caps-100, 500

DOXAZOSIN

CARDURA Pfizer

alpha-1 blocker (quinazoline). Doxazosin (as mesylate) 1mg, 2mg, 4mg, 8mg; scored tabs.

Indications: Hypertension.

Adults: Initially 1 mg once daily. Titrate gradually (based on standing BP at 2-6 hours and 24 hours post-dose) at 2-week intervals if needed; max 16 mg/day.

Children: Not recommended.

Warnings/Precautions: Impaired liver function. Monitor for orthostatic hypotension initially and if dose increased. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution when adding other antihypertensives.

Adverse reactions: Syncope (esp. 1st dose and with increased doses), dizziness, somnolence, fatigue/malaise, edema, rhinitis, abnormal vision, tinnitus, epistaxis, orthostatic hypotension, sexual dysfunction, polyuria, urinary incontinence, ataxia, leukopenia, neutropenia, arrhythmia; rare: priapism.

How supplied: Tabs-100

ENALAPRIL

VASOTEC Valeant

ACE inhibitor. Enalapril maleate 2.5mg, 5mg, 10mg, 20mg; scored tabs.

Indications: Hypertension.

Adults: If on diuretics or CrCl <30mL/min: suspend diuretic for 2-3 days, if possible: initially 2.5mg daily; max 40mg. Monitor closely for first 2 wks. Others: initially 5mg daily. Usual range: 10-40mg daily in 1-2 divided doses.

Children: Neonates or CrCl <30mL/min: not established. Initially 0.08mg/kg (up to 5mg) once daily; max 0.58mg/kg (or 40mg) daily. Suspension

form may be prepared if unable to swallow tabs: see full labeling.

Contraindications: History of ACEI-associated or other angioedema. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment: monitor for worsening renal function. Salt/volume depletion. CHF. Dialysis (esp. high-flux membrane). Renal artery stenosis. Surgery. Monitor for hyperkalemia in diabetics. Monitor WBCs in renal or collagen vascular disease. Discontinue if neutropenia, angioedema, laryngeal edema, jaundice or marked elevations of hepatic enzymes develop. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. Potentiated by, and hypotension with, diuretics. Hyperkalemia with K⁺-sparing diuretics or K⁺ supplements. May increase lithium levels. May be antagonized by, and renal toxicity potentiated by NSAIDs, including COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate).

Adverse reactions: Cough, headache, dizziness, fatigue, diarrhea, rash, orthostatic hypotension, asthenia, hyperkalemia, renal impairment, nausea; rare: hepatic failure.

How supplied: Tabs 2.5mg–30, 90; 5mg, 10mg, 20mg–30, 90, 1000

ENALAPRIL + HYDROCHLOROTHIAZIDE

VASERETIC Valeant

ACE inhibitor + diuretic. Enalapril maleate, hydrochlorothiazide; 10mg/25mg; tabs.

Indications: Hypertension (not for initial therapy).

Adults: Switching from monotherapy with either component: start with Vaseretic 10-25 once daily, then adjust; max 20mg enalapril/day and 50mg HCTZ/day. Allow 2–3 weeks for titration of HCTZ component. Or, substitute for individually titrated components.

Children: Not established.

Elderly: Reduce dose.

Note: See **Enalapril** and **Hydrochlorothiazide** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions.

How supplied: Tabs–100

ENALAPRILAT

ENALAPRILAT INJECTION (various)

ACE inhibitor. Enalaprilat 1.25mg/mL; soln for IV inj.

Indications: To reduce blood pressure when oral therapy is not practical.

Adults: Give by IV inj over 5 minutes (administer over a longer period of time [up to 1 hour] in patients at risk for excessive hypotension). 1.25mg every 6 hours; max 20mg/day. Concomitant diuretics or CrCl ≤30mL/min: initially 0.625mg; if inadequate response after 1 hour, may give additional 0.625mg dose; additional doses of 1.25mg may be given every 6 hours thereafter.

Children: Not recommended.

Contraindications: History of ACEI-associated or other angioedema. Pregnancy (Cat.D in 2nd and 3rd trimesters).

Warnings/Precautions: Renal or hepatic impairment. Salt/volume depletion. Severe CHF. Renal artery or aortic stenosis. Hypertrophic cardiomyopathy. Monitor for neutropenia in renal or collagen vascular disease. Monitor for hyperkalemia in diabetics. Dialysis. Surgery. Discontinue if laryngeal edema, angioedema, marked elevations of liver enzymes or jaundice occurs. Black patients may have higher risk of angioedema than non-black patients. Elderly. Pregnancy (Cat.C in 1st trimester). Nursing mothers.

Interactions: Hypotension with diuretics. Hyperkalemia with K⁺-sparing diuretics or K⁺ supplements. May increase lithium levels. May be antagonized by NSAIDs.

Adverse reactions: Headache, orthostatic hypotension, asthenia, hyperkalemia, renal impairment, nausea, cough; angioedema, liver dysfunction, blood dyscrasias (rare).

How supplied: Contact supplier.

FOSINOPRIL

FOSINOPRIL (various)

ACE inhibitor. Fosinopril sodium 10mg+, 20mg, 40mg; tabs; +scored.

Indications: Hypertension.

Adults: Initially 10mg once daily. Usual maintenance: 20–40mg daily in single or 2 divided doses; max 80mg/day. If on diuretic: suspend diuretic for 2–3 days before starting if possible; resume diuretic if pressure not controlled with fosinopril alone. If diuretic cannot be discontinued: give 10mg and monitor carefully.

Children: <6yrs (≤50kg): not recommended.

≥6yrs (>50kg): 5–10mg once daily.

Contraindications: History of ACEI-associated or other angioedema. Pregnancy (Cat.D in 2nd and 3rd trimesters).

Warnings/Precautions: Salt/volume depletion. Renal or hepatic impairment. Monitor WBCs in renal or collagen vascular disease. CHF. Dialysis (esp. high-flux membrane). Renal artery stenosis. Monitor for hyperkalemia in diabetics. Discontinue if angioedema, laryngeal edema, jaundice, or markedly elevated liver enzymes occurs. Surgery. Pregnancy (Cat.C in 1st trimester). Nursing mothers: not recommended.

Interactions: Potentiated by diuretics. Potassium or K⁺-sparing diuretics may cause hyperkalemia.

May increase lithium levels. Separate antacid dosing by 2hrs. May cause false low serum digoxin measurements.

Adverse reactions: Headache, cough, dizziness, GI upset, hyperkalemia, orthostatic hypotension, angioneurotic edema (discontinue if occurs).

How supplied: Contact supplier.

FUROSEMIDE

LASIX Sanofi Aventis

Diuretic (loop). Furosemide 20mg, 40mg +, 80mg; tabs; + scored.

Indications: Hypertension.

Adults: Initially 40mg twice daily. Adding to other antihypertensives: initially reduce other agent's dose by 50%.

Children: Not recommended.

Contraindications: Anuria.

Warnings/Precautions: Hepatic cirrhosis: do not initiate during hepatic coma or electrolyte depletion.

Discontinue if increasing azotemia and oliguria occur during treatment of severe progressive renal disease. Renal or hepatic dysfunction. Diabetes.

Gout. SLE. Sulfonamide sensitivity. Bladder emptying disorders. Prostatic hyperplasia. Urethral narrowing. Hypoproteinemia. Monitor BP, electrolytes, fluids, blood, BUN. Potassium supplementation may be needed. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant chloral hydrate: not recommended. Concomitant acetylsalicylic acid may reduce creatinine clearance. Digitalis, lithium toxicity.

Alcohol, CNS depressants may increase orthostatic hypotension. Antagonized by indomethacin, phenytoin. May alter excretion of salicylates, lithium. Hypokalemia with corticosteroids, ACTH, large amounts of licorice, prolonged laxatives. Increased risk of cephalosporin-induced nephrotoxicity and radiocontrast nephropathy.

Increased risk of gouty arthritis with cyclosporine. Antagonizes tubocurarine, norepinephrine. Potentiates antihypertensives, succinylcholine, ganglionic or peripheral adrenergic blocking drugs. Ototoxicity with aminoglycosides, ethacrynic acid. Ototoxicity, nephrotoxicity with cisplatin (give lower doses of furosemide with positive fluid balance). Separate sucralfate dosing by at least two hours. Antagonized by, and potentiates, methotrexate.

Adverse reactions: Excessive diuresis, fluid or electrolyte imbalance, GI upset, dizziness, vertigo, paresthesias, orthostatic hypotension, hyperglycemia, jaundice, hyperuricemia, rash, photosensitivity, tinnitus, hearing loss, blood dyscrasias, renal calcification, persistence of patent ductus arteriosus in premature infants.

How supplied: Tabs 20mg-100, 1000; 40mg-100, 500, 1000; 80mg-50, 500

HYDRALAZINE

HYDRALAZINE INJECTION (various)

Vasodilator. Hydralazine (as HCl) 20mg/mL; IM or IV inj; contains parabens.

Indications: Severe essential hypertension when oral therapy not feasible or there is an urgent need to lower blood pressure.

Adults: Monitor BP closely. 20-40mg; repeat as needed. Advanced renal damage: reduce dose.

Children: Not recommended; doses of 1.7-3.5mg/kg per day in 4-6 divided doses have been used.

Also: Hydralazine

HYDRALAZINE TABLETS

Hydralazine HCl 10mg, 25mg, 50mg, 100mg.

Indications: Hypertension.

Adults: Initially 10mg 4 times daily for 2-4 days, then increase to 25mg 4 times daily for rest of 1st week, then to 50mg 4 times daily; max 300mg/day.

Children: Initially 0.75mg/kg per day in 4 divided doses, increase gradually over 3-4 weeks; max 7.5mg/kg or 200mg daily.

Contraindications: Coronary artery disease. Mitral valve disease.

Warnings/Precautions: Suspected coronary artery disease. Cerebrovascular accidents. Aortic aneurysm. Increased intracranial pressure. Renal disease. Treat paresthesias and/or numbness with pyridoxine. Discontinue if blood dyscrasias occur. Obtain CBC and ANA titer periodically; consider discontinuing if SLE occurs. Surgery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with MAOIs. Profound hypotension with potent parenteral antihypertensives (eg, diazoxide). Antagonized by NSAIDs. May block epinephrine.

Adverse reactions: Headache, anorexia, GI disturbances, palpitations, edema, flushing, nasal congestion, lacrimation, rash, tachycardia, angina, orthostatic hypotension, blood dyscrasias, peripheral neuritis, SLE.

How supplied: Contact supplier.

HYDROCHLOROTHIAZIDE

HYDROCHLOROTHIAZIDE (various)

Diuretic (thiazide). Hydrochlorothiazide 25mg, 50mg; scored tabs.

Indications: Hypertension.

Adults: Initially 25mg once daily; usual max 50mg/day in single or divided doses.

Children: See literature. 1-2mg/kg per day in 1 or 2 divided doses. <6months: up to 3mg/kg per day in 2 divided doses. ≤2years: max 37.5mg/day. 2-12years: up to 100mg/day.

Contraindications: Anuria. Sulfonamide allergy.

Warnings/Precautions: Renal or hepatic impairment. Arrhythmia. Diabetes. Gout. Asthma. SLE. Postsympathectomy. Excessive fluid loss.

Monitor electrolytes, BUN (if high). K⁺ supplements or K⁺ sparing diuretics may be needed. Discontinue if electrolyte disorders develop rapidly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Digitalis, lithium toxicity. Adjust antidiabetic, antitumor medications. NSAIDs may cause renal failure. ACTH, corticosteroids, amphotericin B

increase hypokalemia risk. Orthostatic hypotension with alcohol, CNS depressants. Hyperglycemia, hyperuricemia more likely with diazoxide. Antagonized by NSAIDs. May potentiate nondepolarizing muscle relaxants. May antagonize norepinephrine. May interfere with parathyroid tests.

Adverse reactions: Electrolyte disorders (esp. hypokalemia), hyperglycemia, hyperuricemia, photosensitivity, orthostatic hypotension, GI disturbances, adverse lipid values.

How supplied: Contact supplier.

HYDROCHLOROTHIAZIDE

R_x

MICROZIDE Actavis

Diuretic. Hydrochlorothiazide 12.5mg; caps.

Indications: Hypertension.

Adults: 12.5mg once daily; usual max 50mg/day.

Children: Not recommended.

Contraindications: Anuria. Sulfonamide allergy.

Warnings/Precautions: Renal or hepatic impairment. Arrhythmia. Diabetes. Gout. Asthma. SLE. Parathyroid disease. Excessive fluid loss. Monitor electrolytes, BUN (if high). Potassium supplements or K⁺-sparing diuretics may be needed. Discontinue if electrolyte disorders develop rapidly. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May cause digitalis, lithium toxicity. Adjust antidiabetic, antigout medications. ACTH, corticosteroids, amphotericin B increase hypokalemia risk. Orthostatic hypotension with alcohol, CNS depressants. Antagonized by NSAIDs. May potentiate nondepolarizing muscle relaxants. May antagonize norepinephrine. May interfere with parathyroid tests. Additive effects with other antihypertensives.

Adverse reactions: Electrolyte disorders (esp. hypokalemia), hyperglycemia, hyperuricemia, photosensitivity, orthostatic hypotension, GI disturbances, adverse lipid values.

How supplied: Caps-100

IRBESARTAN

R_x

AVAPRO Sanofi Aventis

Angiotensin II receptor blocker. Irbesartan 75mg, 150mg, 300mg; tabs.

Indications: Hypertension.

Adults: ≥16yrs: 150mg once daily; may increase to 300mg once daily. Or, may add a low dose of diuretic. Salt/volume depletion: initially 75mg once daily.

Children: Not recommended.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before beginning therapy, or reduce initial dose. Renal impairment. Severe CHF. Renal artery stenosis. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes.

May be antagonized by NSAIDs including COX-2 inhibitors. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Diarrhea, dyspepsia, fatigue; rhabdomyolysis (rare).

How supplied: Tabs 75mg-30, 90; 150mg, 300mg-30, 90, 500

IRBESARTAN + HYDROCHLOROTHIAZIDE

R_x

AVALIDE Sanofi Aventis

Angiotensin II receptor blocker + diuretic. Irbesartan, hydrochlorothiazide; 150mg/12.5mg, 300mg/12.5mg; tabs.

Indications: Hypertension.

Adults: Take once daily. Not controlled on monotherapy: initially 150/12.5mg, titrate to 300/12.5mg then 300/25mg if needed. Replacement therapy: may be substituted for titrated components. Initial therapy: start at 150/12.5mg for 1-2 weeks, then titrate as needed up to max 300mg/25mg. Maximum effects within 2-4 weeks after dose change. Severe renal impairment (CrCl ≤30mL/min): not recommended.

Children: Not recommended.

Note: See **Irbesartan** and **Hydrochlorothiazide** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions.

How supplied: Tabs-30, 90

LABETALOL

R_x

LABETALOL HCl INJECTION (various)

Noncardioselective beta-blocker/alpha-1 blocker.

Labetalol HCl 5mg/mL; soln for IV inj and infusion after dilution; contains parabens.

Indications: Severe hypertension.

Adults: Individualize. Maintain supine position; monitor BP. Repeated IV inj: 20mg over 2 minutes, may give additional 40mg or 80mg at 10 minute intervals up to max total dose of 300mg or until desired supine BP. Slow continuous infusion: 2mg/min (see literature).

Children: Not recommended.

Contraindications: Bronchial asthma. Overt cardiac failure. 2nd or 3rd-degree AV block. Cardiogenic shock. Severe bradycardia. Other conditions associated with severe and prolonged hypotension. History of obstructive airway disease (eg, asthma).

Warnings/Precautions: Ischemic heart disease or failure. Monitor hepatic function: discontinue at first sign of liver injury. If signs of cardiac failure, treat with digitalis or diuretic, discontinue if failure continues. COPD. Pheochromocytoma. Diabetes. Surgery. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with verapamil. Potentiates hypotension with nitroglycerin. May blunt effects of epinephrine, β -agonist bronchodilators. Avoid alkaline drugs (eg, furosemide) administration in same infusion line. Adjust antidiabetic medication. Potentiated by cimetidine and halothane. Tremor with tricyclic antidepressants. May cause false positive urine test for amphetamine.

Adverse reactions: Symptomatic postural hypotension, GI upset, dizziness, increased BUN and serum creatinine, paresthesias, sweating, somnolence, flushing, ventricular arrhythmia, vertigo, pruritus.

How supplied: Contact supplier.

LABETALOL

LABETALOL HCl TABLETS (various)

Noncardioselective beta-blocker/ α -1 blocker.

Labetalol HCl 100mg, 200mg, 300mg; scored tabs.

Indications: Hypertension.

Adults: Individualize. Initially 100mg twice daily. Titrate at 2–3 day intervals in increments of 100mg twice daily. Usual maintenance: 200–400mg twice daily; max 2.4g/day.

Children: Not recommended.

Elderly: Usual maintenance: 100–200mg twice daily.

Contraindications: Asthma. 2nd or 3rd degree AV block. Overt cardiac failure. Cardiogenic shock. Severe bradycardia, other conditions associated with prolonged or severe hypotension.

Warnings/Precautions: History of heart failure; withdraw gradually if cardiac failure continues despite adequate digitalization and diuretic. Monitor hepatic function; discontinue at first sign of liver injury. COPD. Pheochromocytoma. Diabetes. Surgery. Avoid abrupt cessation (ischemic heart disease may be exacerbated). Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with verapamil. Potentiates hypotension with nitroglycerin. May block epinephrine, β -agonist bronchodilators. Adjust antidiabetic medication. Potentiated by cimetidine. Tremor with tricyclic antidepressants. Synergism with halothane; do not use high concentrations.

Adverse reactions: Dizziness, GI upset, fatigue, nasal stuffiness, ejaculation failure, headache, dyspnea, vertigo, rash, orthostatic hypotension, edema, heart failure, bronchospasm, jaundice.

How supplied: Contact supplier.

LISINAPRIL

ZESTRIL AstraZeneca

ACE inhibitor. Lisinopril 2.5mg, 5mg, 10mg, 20mg, 30mg, 40mg; tabs.

Indications: Hypertension.

Adults: Initially and if not on diuretics: 10mg once daily. Usual range: 20–40mg once daily. If on diuretic: suspend diuretic for 2–3 days before starting; resume diuretic if BP not controlled by lisinopril alone. If diuretic cannot be discontinued: initially 5mg daily (supervise 1st dose). CrCl 10–30mL/min: initially 5mg

daily; CrCl <10mL/min: initially 2.5mg daily; max 40mg daily.

Children: <6yrs or CrCl <30mL/min/1.73m²: not recommended. $\geq$ 6yrs: initially 0.07mg/kg (max 5mg) once daily; usual max 0.61mg/kg (40mg) once daily.

Contraindications: History of ACEI-associated or other angioedema.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment. Dialysis (esp. high-flux membrane). Salt/volume depletion. Hypertrophic cardiomyopathy. CHF. Ischemic heart disease. Cerebrovascular disease. Renal artery stenosis. Surgery. Monitor BP, electrolytes, renal and liver function. Monitor serum potassium in diabetics. Monitor WBC count in renal and collagen vascular disease. Discontinue if angioedema or laryngeal edema (have SC epinephrine available), jaundice or elevated liver enzymes occur. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: May cause hypotension or increased BUN with diuretics, hyperkalemia with K⁺ sparing diuretics or K⁺ supplements. Risk of hypoglycemia with concomitant antidiabetic agents; adjust doses. May increase lithium levels; monitor frequently. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in diabetics or renal impairment (GFR <60mL/min): not recommended. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare.

Adverse reactions: Dizziness, headache, fatigue, diarrhea, upper respiratory symptoms, cough, nausea, orthostatic hypotension, hyperkalemia, renal impairment, angioedema; liver dysfunction, blood dyscrasias (rare).

How supplied: Tabs–100

LISINAPRIL + HYDROCHLOROTHAZIDE

PRINZIDE Merck

ACE inhibitor + diuretic. Lisinopril, hydrochlorothiazide; 10mg/12.5mg, 20mg/12.5mg +; tabs; + scored.

Indications: Hypertension.

Adults: Not for initial therapy. Initially 10mg/12.5mg or 20mg/12.5mg. Wait 2–3 weeks before increasing HCTZ dose. Max 80mg/50mg daily. CrCl <30mL/min: not recommended.

Children: Not recommended.

Contraindications: History of ACEI-associated or other angioedema. Anuria. Sulfonamide hypersensitivity. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Severe CHF. Ischemic heart disease. Cerebrovascular

disease. Arrhythmias. Salt/volume depletion. Postsympathectomy. Renal or hepatic impairment. Dialysis (esp. high-flux membrane). Gout. Asthma. SLE. Acute myopia. Secondary angle-closure glaucoma. Renal or aortic stenosis. Hypertrophic cardiomyopathy. Surgery. Monitor renal function and serum potassium in diabetics, serum electrolytes. Monitor WBCs in renal and collagen vascular disease. Discontinue if angioedema, laryngeal edema, marked elevations of liver enzymes, or jaundice occurs. Black patients may have higher risk of angioedema than non-black patients. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. May cause hypotension or increased BUN with diuretics.

Antagonized by, and increased risk of renal failure with, NSAIDs including selective COX-2 inhibitors; monitor. May increase lithium levels (not recommended); monitor frequently. Nitritoid reactions with concomitant injectable gold (sodium autithiomalate); rare.

Dosage adjustment of antidiabetics (oral agents, insulin) may be required. Impaired absorption with cholestyramine, colestipol resins. May antagonize pressor amines (eg, norepinephrine). Potentiates tubocurarine. Hyperkalemia with K⁺-sparing diuretics, K⁺ supplements and K⁺-containing salt substitutes. Hypokalemia with ACTH, corticosteroids. Orthostatic hypotension may be increased by alcohol, CNS depressants. May interfere with parathyroid tests.

Adverse reactions: Dizziness, headache, cough, fatigue, orthostatic hypotension, diarrhea, vomiting, dyspepsia, upper respiratory infection, muscle cramps, asthenia, paresthesia, rash, impotence, electrolyte disturbances (hypokalemia, hyperkalemia, hyponatremia), hyperuricemia.

How supplied: Tabs-100

LOSARTAN

R

COZAAR Merck

Angiotensin II receptor blocker. Losartan potassium 25mg, 50mg, 100mg; tabs.

Indications: Hypertension (HTN). To reduce stroke risk in hypertensive patients with left ventricular hypertrophy (LVH); this benefit may not apply to black patients.

Adults: Hypovolemia or hepatic insufficiency: initially 25mg once daily. HTN: initially 50mg once daily; range 25–100mg/day; max 100mg/day in 1 or 2 divided doses. HTN with LVH: initially 50mg once daily; then add hydrochlorothiazide (HCTZ) 12.5mg/day and/or increase losartan to 100mg/day, then may increase HCTZ to 25mg/day.

Children: <6yrs or CrCl <30mL/min: not established. ≥6yrs: initially 0.7mg/kg (max 50mg) once daily; usual max 1.4mg/kg (100mg) once daily.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity; discontinue as soon as pregnancy is detected. Correct salt/volume depletion before starting therapy, or reduce initial dose. Renal impairment: monitor for worsening renal function. Hepatic impairment. Severe CHF. Renal artery stenosis. Pregnancy (Cat.C in 1st trimester, Cat.D in 2nd and 3rd trimesters). Nursing mothers: not recommended.

Interactions: Hyperkalemia with K⁺ supplements, K⁺-sparing diuretics, K⁺-containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Monitor lithium. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Dizziness, insomnia, muscle cramps, leg pain, hyperkalemia, angioedema, rhabdomyolysis (rare).

How supplied: Tabs 25mg–90, 1000; 50mg, 100mg–30, 90, 1000

LOSARTAN + HYDROCHLOROTHIAZIDE

R

HYZAAR Merck

Angiotensin II receptor blocker + diuretic. Losartan potassium, hydrochlorothiazide; 50mg/12.5mg, 100mg/12.5mg, 100mg/25mg; tabs.

Indications: Hypertension (not for initial therapy unless HTN is severe). To reduce stroke in hypertensive patients with left ventricular hypertrophy (LVH); this benefit may not apply to black patients.

Adults: ≥18yrs: One 50–12.5mg tab once daily; may increase after about 3 weeks (2–4 weeks for severe HTN) to two 50–12.5mg tabs once daily or one 100–25mg tab once daily. Titrate components: see full labeling. HTN with LVH: switch from losartan monotherapy (see full labeling). Severe renal impairment (CrCl <30mL/min): not recommended.

Children: <18yrs: not established.

Note: See **Losartan and Hydrochlorothiazide** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions.

How supplied: Tabs-30, 90, 1000

METHYLDOPA

R

METHYLDOPA (various)

Central alpha-agonist. Methyldopa 125mg, 250mg, 500mg; tabs.

Indications: Hypertension.

Adults: Initially 250mg 2–3 times daily; titrate at intervals of at least 2 days. Concomitant antihypertensives other than thiazides: initial max 500mg/day. Maintenance: 500mg–2g/day in 2–4 divided doses; max 3g/day.

Children: Initially 10mg/kg per day in 2–4 divided doses; max 65mg/kg or 3g daily (whichever is less).

Contraindications: Active hepatic disease.

History of methylidopa-associated liver dysfunction. Concomitant MAOIs.

Warnings/Precautions: Hepatic or renal dysfunction. Pheochromocytoma. Severe cerebrovascular disease. Monitor blood and liver function. Discontinue if fever, jaundice, liver dysfunction, worsening edema or heart failure occurs. Surgery. Pregnancy (Cat.B). Nursing mothers.

Interactions: MAOIs: see Contraindications.

Antagonized by oral iron preps: not recommended.

May potentiate antihypertensives, general anesthetics, lithium. May interfere with lab tests.

Adverse reactions: Sedation, headache, asthenia, orthostatic hypotension, bradycardia, edema, GI upset, rash, nasal congestion, arthralgia, amenorrhea, hyperprolactinemia, gynecomastia, pancreatitis, impotence, decreased libido, CNS effects, eosinophilia, liver dysfunction, jaundice, (+) Coombs test, hemolytic anemia; rarely: fatal hepatic necrosis, blood dyscrasias.

How supplied: Tabs–100

METOPROLOL

R

LOPRESSOR Validus

Cardioselective beta-blocker. Metoprolol tartrate 50mg, 100mg; scored tabs.

Indications: Hypertension.

Adults: Take with meals. Initially 100mg daily in 1–2 divided doses. May be increased weekly, if needed. Usual range: 100–450mg/day.

Children: Not recommended.

Contraindications: Sinus bradycardia. 2nd or 3rd degree AV block. Overt heart failure. Cardiogenic shock. Sick-sinus syndrome. Severe peripheral arterial circulatory disorders.

Warnings/Precautions: CHF. Ischemic heart disease. Monitor heart rate and rhythm; reduce or stop treatment if severe bradycardia develops. Bronchospastic disease. Hepatic dysfunction. Diabetes. Pheochromocytoma. Hyperthyroidism. Surgery. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Bradycardia with catecholamine-depleting drugs. May be potentiated by potent CYP2D6 inhibitors (eg, fluoxetine, paroxetine, bupropion, thioridazine, quinidine, propafenone, ritonavir, diphenhydramine, hydroxychloroquine, terbinafine, cimetidine), hydralazine, inhalation anesthetics. Increased risk of bradycardia with concomitant digitalis. May block epinephrine. Increased rebound hypertension with clonidine withdrawal. May enhance vasoconstrictive action of ergots. Withhold before dipyrindamole testing.

Adverse reactions: Fatigue, dizziness, depression, diarrhea, rash, dyspnea, bradycardia, cold extremities, palpitations, CHF, peripheral edema, hypotension, bronchospasm, heart block.

How supplied: Tabs–100

METOPROLOL

R

TOPROL-XL AstraZeneca

Cardioselective beta-blocker. Metoprolol succinate 25mg, 50mg, 100mg, 200mg; scored ext-rel tabs.

Indications: Hypertension.

Adults: Initially 25–100mg once daily, alone or with a diuretic. May increase at 1-week intervals; max 400mg/day.

Children: Not recommended.

Contraindications: Severe bradycardia. Heart block >1st degree. Cardiogenic shock. Overt heart failure. Sick sinus syndrome (unless paced).

Warnings/Precautions: Mild or compensated heart failure. Ischemic heart or peripheral vascular disease. Bronchospastic disease. Hepatic dysfunction. Surgery. Diabetes. Hyperthyroidism. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May potentiate hypotension with prazosin, reserpine, hydralazine, cimetidine, antihypertensive drugs. May increase cardiac effects of verapamil, lidocaine. Indomethacin, barbiturates, rifampin may decrease effectiveness. Potentiated by felodipine, possibly quinidine, fluoxetine, paroxetine, propafenone. May block epinephrine.

Adverse reactions: Fatigue, dizziness, rash, depression, GI upset, dyspnea, bradycardia, cold extremities, palpitations, CHF, edema, syncope, chest pain, hypotension, bronchospasm, heart block, MI, angina.

How supplied: Tabs–100

MOEXIPRIL

R

UNIVASC UCB

ACE inhibitor. Moexipril HCl 7.5mg, 15mg; scored tabs.

Indications: Hypertension.

Adults: Take 1 hr before meals. Initially and if not on diuretics: 7.5mg once daily; usual range 7.5–30mg/day in 1–2 divided doses. If on diuretic: suspend diuretic for 2–3 days before starting therapy; resume diuretic if BP not controlled by moexipril alone. If diuretic cannot be discontinued: initially 3.75mg once daily. CrCl ≤40mL/min: initially 3.75mg once daily; max 15mg/day.

Children: Not established.

Contraindications: History of ACEI-associated or other angioedema. Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Hepatic impairment. Renal impairment: monitor for worsening renal function. Hypovolemia. Correct salt/volume depletion before starting therapy. CHF. Renal artery or aortic stenosis. Cerebrovascular or ischemic heart disease. Diabetes. Dialysis (esp. high-flux membrane). Surgery. Monitor WBCs in collagen vascular disease. Discontinue if angioedema, laryngeal edema, jaundice or markedly elevated liver enzymes occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: See Contraindications. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended. Hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. Excessive hypotension with diuretics. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors); monitor renal function in elderly and/or volume-depleted. May increase lithium levels; monitor. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare.

Adverse reactions: Cough, dizziness, diarrhea, flu syndrome, fatigue, pharyngitis, flushing, rash, myalgia; angioedema (eg, intestinal), hyperkalemia, hyponatremia; rare: hepatic failure.

How supplied: Tabs-100

MOEXIPRIL + HYDROCHLOROTHIAZIDE

UNIRETIC UCB

ACE inhibitor + diuretic. Moexipril HCl, hydrochlorothiazide; 7.5mg/12.5mg, 15mg/12.5mg, 15mg/25mg; scored tabs.

Indications: Hypertension (not for initial therapy).

Adults: Take 1 hour before a meal. Switching from monotherapy with either component: 1 tab once daily; adjust at 2-3 week intervals; usual max 30mg/50mg per day. Or, substitute for individually-titrated components.

Children: Not established.

Note: See **Moexipril** and **Hydrochlorothiazide** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions.

How supplied: Tabs-100

NADOLOL

CORGARD King

Noncardioselective beta-blocker. Nadolol 20mg, 40mg, 80mg; scored tabs.

Indications: Hypertension.

Adults: Initially 40mg once daily. Usual maintenance: 40-80mg once daily; max 320mg daily. Renal impairment: reduce dosage, see literature.

Children: Not recommended.

Contraindications: Asthma. Sinus bradycardia. 2nd or 3rd-degree AV block. Overt heart failure. Cardiogenic shock. CHF.

Warnings/Precautions: Ischemic heart disease. Bronchospastic disease, COPD. Renal or hepatic dysfunction. Diabetes. Hyperthyroidism. Surgery. SLE. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Hypotension, bradycardia with catecholamine-depleting drugs, general anesthetics. May increase cardiac effects of calcium channel blockers, digitalis. Antagonized by NSAIDs. Adjust

antidiabetic medications. May interfere with glaucoma screening tests. May block epinephrine.

Adverse reactions: Bradycardia, dizziness, fatigue, cold extremities, heart failure, heart block, bronchospasm, GI upset, rash, pruritus.

How supplied: Tabs-100

NICARDIPINE

NICARDIPINE (various)

Calcium channel blocker (dihydropyridine). Nicardipine HCl 20mg, 30mg; caps.

Indications: Hypertension.

Adults: Initially 20mg 3 times daily; adjust at intervals of at least 3 days; max 120mg daily. Severe hepatic impairment: initially 20mg twice daily.

Children: <18yrs: not recommended.

Also: Nicardipine

CARDENE SR PDL BioPharma

Nicardipine HCl 30mg, 45mg, 60mg; sust-rel caps.

Adults: ≥18yrs: 30-60mg twice daily.

Children: <18yrs: not recommended.

Also: Nicardipine

CARDENE IV EKR Therapeutics

Nicardipine HCl 2.5mg/mL; soln for slow IV infusion (after dilution to 0.1mg/mL).

Also: Nicardipine

CARDENE IV PREMIXED EKR Therapeutics

Nicardipine HCl 0.1mg/mL, 0.2mg/mL; soln for slow IV infusion.

Indications: Short-term treatment of hypertension when oral therapy is not feasible or desirable.

Adults: Individualize; see literature.

Children: <18yrs: not recommended.

Contraindications: Advanced aortic stenosis.

Warnings/Precautions: Cardiac failure. Angina. Acute cerebral infarction or hemorrhage. Hepatic or renal impairment. Pheochromocytoma. For regular capsules: measure blood pressure (BP) 1-2 hrs and 8 hrs after dosing. For SR: measure BP at 2-4 hrs and at end of dosing interval. For IV: monitor BP before and during infusion; avoid rapid or excessive reductions; switch to oral form when possible. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by cimetidine. Increases serum levels of cyclosporine, possibly digoxin (monitor).

Adverse reactions: Increased angina, flushing (caps, SR), headache, pedal edema, asthenia, dizziness, somnolence (caps), tachycardia, GI upset, sweating; ECG abnormalities, orthostatic hypotension, ventricular extrasystoles, local reactions (inj).

How supplied: Caps 20mg, 30mg-contact supplier; SR-60; IV (10mL amps)-10; Premixed-200mL

NIFEDIPINE

ADALAT CC Bayer

Calcium channel blocker (dihydropyridine). Nifedipine 30mg, 60mg, 90mg; ext-rel tabs.

Indications: Hypertension.

Adults: Swallow whole on empty stomach. Initially 30mg once daily. Usual maintenance: 30–60mg once daily. Titrate over 7–14 days; max 90mg/day.

Children: Not recommended.

Warnings/Precautions: Aortic stenosis. Angina. Severe obstructive coronary artery disease. Heart failure. Surgery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates antihypertensives, digoxin, tacrolimus. Angina and heart failure possible with β -blockers. Potentiated by cimetidine, doxazosin, ketoconazole, valproic acid, grapefruit juice, other CYP3A4 inhibitors. Antagonized by rifampin, phenytoin, carbamazepine, St. John's wort, other CYP3A4 inducers. Monitor oral anticoagulants, quinidine. Hypotension possible with fentanyl.

Adverse reactions: Peripheral edema, headache, flushing, dizziness, fatigue, constipation, muscle cramps, rash; exacerbation of angina, heart failure (rare).

How supplied: Tabs–100

NIFEDIPINE

NIFEDICAL XL Teva US Generics

PROCARDIA XL Pfizer

Calcium channel blocker (dihydropyridine). Nifedipine 30mg, 60mg, 90mg; ext-rel tabs.

Indications: Hypertension.

Adults: Swallow whole. Initially 30–60mg once daily, titrate over 7–14 days; max 120mg/day.

Children: Not recommended.

Warnings/Precautions: Aortic stenosis. Angina. Severe obstructive coronary artery disease. Heart failure. Surgery. GI narrowing. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Hypotension, angina and heart failure possible with β -blockers. Potentiated by cimetidine, grapefruit juice. Potentiates digoxin. Hypotension possible with fentanyl. Monitor oral anticoagulants, quinidine.

Adverse reactions: Edema, headache, fatigue, dizziness, constipation, nausea, palpitations, muscle cramps; rare: increased angina, acute MI.

How supplied: Tabs 30mg, 60mg–100, 300; Tabs 90mg–100

OLMESARTAN

BENICAR Daiichi Sankyo

Angiotensin II receptor blocker. Olmesartan medoxomil 5mg, 20mg, 40mg; tabs.

Indications: Hypertension.

Adults: Individualize. ≥ 16 ys: Monotherapy, not volume-depleted: initially 20mg once daily; may increase to max 40mg once daily after 2 weeks. Volume-depleted (eg, concomitant diuretic): consider lower initial dose.

Children: Individualize. <1 yr: do not give. <6 ys: not recommended. 6–16ys: (20kg to <35 kg): initially 10mg once daily; may increase to max 20mg

once daily after 2 weeks; (≥ 35 kg): initially 20mg once daily; may increase to max 40mg once daily after 2 weeks. Tablets may be prepared as an oral suspension if unable to swallow: see literature.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before beginning therapy, or monitor closely. Renal impairment: monitor for worsening renal function. Severe CHF. Renal artery stenosis. Possibly less effective in black patients. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60 mL/min): not recommended. Take 4hrs before colessevelam HCl dose.

Adverse reactions: Dizziness, rhabdomyolysis (rare).

How supplied: Tabs 5mg–30; 20mg, 40mg–30, 90

PHENOXYBENZAMINE

DIBENZYLIN WellSpring

Alpha-receptor blocker. Phenoxybenzamine HCl 10mg; caps.

Indications: Treatment of pheochromocytoma, to control episodes of hypertension and sweating. May use concomitant β -blocker if tachycardia is excessive.

Adults: Individualize. Initially 10mg twice daily. Increase dose every other day, usually to 20–40mg 2 or 3 times daily, until optimal dose obtained. Observe patients after each increase before instituting another increase.

Children: Not recommended.

Contraindications: Conditions where a fall in BP may be undesirable.

Warnings/Precautions: Cerebral or coronary arteriosclerosis. Renal damage. May aggravate respiratory infections. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant drugs that stimulate both alpha- and beta-adrenergic receptors (eg, epinephrine) may produce exaggerated hypotensive response and tachycardia. Blocks hyperthermia production by levartelenol. Blocks hypothermia production by reserpine.

Adverse reactions: Postural hypotension, tachycardia, inhibition of ejaculation, nasal congestion, miosis, GI upset, drowsiness, fatigue. May be carcinogenic (w. long-term use: not recommended).

How supplied: Caps–100

PHENTOLAMINE

R

PHENTOLAMINE (various)*alpha* adrenergic blocker. Phentolamine mesylate 5mg/vial; for IM or IV inj after reconstitution; contains mannitol.**Indications:** Hypertensive episodes in patients with pheochromocytoma.**Adults:** Pre-op: 5mg IV or IM 1–2 hrs before surgery; may repeat. During surgery: 5mg IV as needed. See literature.**Children:** Pre-op: 1mg IV or IM 1–2 hrs before surgery; may repeat. During surgery: 1mg IV as needed. See literature.**Contraindications:** MI or history of MI. Coronary insufficiency. Angina. Coronary artery disease.**Warnings/Precautions:** Arrhythmias. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** Avoid concomitant cardiac glycosides.**Adverse reactions:** Cerebrovascular spasms or occlusion, MI, tachycardia, arrhythmias, hypotension, weakness, dizziness, flushing, nasal congestion, GI disturbances.**How supplied:** Vial–1**PRazosin**

R

MINIPRESS Pfizer*alpha*-1 blocker (quinazoline). Prazosin HCl 1mg, 2mg, 5mg; caps.**Indications:** Hypertension.**Adults:** Give 1st dose at bedtime. 1mg 2–3 times daily. Increase dose slowly. Usual dose: 6–15mg/day in divided doses; max 20–40mg/day. When adding another antihypertensive, reduce dose to 1–2mg 3 times daily and retitrate.**Children:** Not recommended.**Warnings/Precautions:** Syncope. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Limit alcohol intake. Hypotension with propranolol, diuretics, other antihypertensives. False (+) pheochromocytoma test.**Adverse reactions:** Syncope (esp. 1st dose), dizziness, headache, drowsiness, weakness, palpitations, GI upset, edema, orthostatic hypotension, dyspnea, vertigo, depression, nervousness, rash, urinary frequency, blurred vision, reddened sclera, epistaxis, dry mouth, nasal congestion; priapism (rare).**How supplied:** Caps 1mg, 2mg–250, 1000 Caps 5mg–250, 500**PROPRANOLOL**

R

INDERAL Akrimax*Noncardioselective beta-blocker.* Propranolol HCl 10mg, 20mg, 40mg, 60mg, 80mg; scored tabs.**Indications:** Hypertension. Adjunct in pheochromocytoma.**Adults:** Initially 40mg twice a day. Usual maintenance: 120–240mg daily; max 640mg daily. Pheochromocytoma: 60mg daily in divided doses for 3 days pre-op or 30mg daily in inoperable cases.**Children:** Initially 1mg/kg daily. Usual range: 2–4mg/kg per day in 2 divided doses; max 16mg/kg per day.**Also: Propranolol**

R

INDERAL LA

Propranolol HCl 60mg, 80mg, 120mg, 160mg; sust-rel caps.

Adults: Initially 80mg daily. Usual maintenance: 120–160mg daily; max 640mg daily.**Children:** Not recommended.**Contraindications:** Asthma. Sinus bradycardia. 2nd- or 3rd-degree AV block. Overt heart failure. Cardiogenic shock.**Warnings/Precautions:** CHF. Wolff-Parkinson-White syndrome. Renal or hepatic dysfunction.

Bronchospastic disease, COPD. Diabetes.

Hyperthyroidism. Surgery. SLE. Avoid abrupt cessation.

Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiated by alcohol, CNS depressants, other antihypertensives, antithyroid drugs, haloperidol, chlorpromazine, cimetidine. Bradycardia with catecholamine-depleting drugs. Antagonized by NSAIDs, barbiturates, rifampin, phenytoin. May increase cardiac effects of calcium channel blockers, digitalis, lidocaine. Potentiates theophylline, antipyrine, lidocaine. May block epinephrine. May interfere with glaucoma screening tests.**Adverse reactions:** Heart failure, hypotension, bronchospasm, bradycardia, heart block, fatigue, dizziness, depression, GI upset, skin reactions (eg, rash, Stevens-Johnson syndrome, urticaria), pharyngitis, agranulocytosis.**How supplied:** Tabs 60mg–100; 10mg, 20mg, 40mg, 80mg–100, 5000; LA–100**QUINAPRIL**

R

ACCUPRIL Pfizer*ACE inhibitor.* Quinapril (as HCl) 5mg+, 10mg, 20mg, 40mg; tabs; + scored.**Indications:** Hypertension.**Adults:** Monotherapy: initially 10–20mg once daily.

Usual maintenance: 20–80mg daily in 1–2 divided doses. Elderly: initially 10mg once daily. Patients on diuretic: suspend diuretic for 2–3 days before starting; resume diuretic if BP not controlled by quinapril alone. If diuretic cannot be discontinued, or if creatinine clearance (CrCl) 30–60mL/min: initially 5mg daily. CrCl 10–30mL/min: initially 2.5mg daily.

Children: Not established.**Contraindications:** History of ACEI-associated or other angioedema. Concomitant aliskiren in patients with diabetes.**Warnings/Precautions:** Fetal toxicity may develop; discontinue if pregnancy is detected. Salt/volume depletion. Renal or hepatic impairment. CHF. Dialysis (esp. high-flux membrane). Monitor renal function in severe CHF, hypertension, or renal artery stenosis. Monitor WBCs in renal or collagen vascular disease. Monitor for hyperkalemia in diabetics. Surgery. Discontinue if angioedema, laryngeal

edema, jaundice or marked elevation in liver enzymes occurs. Black patients: increased risk of angioedema, possibly less effective. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers.

Interactions: See Contraindications. K^+ supplements, K^+ sparing diuretics, K^+ containing salt substitutes may cause hyperkalemia. May increase lithium levels; monitor frequently. Antagonizes tetracycline. Potentiated by diuretics. May be antagonized by NSAIDs including COX-2 inhibitors. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Headache, dizziness, fatigue, cough, GI upset, hypotension, hyperkalemia, back pain, tachycardia, dry mouth, somnolence, sweating; rare: angioedema, anaphylactoid reactions, excessive hypotension, hepatic failure, neutropenia, agranulocytosis.

How supplied: Tabs-90

RAMIPRIL

ALTACE King

ACE inhibitor. Ramipril 1.25mg, 2.5mg, 5mg, 10mg; gel caps.

Indications: Hypertension. To reduce risk of MI, stroke, or death from cardiovascular causes in high-risk patients ≥ 55 years old (see literature).

Adults: Swallow whole. Hypertension: initially 2.5mg once daily; maintenance: 2.5-20mg daily in single or 2 divided doses. May add a diuretic if BP is not controlled. Cardiovascular risk reduction: initially 2.5mg once daily for 1 week, then 5mg once daily for 3 weeks; maintenance 10mg once daily or in 2 divided doses. For both: (CrCl <40mL/min): 1.25mg once daily; max 5mg/day.

Children: Not recommended.

Contraindications: History of ACE-associated or other angioedema.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Salt/volume depletion. Renal or hepatic impairment (discontinue if jaundice or marked increases in hepatic enzymes occur). Severe CHF. Dialysis (esp. high-flux membrane). Monitor WBCs in collagen vascular disease. Monitor renal function in severe CHF, hypertension, or renal artery stenosis. Monitor for hyperkalemia in diabetes or renal insufficiency. Surgery. Discontinue if angioedema or laryngeal stridor occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Concomitant telmisartan: not recommended. K^+ supplements, K^+ sparing diuretics, K^+ containing salt substitutes may cause hyperkalemia. May increase lithium levels. Excessive hypotension with diuretics (reduce diuretic dose if

possible). May be antagonized by NSAIDs, including COX-2 inhibitors. Nitritoid reactions with concomitant injectable gold (eg, sodium aurothiomalate); rare.

Adverse reactions: Headache, dizziness, fatigue, cough, hypotension, hyperkalemia.

How supplied: Caps-100

SPIRONOLACTONE

ALDACTONE Pfizer

Diuretic (K^+ sparing). Spironolactone 25mg, 50mg+, 100mg+; tabs; +scored.

Indications: Adjunct in hypertension.

Adults: Initially 50-100mg/day in single or divided doses. Titrate at 2 week intervals.

Children: Not recommended.

Contraindications: Hyperkalemia. Renal impairment. Anuria.

Warnings/Precautions: Hepatic cirrhosis.

Hyponatremia. Surgery. Monitor electrolytes. Pregnancy. Nursing mothers: not recommended.

Interactions: Avoid K^+ sparing diuretics, K^+ supplements, K^+ containing salt substitutes, lithium. Hyperkalemia more likely with ACE inhibitors, NSAIDs. Hypokalemia with corticosteroids, ACTH. Antagonized by NSAIDs. Potentiates ganglionic blockers, alcohol, barbiturates, narcotics, skeletal muscle relaxants. Digitalis toxicity.

Adverse reactions: Hyperkalemia, hyponatremia, gynecomastia, GI disturbances, drowsiness, headache, rash, confusion, drug fever, ataxia, impotence, hirsutism, voice deepening, menstrual changes, gastric ulcers, agranulocytosis.

How supplied: Tabs 25mg-100, 500, 2500; 50mg, 100mg-100

TELMISARTAN

MICARDIS Boehringer Ingelheim

Angiotensin II receptor blocker. Telmisartan 20mg, 40mg, 80mg; tabs.

Indications: Hypertension.

Adults: Not volume-depleted: initially 40mg once daily; usual range 20-80mg/day. Salt/volume

depleted: monitor closely or consider reduced dose. May add diuretic if insufficient response at 80mg/day.

Children: Not recommended.

Contraindications: Concomitant aliskiren in patients with diabetes.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct hypovolemia before starting therapy or monitor closely. Severe CHF. Biliary obstruction. Hepatic or renal impairment. Renal artery stenosis. Dialysis (monitor for orthostatic hypotension). Neonates. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant ACE inhibitors (eg, ramipril): not recommended. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment

(CrCl <60mL/min): not recommended. Hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. May potentiate digoxin. Monitor lithium levels. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted.

Adverse reactions: Back pain, upper respiratory tract infection, sinusitis, diarrhea, pharyngitis, angioedema; rare: rhabdomyolysis.

How supplied: Tabs-3 × 10 (blister cards)

TERAZOSIN

R

HYTRIN AbbVie

alpha-1 blocker (quinazoline). Terazosin (as HCl) 1mg, 2mg, 5mg, 10mg; caps.

Indications: Hypertension.

Adults: 1 mg at bedtime, then increase slowly. Usually: 1-5mg once daily in the AM; max 20mg/day. Monitor at peak (2-3 hours after dose) and trough. If BP response is substantially diminished at 24 hours, may increase dose or give in 2 divided doses. If hypotensive effects occur at peak, consider twice daily dosing. If another antihypertensive is added, dosage reduction and retitration may be necessary.

Children: Not recommended.

Warnings/Precautions: Syncope. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with verapamil, other antihypertensives.

Adverse reactions: Syncope (esp. 1st dose), dizziness, somnolence, asthenia, nausea, nasal congestion, palpitations, orthostatic hypotension, blurred vision, peripheral edema; priapism (rare).

How supplied: Caps-100

TORSEMIDE

R

DEMADEX Roche

Diuretic (loop). Torsemide 5mg, 10mg, 20mg, 100mg; scored tabs.

Indications: Hypertension.

Adults: 5mg once daily, may increase to 10mg once daily. Give IV dose over a period of 2 minutes.

Children: Not recommended.

Contraindications: Anuria. Sulfonamide allergy.

Warnings/Precautions: Hepatic disease with cirrhosis and ascites. Monitor electrolytes, BUN, creatinine, uric acid, and fluids. Pregnancy (Cat.B). Nursing mothers.

Interactions: Lithium and salicylate toxicity. Caution with NSAIDs. Antagonized by probenecid and indomethacin. Give oral dose 2 hours before or 4 hours after cholestyramine. Ototoxicity with aminoglycosides and ethacrynic acid.

Adverse reactions: Dizziness, headache, nausea, weakness, vomiting, hyperglycemia, excessive urination, hyperuricemia, hypokalemia, excessive thirst, hypovolemia, impotence, esophageal hemorrhage, dyspepsia.

How supplied: Tabs-100; Ampules-Contact supplier

TRANDOLAPRIL

R

MAVIK AbbVie

ACE inhibitor. Trandolapril 1mg+, 2mg, 4mg; tabs; +scored.

Indications: Hypertension.

Adults: If not on diuretic: initially 1mg once daily in non-black patients; 2mg in black patients. If on diuretic: suspend diuretic for 2-3 days before starting therapy; resume diuretic if BP not controlled with trandolapril alone. If diuretic cannot be discontinued (supervise closely until stabilized), or in renal impairment (CrCl <30mL/min) or hepatic cirrhosis: initially 0.5mg once daily. For all: adjust at 1-week intervals; usual range 2-4mg once daily; usual max 8mg/day; may give in 2 divided doses.

Children: Not established.

Contraindications: History of ACEI-associated or other angioedema.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Renal impairment: monitor for worsening renal function. Salt/volume depletion. Renal artery stenosis. Monitor for neutropenia in collagen vascular and/or renal disease. Monitor for hyperkalemia in diabetics. Dialysis (esp. high-flux membrane). Surgery. Discontinue if laryngeal edema, angioedema, or jaundice occurs. Avoid hypotension in CHF, aortic stenosis, ischemic heart disease, or cerebrovascular disease. Black patients may have higher risk of angioedema than non-black patients. Neonates. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: Concomitant aliskiren in patients with diabetes, renal impairment (CrCl <60mL/min): not recommended. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Excessive hypotension with diuretics, inhalation anesthetics. Hyperkalemia with K⁺ supplements, K⁺-sparing diuretics, or salt substitutes. May increase lithium levels. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors): monitor renal function in elderly and/or volume-depleted. Potentiates antidiabetic medicines (insulin or oral hypoglycemic agents). Nitritoid reactions with injectable gold (sodium aurothiomalate); rare.

Adverse reactions: Cough, dizziness, diarrhea; rare: hepatic failure.

How supplied: Tabs-100

TRIAMTERENE + HYDROCHLOROTHIAZIDE

R

DYAZIDE GlaxoSmithKline

Diuretic combination. Triamterene 37.5mg, hydrochlorothiazide 25mg; caps.

Indications: Hypertension when normokalemia is essential.

Adults: 1-2 caps once daily.

Children: Not recommended.

Contraindications: Hyperkalemia. Renal impairment. Anuria. Sulfonamide allergy. Concomitant potassium or K⁺-sparing diuretics.

Warnings/Precautions: Diabetes. Acidosis predisposition. Electrolyte imbalance. Hypochloremia with metabolic alkalosis. Excess diuresis. History of renal stones. Gout. Surgery. SLE. Monitor electrolytes, renal function. Discontinue if serum potassium >5.5mEq/L or <3mEq/L. Hepatic impairment: monitor for hepatic coma, if confusion increases, discontinue for a few days. Severely ill. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Digoxin, lithium toxicity. Hyperkalemia more likely with ACE inhibitors, parenteral penicillin G. Hypokalemia with ACTH, corticosteroids, amphotericin B. Hyponatremia with sulfonylureas. NSAIDs may cause renal failure. Adjust antidiabetic, antigout medications. May potentiate nondepolarizing muscle relaxants, antihypertensives. Antagonizes oral anticoagulants, methenamine. May interfere with parathyroid tests.

Adverse reactions: Drowsiness, muscle cramps, weakness, headache, GI disturbances, dizziness, impotence, arrhythmias, hypotension, dry mouth, urine discoloration.

How supplied: Caps-100, 1000

VALSARTAN

DIOVAN Novartis

Angiotensin II receptor blocker. Valsartan 40mg+, 80mg, 160mg, 320mg; + scored; tabs.

Indications: Hypertension.

Adults: Monotherapy and not volume-depleted: initially 80mg or 160mg once daily; max 320mg once daily. Or, add a diuretic (more effective than increasing dose above 80mg).

Children: <6yrs or CrCl<30mL/min: not recommended. 6–16yrs: Initially 1.3mg/kg once daily (up to 40mg total); max 2.7mg/kg (up to 160mg) once daily. If unable to swallow tabs, or calculated dose (mg/kg) does not correspond to available tablet strengths, use suspension (see literature for susp preparation).

Contraindications: Concomitant aliskiren in diabetics.

Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct hypovolemia before beginning therapy (may need to reduce diuretic) or monitor closely for hypotension. Hepatic or renal impairment (monitor). Renal artery stenosis. Severe CHF (if renal function depends on renin-angiotensin-aldosterone system). Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.

Interactions: Concomitant K⁺ supplements, K⁺-sparing diuretics, K⁺-containing salt substitutes may lead to hyperkalemia and, in heart failure patients, increased serum creatinine. May be antagonized by, and renal toxicity potentiated by,

NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume depleted). May be potentiated by inhibitors of OATP1B1 (eg, rifampin, cyclosporine) or MPR2 (eg, ritonavir). Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Headache, dizziness, viral infection, fatigue, abdominal pain, neutropenia, rhabdomyolysis (rare).

How supplied: Tabs 40mg–30; 80mg, 160mg, 320mg–90

2G Hypotension

MIDODRINE

MIDODRINE (various)

alpha-1 agonist. Midodrine HCl 2.5mg, 5mg, 10mg; scored tabs.

Indications: Symptomatic orthostatic hypotension.

Adults: Take during the day while upright; allow at least 4 hours between last dose and bedtime. 10mg 3 times daily at 3–4 hour intervals. Renal dysfunction: initially 2.5mg 3 times daily. Discontinue if no improvement after initial therapy.

Children: Not recommended.

Contraindications: Severe heart disease. Acute renal disease. Urinary retention. Pheochromocytoma. Thyrotoxicosis. Persistent, excessive supine hypertension. Initial supine systolic pressure >180 mmHg; not recommended.

Warnings/Precautions: Monitor supine and sitting BP. Discontinue if supine hypertension occurs. Diabetes. Renal or hepatic impairment. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiated by α-agonists (eg, pseudoephedrine, ergots) and sodium-retaining steroids (eg, fludrocortisone); caution in increased intraocular pressure with fludrocortisone. Antagonized by α-antagonists (eg, prazosin). Levels may be affected by renally-excreted alkaline drugs (eg, metformin, cimetidine, ranitidine, procainamide, triamterene, flecainide, quinidine). Cardiac glycosides, β-blockers, CNS drugs may cause bradycardia, AV block, arrhythmias; discontinue if bradycardia occurs.

Adverse reactions: Paresthesia, piloerection, dysuria, pruritus, supine hypertension, chills, pain, rash.

How supplied: Contact supplier.

NOREPINEPHRINE

LEVOPHED Hospira

Sympathomimetic. Norepinephrine bitartrate 1mg/mL (equivalent of 1mg base of norepinephrine); soln for IV infusion after dilution; contains sulfites.

Indications: To restore blood pressure control in certain acute hypotensive states

(eg, pheochromocytectomy, sympathectomy, poliomyelitis, spinal anesthesia, MI, septicemia, blood transfusion, and drug reactions).

Adults: Correct blood volume depletion before administration. Give by IV infusion after dilution (contains 4mcg of base/mL) into a large vein. Initially 2mL to 3mL (or 8–12mcg of base) per minute; adjust flow rate until adequate low normal BP (usually 80–100 mmHg systolic) and maintain tissue perfusion. Usual maintenance: 0.5mL to 1mL (or 2–4mcg of base) per minute. Withdraw gradually. Titrate dose based on response; see literature.

Children: Not recommended.

Contraindications: Hypotension due to blood volume deficits except as an emergency measure. Mesenteric or peripheral vascular thrombosis. Profound hypoxia or hypercapnia. Concomitant cyclopropane and halothane anesthesia.

Warnings/Precautions: Hypertension. Monitor BP every 2 minutes initially until desirable level is obtained, then every 5 minutes if administration is continued. Avoid extravasation. Asthma. Sulfite sensitivity. Elderly (avoid infusion into leg veins). Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Risk of ventricular tachycardia or fibrillation with cyclopropane, halothane anesthesia. Caution with MAOIs, triptiline or imipramine antidepressants; may cause prolonged hypertension.

Adverse reactions: Ischemic injury, reflex bradycardia, arrhythmias, anxiety, transient headache, respiratory difficulties, extravasation necrosis, volume depletion (esp. long-term use).

How supplied: Ampuls (4mL)–10

PHENYLEPHRINE

Rx

PHENYLEPHRINE HCl INJECTION (various)

Sympathomimetic. Phenylephrine HCl 10mg/mL; soln for IV, IM, or SC inj; contains sulfites.

Indications: To maintain adequate blood pressure during spinal and inhalation anesthesia. Vascular failure in shock, shock-like states and drug-induced hypotension or hypersensitivity.

Adults: Spinal anesthesia hypotension: treatment or prophylaxis: 2–3mg SC or IM 3–4 minutes prior to spinal anesthesia; hypotensive crisis: initially 0.2mg by IV inj, subsequent doses not to exceed preceding dose by 0.1–0.2mg; max: 0.5mg/dose. Mild or moderate hypotension: SC or IM: usually 2–5mg; initial max dose: 5mg. Range: 1–10mg; IV: usually 0.2mg; initial max dose: 0.5mg. Range: 0.1–0.5mg. Do not repeat injections more often than every 10–15mins. Shock and drug-induced: initially 10mg by continuous IV infusion, if non-responsive, add additional 10mg (or more) into infusion bottle. See literature.

Children: Spinal anesthesia hypotension: 0.5–1mg/25lbs body weight by SC or IM.

Contraindications: Severe hypertension. Ventricular tachycardia.

Warnings/Precautions: Cardiovascular disease. Hypertension. Thyroid disease. Asthma. Sulfite sensitivity. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers.

Interactions: Potentiated by oxytocic drugs, tricyclic antidepressants, or MAOIs. Caution with halothane anesthesia.

Adverse reactions: Headache, reflex bradycardia, excitability, restlessness: rare: arrhythmias.

How supplied: Vial 10mg/mL (1mL, 5mL)–25

2H Pulmonary hypertension

EPOPROSTENOL

Rx

FLOLAN GlaxoSmithKline

Prostaglandin. Epoprostenol (as sodium)

0.5mg, 1.5mg; per vial; pvd for IV infusion after reconstitution.

Indications: Primary pulmonary hypertension.

Pulmonary hypertension due to scleroderma disease in NYHA Class III and Class IV patients who do not respond adequately to conventional therapy.

Adults: Give by continuous chronic IV infusion through a central venous catheter. Initially 2 nanograms/kg per min; increase in increments of 2 nanograms/kg per min at ≥ 15 minute intervals until response achieved or tolerance develops. Dose decreases should be made gradually in 2 nanograms/kg/min decrements at ≥ 15 minute intervals until dose-limiting effects resolve.

Children: Not recommended.

Contraindications: Chronic use with CHF due to severe left ventricular systolic dysfunction. Pulmonary edema.

Warnings/Precautions: Avoid abrupt withdrawal or large dose reductions (may cause rebound pulmonary hypertension). Bleeding disorders. Start anticoagulant therapy, unless contraindicated. Monitor BP and heart rate for several hours after dose changes. Pregnancy (Cat.B). Labor & delivery. Nursing mothers.

Interactions: Potentiated hypotensive effects with diuretics, antihypertensive agents, other vasodilators. Potentiates anticoagulants, antiplatelet agents. May potentiate digoxin (monitor).

Adverse reactions: Headache, jaw pain, flushing, GI upset, flu-like symptoms, anxiety, dizziness, tachycardia, myalgia.

How supplied: Vials–1 (w. diluent)

ILOPROST

Rx

VENTAVIS Actelion

Prostacyclin analogue. Iloprost 10mcg/mL,

20mcg/mL; soln for inhalation using I-neb or Prodose AAD System; preservative-free.

Indications: Pulmonary arterial hypertension (WHO Group I) in patients with NYHA Class III or IV symptoms to improve exercise ability and delay clinical worsening.

Adults: Initially 2.5mcg, if tolerated, uptitrate to 5micrograms 6–9 times daily based on tolerability (no more than every 2 hrs); max 45mcg/day. Monitor vital signs while initiating therapy. Hepatic impairment: consider increasing dosing interval (eg, 3–4 hours) between doses.

Children: Not recommended.

Warnings/Precautions: Do not start therapy if systolic BP <85 mmHg. Discontinue immediately if pulmonary edema occurs (may indicate pulmonary venous hypertension). Bleeding disorders. Avoid contact with eyes and skin, oral ingestion. COPD. Severe asthma. Acute pulmonary infections. Hepatic or renal impairment. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates hypotensive effect of vasodilators and antihypertensives. May potentiate anticoagulants. Do not mix with other drugs.

Adverse reactions: Vasodilation, increased cough, headache, lockjaw, insomnia, GI upset, hypotension, flu syndrome, back pain, abnormal lab tests (eg, increased GGT, alkaline phosphatase), tongue pain, palpitations, syncope, muscle cramps, hemoptysis, pneumonia, CHF, chest pain, supraventricular tachycardia, dyspnea, peripheral edema, kidney failure.

How supplied: Single-use ampule–30

SILDENAFIL

REVATIO Pfizer

Phosphodiesterase type 5 inhibitor (cGMP-specific). Sildenafil citrate 20mg; tabs.

Indications: Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening.

Adults: 20mg three times daily; separate dosing by 4–6 hrs (see Interactions).

Children: Not recommended.

Also: Sildenafil

REVATIO INJECTION

Sildenafil 10mg/vial; soln for IV inj.

Indications: Pulmonary arterial hypertension (PAH) (WHO Group I) to improve exercise ability and delay clinical worsening, in patients who are temporarily unable to take oral Revatio.

Adults: Give by IV bolus inj. 10mg 3 times daily.

Children: Not recommended.

Contraindications: Concomitant organic nitrates.

Warnings/Precautions: Pulmonary veno-occlusive disease: not recommended. PAH secondary to sickle cell anemia. Underlying conditions that could be affected by vasodilatory effects (eg, concomitant antihypertensive therapy, BP <90/50, fluid depletion, severe left ventricular outflow obstruction, autonomic dysfunction). Retinitis pigmentosa. Anatomical penile deformation. Predisposition to priapism. Severe renal or hepatic impairment. Active peptic ulcer. Bleeding disorders. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: See Contraindications. Hypotension with nitrates. Concomitant potent CYP3A4 inhibitors

(eg, ketoconazole, itraconazole, ritonavir): not recommended. Potentiated by inhibitors of CYP3A4 or CYP2C9, or cimetidine; may need dose adjustment. Antagonized by CYP3A4 inducers (eg, rifampin), bosentan; may need to adjust dose. Concomitant α -blockers (eg, doxazosin) may cause symptomatic hypotension (monitor BP). Potentiates bleeding risk with Vit. K antagonists. Concomitant Viagra or other PDE5 inhibitors: not recommended.

Adverse reactions: Epistaxis, headache, GI upset, flushing, insomnia, erythema, dyspnea worsened, rhinitis, sinusitis, myalgia, pyrexia, paresthesia; hypotension, vision or hearing loss, priapism.

How supplied: Tabs–90

Single-use vial–1

SECTION 3:

DERMATOLOGICAL DISORDERS 3A Pressure/neuropathic ulcers

BECAPLERMIN

R

REGANEX Healthpoint

Growth factor. Becaplermin 0.01%; gel; contains parabens, m-cresol.

Indications: Adjunct in the treatment of lower extremity diabetic neuropathic ulcers that extend into the subcutaneous tissue or beyond and have an adequate blood supply.

Adults: ≥ 16 yrs: Apply once daily until complete healing has occurred. Measure size of ulcer and adjust at 1–2 week intervals. Calculate amount of gel needed based on ulcer size and product tube size. Squeeze calculated length of gel from tube onto clean measuring surface (eg, wax paper).

Spread gel over entire ulcer to thickness of about 1/16 inch. Cover with saline dressing for about 12 hrs. Remove dressing and rinse. Replace with clean saline dressing (no gel). Reevaluate if ulcer does not decrease in size by about 30% after 10 weeks, or if complete healing has not occurred after 20 weeks.

To calculate amount of gel in centimeters: If using the 15g tube: Length of gel (in cm) to be applied daily = wound area (length $\times$ width in cm^2) $\div$ 4. If using the 2g tube: Length of gel (in cm) to be applied daily = wound area (length $\times$ width in cm^2) $\div$ 2.

Children: <16 yrs: not recommended.

Contraindications: Neoplasm(s) at application site.

Warnings/Precautions: Systemic malignancies (increased death rate with ≥ 3 tubes of becaplermin gel treatment). Not for use in wounds that close by primary intention. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Erythematous rash.

How supplied: Gel–2g, 15g

COLLAGENASE

SANTYL Healthpoint

Debriding agent. Collagenase 250units/g; oint.

Indications: Chronic dermal ulcers and severely burned areas.**Adults:** Apply once daily to cleansed wounds or sterile gauze pad.**Children: Not recommended.****Warnings/Precautions:** Avoid detergents, antiseptics, or soaks with metal ions (eg, mercury, silver) or acidic solutions (pH<6). Debilitated.**Adverse reactions:** Systemic bacterial infections, erythema.**How supplied:** Oint-15g, 30g**TRYPSIN + BALSAM PERU + CASTOR OIL**

GRANULEX Mylan

Debriding agent/capillary stimulant. Trypsin 0.1mg, balsam peru 72.5mg, castor oil 650mg; per 0.82mL; aerosol liquid.

Indications: Decubitus and varicose ulcers; debridement.**Adults and Children:** Apply at least twice daily. Wet bandage may be applied.**Contraindications:** Do not spray on fresh arterial clots.**Warnings/Precautions:** Avoid eyes.**Adverse reactions:** Sensitization may occur.**How supplied:** Aerosol-2oz, 4oz**TRYPSIN + BALSAM PERU + CASTOR OIL**

XENADERM Healthpoint

Debriding agent/capillary stimulant. Trypsin 90Units, balsam peru 87mg, castor oil 788mg; per gram; oint.

Indications: Decubitus and varicose ulcers, dehiscent wounds; debridement.**Adults and Children:** Apply at least twice daily. Dressing may be applied.**Contraindications:** Do not apply to fresh arterial clots.**Warnings/Precautions:** Avoid eyes.**Adverse reactions:** Sensitization may occur.**How supplied:** Oint-60g**3B Psoriasis****ACITRETIN**

SORIATANE Stiefel

Retinoid. Acitretin 10mg, 25mg; caps.

Indications: Severe psoriasis (in female patients of reproductive potential, use only if unresponsive to or cannot take other agents).**Adults:** 25-50mg once daily with main meal; may discontinue when lesions resolve. May repeat if

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relapse occurs. Prescribe limited supply. Decrease phototherapy dose.

Children: Not recommended.**Contraindications:** Alcohol. Concomitant methotrexate, tetracyclines. Severe hepatic or renal dysfunction. Dyslipidemias. Pregnancy (Cat.X). Nursing mothers.**Warnings/Precautions:** Be fully familiar with toxicity and teratogenicity before use. Transient worsening of symptoms may occur. Females of reproductive potential (including history of infertility): obtain 2 reliable (-) pregnancy tests (when decision is made to start and within 1 week of start) and repeat periodically (eg, monthly); use at least 2 reliable methods of contraception or abstain for at least 1 month before, during, and for 3 years after therapy (if etretinate had been used previously, continue to follow contraception recommendations for that product). Discontinue if hepatotoxicity is suspected, if papilledema (refer to neurologist), visual difficulties (refer to ophthalmologist), or CNS disturbances (eg, depression) occur. Do pretreatment blood lipid evaluation and repeat at 1-2 week intervals until lipid response established; control significant triglyceride elevations with diet, drugs, or dose reduction. Hypertriglyceridemia risk. Avoid sun and UV light. Monitor diabetics. Do not donate blood during and for 3 years after therapy. Get written informed consent. Elderly.**Interactions:** See Contraindications (methotrexate increases risk of hepatitis; tetracycline increases intracranial pressure). Females must not ingest ethanol during or for 2 months after therapy (prolongs teratogenic potential). Interferes with efficacy of low-dose progestin-only contraceptives and possibly other progestin-only contraceptives (eg, injectables, implants); avoid St. John's wort, others that may decrease efficacy of contraceptives. Avoid phenytoin, vitamin A, other oral retinoids. May potentiate phenytoin, sulfonyleureas.**Adverse reactions:** Lipid elevations, abnormal liver function and other lab tests, cardiovascular effects, depression or other psychiatric symptoms, chelitis, alopecia, skin peeling, dry or sticky skin, nail disorder, pruritus, dry mouth, rhinitis, hypervitaminosis A syndrome, epistaxis, rash, hyperesthesia, paresthesia, xerophthalmia, dry or irritated eye, loss of eye brow or lashes, decreased night vision, intolerance to contact lenses, arthralgia, spinal hyperostosis, rigors; rare: pseudotumor cerebri, pancreatitis, hepatitis.**How supplied:** Caps-30**ADALIMUMAB**

HUMIRA AbbVie

Tumor necrosis factor- α blocker. Adalimumab 20mg/0.4mL, 40mg/0.8mL; soln for SC inj; preservative-free.**Indications:** Moderate-to-severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

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Adults: Inject SC into thigh or abdomen; rotate inj sites; supervise 1st dose. ≥ 18 yrs: initially 80mg, followed by 40mg every other week starting one week after initial dose.

Children: < 18 yrs: not recommended.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Lymphoma and other malignancies. Active infections: do not initiate therapy. Chronic or history of recurring infections. Conditions that predispose to infection.

Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. CHF (monitor). Immunosuppression. Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs. CNS demyelinating disorders. Juvenile arthritis: follow up on current immunizations before starting therapy. Latex allergy. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent abatacept, anakinra, live vaccines, or other TNF blockers: not recommended. Immunosuppressants increase risk of infection.

Adverse reactions: Inj site reactions, infections (may be serious), headache, nausea, rash, abdominal pain; rare: malignancies (eg, lymphoma; esp children), blood dyscrasias, hypertension, neurological events, antibody formation, lupus-like syndrome.

How supplied: Single-dose prefilled syringe-2; Single-dose prefilled pen (40mg)-2, 4 (Starter Package)

CYCLOSPORINE

NEORAL Novartis

Immunosuppressant. Cyclosporine (modified) 25mg, 100mg; caps; contains alcohol.

Also: Cyclosporine

NEORAL ORAL SOLUTION

Cyclosporine (modified) 100mg/mL; contains alcohol.

Indications: Treatment of adult, non-immunocompromised patients with severe, recalcitrant, plaque psoriasis who have failed to respond to at least one systemic therapy or in patients for whom other systemic therapies are contraindicated or intolerable.

Adults: Give consistently with regard to meals and time of day. ≥ 18 yrs: 1.25mg/kg twice daily; may increase after 4 weeks by 0.5mg/kg per day, then adjust at 2-week intervals; max 4mg/kg per day. Dilute soln in glass of room temp orange or apple juice. Reduce by 25–50% if adverse events (eg, hypertension or serum creatinine increases $\geq 25\%$ above baseline) occur. Renal or severe hepatic impairment: consider reducing dose. Discontinue if adverse events are severe or persistent.

Children: < 18 yrs: not established.

Contraindications: Concomitant PUVA or UVB therapy; methotrexate, other immunosuppressants, coal tar, or radiation therapy.

Warnings/Precautions: Be fully familiar with immunosuppressive therapy before prescribing. Not bioequivalent to all other forms of cyclosporine; do not interchange without physician supervision. Increased risk of infections, lymphomas and other malignancies (eg, skin). Avoid sun or UV light exposure. Monitor renal and hepatic function, BP, CBC, serum magnesium, potassium, uric acid, lipids (see full labeling for monitoring frequency). Reduce dose if hypertension occurs; do not attempt to manage medically. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid other nephrotoxic drugs (eg, ciprofloxacin, gentamicin, tobramycin, vancomycin, SMX/TMP, melphalan, amphotericin B, ketoconazole, cimetidine, nifedipine, tacrolimus, NSAIDs, colchicine), fibric acid derivatives. Cyclosporine levels increased by CYP3A inhibitors (eg, calcium channel blockers, amiodarone, azithromycin, azole antifungals, erythromycin, clarithromycin, quinupristin/dalfopristin, boceprevir, telaprevir, methylprednisolone, allopurinol, colchicine, bromocriptine, danazol, metoclopramide; probably indinavir, saquinavir, nelfinavir, ritonavir, imatinib, nefazodone, oral contraceptives). Avoid alcohol, grapefruit juice. Cyclosporine levels decreased by CYP3A inducers (eg, nafcillin, rifampin, carbamazepine, oxcarbazepine, bosentan, phenobarbital, phenytoin, octreotide, ticlopidine, St. John's wort), orlistat. Avoid potassium-sparing diuretics. Concomitant repaglinide: monitor blood glucose. Concomitant aliskiren: not recommended. Concomitant sirolimus: separate by 4 hours. May decrease effectiveness of vaccines; avoid live attenuated vaccines. May increase levels of digoxin (monitor), colchicine, prednisolone, statins (reduce dose), ambrisentan, and anthracycline antibiotics. Gingival hyperplasia with nifedipine (avoid). Convulsions with high-dose methylprednisolone.

Adverse reactions: Renal dysfunction, hypertension, headache, GI disturbances, hirsutism, hypertrichosis, leg cramps, pain, tremor, paresthesia, edema, dizziness, gum hyperplasia, liver dysfunction; increased risk of infections or malignancies, progressive multifocal leukoencephalopathy, hyperkalemia, thrombotic microangiopathy, possible encephalopathy.

How supplied: Caps-30; Soln-50mL

ETANERCEPT

ENBREL Amgen

Tumor necrosis factor (TNF) blocker. Etanercept 25mg; per vial (pwd for SC inj) after reconstitution; preservative-free; diluent contains benzyl alcohol; 50mg/mL prefilled syringe (soln for SC inj; preservative free); 50mg/mL prefilled syringe SureClick autoinjector (soln for SC inj; preservative-free).

Indications: Moderate to severe chronic plaque psoriasis in adults who are candidates for systemic and phototherapy.

Adults: ≥ 18 yrs: Inject SC into thigh, abdomen, or upper arm; rotate inj sites. Initially 50mg twice weekly (3–4 days apart) (use prefilled syringe), or 25mg or 50mg per week; both for 3 months; then 50mg/week (maintenance).

Children: < 18 yrs: not recommended.

Contraindications: Sepsis.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections. Conditions that predispose to infection (eg, diabetes, immunosuppression). Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. Suspend if significant exposure to varicella occurs (consider varicella prophylaxis). Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs. CNS demyelinating disorders (eg, multiple sclerosis, myelitis, optic neuritis), seizures. Heart failure. Malignancies. Attempt to complete childhood immunizations first. Wegener's granulomatosis patients receiving immunosuppressive agents: not recommended. Moderate to severe alcoholic hepatitis. Latex allergy (syringe). Supervise 1st dose. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent cyclophosphamide, anakinra, abatacept, live vaccines, other TNF blockers: not recommended. Immunosuppressants increase risk of infection.

Adverse reactions: Inj site reactions, infections (eg, sepsis, osteomyelitis, cellulitis, pneumonia, pyelonephritis), antibody formation, respiratory disorders; worsening psoriasis; rare: CNS demyelinating disorders, pancytopenia, aplastic anemia, tuberculosis, malignancies (eg, lymphoma; esp. children), others. Children: also varicella, headache, GI disturbances.

How supplied: Multi-use vials–4 (w. supplies); Single-use prefilled syr (1mL)–4 (w. needles); Single-use prefilled SureClik autoinjector–4 (w. needles)

INFLIXIMAB

REMICADE Janssen Biotech

Tumor necrosis factor- α blocker. Infliximab 100mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free.

Indications: Severe chronic plaque psoriasis in adults who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

Adults: Give by IV infusion over at least 2 hours. 5mg/kg at weeks 0, 2, 6, then once every 8 weeks.

Children: Not recommended.

R

Contraindications: Moderate to severe heart failure (doses > 5 mg/kg). Allergy to murine proteins.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, viral, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections or hematological abnormalities. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. Discontinue if lupus-like syndrome with autoantibody formation, severe hypersensitivity reactions, or jaundice with liver enzymes $\geq 5 \times$ ULN occurs. Pre-existing heart failure; closely monitor and discontinue if new or worsening symptoms occur. CNS demyelinating or seizure disorders; discontinue if significant CNS effects occur. Malignancies (eg, melanoma; perform periodic skin exams). Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent anakinra, abatacept, tocilizumab, live vaccines, other TNF blockers or biological therapeutics: not recommended. Concomitant immunosuppressants (eg, corticosteroids, methotrexate) may increase risk of infection. May be potentiated by methotrexate. Concomitant CYP450 substrates with narrow therapeutic index (eg, warfarin, cyclosporine, theophylline): monitor and may need to adjust dose of these drugs. Caution with switching between DMARDs; overlapping may further increase the risk of infection.

Adverse reactions: Infections, infusion reactions (esp. after a period of no treatment), headache, abdominal pain, GI upset, fatigue, cough, fever, pain, dizziness, rash, pruritus, CHF, autoantibody formation; malignancies (eg, skin, lymphoma; esp. children), optic neuritis, seizures, lupus-like syndrome, blood dyscrasias, hepatotoxicity.

How supplied: Single-use vials–1

3C Skin infections (topicals)

ACYCLOVIR

R

ZOVIRAX OINTMENT Valeant

Nucleoside analogue antiviral. Acyclovir 5%.

Indications: Initial herpes genitalis. Limited non-life threatening mucocutaneous herpes simplex infections in immunocompromised patients.

Adults and Children: Apply using finger cot or rubber glove every 3 hrs 6 times daily for 7 days.

Also: Acyclovir ZOVIRAX CREAM Acyclovir 5%.

R

Indications: Recurrent herpes labialis.

Adults: Apply 5 times daily for 4 days. Begin treatment at earliest sign or symptom.

Children: Not recommended.

Warnings/Precautions: Avoid eyes, mucous membranes. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Local reactions.

How supplied: Oint-30g; Crm-5g

BETAMETHASONE + CLOTRIMAZOLE

LOTIRISONE Merck

Steroid + azole antifungal. Betamethasone (as dipropionate) 0.05%, clotrimazole 1%; crm; lotion.

Indications: Fungal skin infections.

Adults: Apply sparingly twice daily; max 45g (cream), 45mL (lotion) per week. Max 2 wks for t. cruris, t. corporis; 4 wks for t. pedis.

Children: Not recommended.

Contraindications: Varicella, vaccinia.

Warnings/Precautions: Do not occlude. Use lowest effective dose (esp. in children). Monitor patients regularly. Discontinue steroid if infection persists, worsens or superinfection occurs. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Irritation, erythema, stinging, folliculitis, hypertrichosis, dermatitis, HPA axis suppression (esp. in children), epidermal and dermal atrophy (esp. in thin-skinned or occluded areas).

How supplied: Crm-15g, 45g; Lotion-30mL

CICLOPIROX

LOPROX Medicis

N-hydroxypyridinone antifungal. Ciclopirox 0.77%; crm; lotion.

Indications: Tinea pedis, t. cruris, t. corporis, t. versicolor. Cutaneous candidiasis.

Adults and Children: <10yrs: not recommended. ≥10yrs: Apply and gently massage into affected and surrounding areas twice daily for up to 4 wks.

Also: Ciclopirox

LOPROX GEL

Ciclopirox 0.77%.

Indications: Seborrheic scalp dermatitis.

T. corporis, interdigital t. pedis.

Adults and Children: <16yrs: not recommended.

≥16yrs: Apply and gently massage (for t. corporis, t. pedis) into affected and surrounding areas twice daily for up to 4 wks.

Also: Ciclopirox

LOPROX SHAMPOO

Ciclopirox 1%.

Indications: Seborrheic scalp dermatitis.

Adults and Children: <16yrs: not recommended.

≥16yrs: Shampoo using 5-10mL; leave lather on for 3 minutes before rinsing. Repeat twice weekly for 4 wks (at least 3 days apart).

Warnings/Precautions: Avoid eyes, mucous membranes, occlusion. Discontinue if irritation or

sensitization occurs. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Pruritus, burning sensation, contact dermatitis.

How supplied: Crm-15g, 30g, 90g; Lotion-30mL, 60mL; Gel-30g, 45g; Shampoo-120mL

CLOTRIMAZOLE

OTC

LOTIRIMIN AF Merck

Azole antifungal. Clotrimazole 1%; crm; soln; lotion.

Indications: Tinea pedis, t. cruris, t. corporis.

Adults and Children: Apply to affected and surrounding areas twice daily for up to 4 weeks.

Warnings/Precautions: Discontinue if sensitization occurs. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Erythema, stinging, irritation.

How supplied: Crm-12g

Soln, lotion-10mL

ECONAZOLE

R

ECONAZOLE NITRATE CREAM 1% (various)

Azole antifungal. Econazole nitrate 1%; crm.

Indications: Tinea pedis, t. cruris, t. corporis, t. versicolor, cutaneous candidiasis.

Adults and Children: T. pedis, t. versicolor, t. cruris, t. corporis: apply once daily. Cutaneous candidiasis: twice daily. Continue for 4 weeks for t. pedis; others 2 weeks.

Warnings/Precautions: Discontinue if sensitization or excessive irritation occurs. Pregnancy (Cat.C; not recommended in 1st trimester, unless essential). Nursing mothers.

Adverse reactions: Burning, itching, erythema, stinging.

How supplied: Contact supplier.

HYDROCORTISONE + POLMYXIN B + NEOMYCIN

R

CORTISPORIN King

Steroid + antibiotics. Hydrocortisone acetate 0.5%, polymyxin B (as sulfate) 10000 Units/g, neomycin (as sulfate) 0.35%; crm.

Also: Hydrocortisone + Polymyxin B + Neomycin

CORTISPORIN OINTMENT

Hydrocortisone 1%, polymyxin B (as sulfate)

5000 Units/g, neomycin (as sulfate) 0.35%,

bacitracin (as zinc) 400 Units/g.

Indications: Short-term use in corticosteroid-responsive dermatoses with secondary infection.

Adults: Apply sparingly and massage in 2-4 times daily.

Children: Not recommended.

Contraindications: Do not use in eyes, external ear canal if eardrum perforated. Tuberculous, fungal, or viral lesions.

Warnings/Precautions: Intertrigo, diaper or stasis dermatitis or ulceration, extensive burns

(neomycin may be absorbed). Avoid prolonged use or on large areas. Use lowest effective dose. Monitor for HPA axis suppression; avoid abrupt cessation if used for chronic conditions. Discontinue if infection persists or worsens or if superinfection occurs. Occlusion: not recommended. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Local irritation, folliculitis, hypertrichosis, dermatitis, sensitization, ototoxicity, nephrotoxicity (if neomycin is significantly absorbed), HPA axis suppression (esp. in children), epidermal and dermal atrophy (esp. in thin-skinned or occluded areas).

How supplied: Crm-7.5g; Oint-½oz

KETOCONAZOLE

KETOCONAZOLE CREAM (various)

Azole antifungal. Ketoconazole 2%; contains sulfites.

Indications: Tinea corporis, t. cruris, t. versicolor, t. pedis, cutaneous candidiasis, seborrheic dermatitis.

Adults: Apply once daily to affected and adjacent area. Treat for at least 2 wks. T. pedis: treat for 6 wks. Seborrheic dermatitis: apply to affected area twice daily for 4 wks or until clinical clearing. Reevaluate if no improvement after full course of treatment.

Children: Not recommended.

Also: Ketoconazole

NIZORAL SHAMPOO Janssen
Ketoconazole 2%.

Indications: Tinea (pityriasis) versicolor.

Adults: Apply to damp skin of affected area and a wide margin surrounding area. Lather, leave in place for 5 minutes, rinse. One application should suffice.

Children: Not recommended.

Also: Ketoconazole

NIZORAL A-D SHAMPOO McNeil Cons & Specialty
Ketoconazole 1%.

Indications: Dandruff.

Adults: Wet hair. Lather, rinse, repeat. Use once every 3-4 days for up to 8 weeks, then as needed. Reevaluate if no improvement in 2-4 weeks.

Children: Not recommended.

Warnings/Precautions: Asthma (crm). Discontinue if sensitization occurs. Avoid eyes. Shampoo may interfere with permanent waving. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Cream: Irritation, pruritus, stinging, allergic reaction. Shampoo: changes in hair texture, scalp pustules, dry or oily scalp or hair, pruritus.

How supplied: Crm-contact supplier.
Shampoo-4oz; A-D Shampoo-4oz, 7oz

MUPIROICIN

BACTROBAN GlaxoSmithKline

Antibacterial. Mupirocin 2%; oint.

Indications: Impetigo due to *S. pyogenes* or *S. aureus*.

Adults and Children: Apply small amount 3 times daily. May cover with gauze dressing. Reevaluate if no response within 3-5 days.

Also: Mupirocin

BACTROBAN CREAM

Mupirocin (as calcium) 2%.

Indications: Secondarily-infected traumatic skin lesions (up to 10cm in length or 100cm² in area) due to susceptible strains of *S. aureus* or *S. pyogenes*.

Adults and Children: <3months: not recommended. ≥3months: Apply small amount 3 times daily for 10 days. May use gauze dressing. Reevaluate if no response in 3-5 days.

Also: Mupirocin

BACTROBAN NASAL

Mupirocin (as calcium) 2%; oint.

Indications: Eradication of nasal colonization of methicillin-resistant *S. aureus* (MRSA) in adult patients and healthcare workers in certain institutional settings during outbreaks of infections with MRSA (see literature).

Adults: Apply approximately 0.25g to inside of each nostril twice daily for 5 days. Spread ointment by repeatedly closing and releasing the nostrils for 1 minute after application.

Children: Not recommended.

Warnings/Precautions: Avoid eyes. Nasal use in high-risk patients: see literature regarding autoinfection. Discontinue if irritation or sensitization occurs. Prolonged use may result in superinfection. Pregnancy (Cat.B). Nursing mothers.

Interactions: Nasal: avoid other concomitant nasal products.

Adverse reactions: Topical: burning, stinging, pain, itching. Nasal: headache, rhinitis, respiratory disorder, pharyngitis, taste perversion, burning/stinging, cough, pruritus.

How supplied: Oint-22g; Crm-15g, 30g; Nasal (single-use) (1g)-10

NYSTATIN

NYSTATIN CREAM (various)

Polyene antifungal. Nystatin 100000Units/g.

Indications: Cutaneous or mucocutaneous candidiasis.

Adults and Children: Apply liberally twice daily.

Also: Nystatin

NYSTATIN POWDER

Nystatin 100000Units/g; in talc.

Indications: Candidiasis (esp. moist lesions).

Adults and Children: Apply 2-3 times daily, dust shoes and socks if feet are infected.

Warnings/Precautions: Discontinue if hypersensitivity occurs.

Adverse reactions: Irritation (rare).

How supplied: Contact supplier.

POLYMYXIN B + BACITRACIN

POLYSPORIN McNeil Cons & Specialty

Antibacterial. Polymyxin B sulfate 10000Units, bacitracin zinc 500Units; per gram; oint.

Also: Polymyxin B + Bacitracin

OTC

POLYSPORIN POWDER

Polymyxin B sulfate 10000Units, bacitracin zinc 500Units; per gram; powder.

Indications: Help prevent infection of minor cuts, scrapes, and burns.

Adults and Children: Apply 1–3 times daily.

Adverse reactions: Superinfection, allergic dermatitis (rare).

How supplied: Oint-½ oz, 1oz
Pw-10g

SILVER SULFADIAZINE

Rx

SILVADENE King

Sulfonamide antibacterial. Silver sulfadiazine 1%; cream.

Indications: Prophylaxis and treatment of sepsis in 2nd and 3rd degree burns.

Adults: Apply 1–2 times daily aseptically to approximately 1/16 inch depth to cleansed and debrided burns. Reapply promptly if removed. Continue until wound closed.

Children: Not established.

Contraindications: Premature infants. Within first 2 months of birth. Late pregnancy.

Warnings/Precautions: G6PD deficiency. Impaired renal or hepatic function. Monitor serum sulfa levels and renal function in extensive burns. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Leukopenia increased with concomitant cimetidine. May inactivate debriding enzymes.

Adverse reactions: Transient leukopenia, skin necrosis, erythema multiforme, skin discoloration, burning sensation, rash, pruritus, interstitial nephritis, reduction in bacterial growth; systemic sulfonamide reactions, fungal overgrowth.

How supplied: Crm-20g, 50g, 85g, 400g, 1000g

TRIAMCINOLONE + NYSTATIN

Rx

TRIAMCINOLONE + NYSTATIN (various)

Steroid + polyene antifungal. Triamcinolone acetate 0.1%, nystatin 100000Units/g; crm; oint.

Indications: Cutaneous candidiasis.

Adults and Children: Apply sparingly 2 times daily; max 25 days treatment.

Contraindications: Varicella, vaccinia.

Warnings/Precautions: Avoid prolonged use or on large areas. Use lowest effective dose (esp. in children). Do not occlude. Discontinue gradually in chronic use. Discontinue if superinfection or irritation occurs. Reevaluate if no improvement after 25 days. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Local irritation, folliculitis, hypertrichosis, dermatitis, sensitization, HPA axis suppression (esp. in children), epidermal and dermal atrophy (esp. in thin-skinned or occluded areas).

How supplied: Contact supplier.

3D Topical steroids**BETAMETHASONE**

Rx

DIPROLENE Merck

Betamethasone, augmented (as dipropionate) 0.05%; oint; lotion; gel.

Also: Betamethasone

Rx

DIPROLENE AF

Betamethasone, augmented (as dipropionate) 0.05%; emollient crm.

Indications: Corticosteroid-responsive dermatoses.

Adults: Apply thin film 1–2 times daily; max 45g/week (oint, AF) or 50g/week (gel). Lotion: apply a few drops 1–2 times daily; max 50mL/week; max 2 consecutive weeks' treatment per course (lotion, gel). Do not occlude or use in diaper area.

Children: Not recommended.

Contraindications: Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).

Warnings/Precautions: Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).

How supplied: Oint, gel, AF crm-15g, 50g
Lotion-30mL, 60mL

CLOBETASOL

Rx

TEMOVATE PharmaDerm

Clobetasol propionate 0.05%; crm; oint; gel; scalp application.

Indications: Corticosteroid-responsive dermatoses.

Adults: Apply thin layer twice daily (AM & PM); max 50 g/week or 50 mL/week and 2 consecutive weeks' treatment per course.

Children: Not recommended.

Also: Clobetasol**TEMOVATE-E EMOLLIENT**

Clobetasol propionate 0.05%; emollient crm.

Adults: Apply thin layer twice daily (AM & PM); max 50 g/week and 2 consecutive weeks' treatment per course. Moderate to severe plaque-type psoriasis: may use on 5–10% BSA for up to 4 consecutive weeks.**Children:** <16yrs: not recommended.**Contraindications:** Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).**Warnings/Precautions:** Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.**Adverse reactions:** Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).**How supplied:** Crm, oint-15g, 30g, 45g, 60g Gel, E crm-15g, 30g, 60g Scalp-25mL, 50mL**DESOXIMETASONE****TOPICORT** TaroPharma

Desoximetasone 0.25%; emollient crm; oint.

Also: Desoximetasone**TOPICORT-LP CREAM**

Desoximetasone 0.05%; emollient crm.

Also: Desoximetasone**TOPICORT GEL**

Desoximetasone 0.05%.

Indications: Corticosteroid-responsive dermatoses.**Adults:** Apply thin film twice daily.**Children:** Oint: <10yrs: not recommended; ≥10yrs: as adult. Cream or gel: as adult.**Contraindications:** Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).**Warnings/Precautions:** Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.**Adverse reactions:** Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).**How supplied:** Crm, LP crm, gel-15g, 60g Oint-60g**FLUCINONIDE****LIDEX** (various)

Fluocinonide 0.05%; crm; gel; oint; soln.

Also: Fluocinonide**LIDEX-E CREAM**

Fluocinonide 0.05%; emollient base.

Indications: Corticosteroid-responsive dermatoses.**Adults and Children:** Apply thin film 2–4 times daily.**Contraindications:** Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).**Warnings/Precautions:** Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are

flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).

How supplied: Contact supplier.

HALOBETASOL

ULTRAVATE Ranbaxy

Halobetasol propionate 0.05%; crm; oint.

Indications: Corticosteroid-responsive dermatoses.

Adults: Apply thin layer 1–2 times daily; max 50 g/week and 2 consecutive weeks' treatment per course.

Children: Not recommended.

Contraindications: Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).

Warnings/Precautions: Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).

How supplied: Crm, oint-15g, 45g
X-PAC crm, oint-50g (w. Lac-Hydrin Ten Plus Cream)

HYDROCORTISONE

HYDROCORTISONE (various)

Hydrocortisone 1%; crm; oint.

Also: Hydrocortisone

HYDROCORTISONE 2.5%

Hydrocortisone 2.5%; crm; oint, lot.

Indications: Corticosteroid-responsive dermatoses.

Adults and Children: Apply thin film 2–4 times daily.

Contraindications: Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).

Warnings/Precautions: Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).

How supplied: Contact supplier.

MOMETASONE FUROATE

ELOCON Merck

Mometasone furoate 0.1%; crm; oint.

Indications: Corticosteroid-responsive dermatoses.

Adults and Children: <2yrs: not recommended.

≥2yrs: apply thin film once daily; max 3 weeks' therapy for children.

Also: Mometasone furoate

ELOCON LOTION

Mometasone furoate 0.1%.

Adults: Apply thin film once daily.

Children: Not recommended.

Contraindications: Do not use superpotent forms on face, groin, or axillae. Exclude viral disease (eg, chickenpox, measles).

Warnings/Precautions: Treat infection if present; discontinue if infection persists or worsens. Do not use near eyes, or on diaper dermatitis or pre-existing skin atrophy. Do not use fluorinated steroids longer than 1 week on the face. Avoid abrupt cessation in chronic use. Systemic absorption increased by broken or inflamed skin, prolonged use, application to large surface area, or use of occlusive dressings. Occlude only if necessary; do not occlude higher potency products. Monitor adrenal function in children if a high potency product or occlusion is used, and in adults if more than 50g weekly of a high potency product is used. Discontinue or reduce dose or

potency if HPA axis suppression, Cushing's syndrome, hyperglycemia, glucosuria, or irritation occurs. Use lowest effective dose and potency (esp. in children). Use caution if applying to face or body folds. Do not use continuously or for prophylaxis. Foams are flammable. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Burning, stinging, pruritus, erythema, skin atrophy, striae, miliaria, secondary infections, hypopigmentation, folliculitis, hypertrichosis, acneiform eruptions, dermal cracking and fissuring, telangiectasia, contact dermatitis, other local effects, immunosuppression, masks infections, HPA axis suppression (esp. in children).

How supplied: Crm, oint-15g, 45g
Lotion-30mL, 60mL

SECTION 4: ENDOCRINE DISORDERS 4A Corticosteroid- responsive disorders

DEXAMETHASONE

DEXAMETHASONE (various)

Glucocorticoid. Dexamethasone 0.5mg, 0.75mg, 1mg, 1.5mg, 2mg, 4mg, 6mg; scored tabs.

Indications: Steroid-responsive disorders.

Adults and Children: See literature. Initially 0.75-9mg daily.

Contraindications: Systemic fungal infection. Live vaccination. Ocular herpes simplex. Cerebral malaria.

Warnings/Precautions: Asthma (inj).

Strongyloides infestation. Varicella. Vaccinia. Recent MI. Tuberculosis. Latent amebiasis. Hypothyroidism. Cirrhosis. If exposed to chickenpox or measles, consider prophylactic passive immune therapy. Renal insufficiency. Ulcerative colitis. Intestinal anastomoses. Diverticulitis. Peptic ulcer. CHF. Hypertension. Osteoporosis. Diabetes. Myasthenia gravis. Hypoprothrombinemia. Supplement with additional steroids in physiologic stress. Avoid abrupt cessation. Monitor weight, growth, fluid and electrolyte balance. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by CYP3A4 inhibitors (eg, ketoconazole, macrolides), cyclosporine, estrogens. Antagonized by CYP3A4 inducers (eg, barbiturates, phenytoin, carbamazepine, rifampin), ephedrine. May potentiate cyclosporine. May antagonize anticoagulants (monitor), isoniazid, other CYP3A4 substrates (eg, indinavir, erythromycin). Increased risk of arrhythmias with digitalis. May need to adjust dose of antidiabetic agents. Increased GI effects with aspirin. Monitor for hypokalemia with potassium-depleting drugs (eg, amphotericin B, diuretics). Toxic epidermal necrolysis possible with thalidomide. Concomitant indomethacin: may get false-negative

on dexamethasone suppression test. May suppress reactions to skin tests.

Adverse reactions: HPA axis suppression, masks infection, increased susceptibility to infection, glaucoma, cataracts, secondary infections, hypokalemia, hypocalcemia, hyponatremia, hypertension, psychic disorders, myopathy, osteoporosis, peptic ulcer, dermal atrophy, increased intracranial pressure, carbohydrate intolerance, inj site reactions.

How supplied: Contact supplier.

DEXAMETHASONE

Rx

DEXAMETHASONE INJECTION (various)

Glucocorticoid. Dexamethasone phosphate (as sodium); 4mg/mL, 10mg/mL; for IV inj; contains sulfites.

Indications: Steroid-responsive disorders when oral therapy not feasible.

Adults and Children: See literature. Initially usually 0.5-9mg daily IV.

Contraindications: Systemic fungal infection. Live vaccination. Ocular herpes simplex. Cerebral malaria.

Warnings/Precautions: Asthma (inj).

Strongyloides infestation. Varicella. Vaccinia. Recent MI. Tuberculosis. Latent amebiasis. Hypothyroidism. Cirrhosis. If exposed to chickenpox or measles, consider prophylactic passive immune therapy. Renal insufficiency. Ulcerative colitis. Intestinal anastomoses. Diverticulitis. Peptic ulcer. CHF. Hypertension. Osteoporosis. Diabetes. Myasthenia gravis. Hypoprothrombinemia. Supplement with additional steroids in physiologic stress. Avoid abrupt cessation. Monitor weight, growth, fluid and electrolyte balance. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by CYP3A4 inhibitors (eg, ketoconazole, macrolides), cyclosporine, estrogens. Antagonized by CYP3A4 inducers (eg, barbiturates, phenytoin, carbamazepine, rifampin), ephedrine. May potentiate cyclosporine. May antagonize anticoagulants (monitor), isoniazid, other CYP3A4 substrates (eg, indinavir, erythromycin). Increased risk of arrhythmias with digitalis. May need to adjust dose of antidiabetic agents. Increased GI effects with aspirin. Monitor for hypokalemia with potassium-depleting drugs (eg, amphotericin B, diuretics). Toxic epidermal necrolysis possible with thalidomide. Concomitant indomethacin: may get false-negative on dexamethasone suppression test. May suppress reactions to skin tests.

Adverse reactions: HPA axis suppression, masks infection, increased susceptibility to infection, glaucoma, cataracts, secondary infections, hypokalemia, hypocalcemia, hyponatremia, hypertension, psychic disorders, myopathy, osteoporosis, peptic ulcer, dermal atrophy, increased intracranial pressure, carbohydrate intolerance, inj site reactions.

How supplied: Contact supplier.

HYDROCORTISONE

CORTEF Pfizer

Glucocorticoid. Hydrocortisone 5mg, 10mg, 20mg; tabs.

Indications: Steroid-responsive disorders.

Also: Hydrocortisone

SOLU-CORTEF INJECTION

Hydrocortisone (as sodium succinate) 100mg, 250mg, 500mg, 1g; for IV or IM inj.

Indications: Steroid-responsive disorders when oral therapy not feasible.

Adults: See literature. Oral: initially 20–240mg daily. Parenteral: initially 100–500mg.

Children: See literature. Oral: in single or divided doses. Replacement: 0.56mg/kg per day. Other indications: 2–8mg/kg per day. Parenteral: not less than 25mg daily.

Contraindications: Systemic mycoses. Live vaccination. Premature infants (inj).

Warnings/Precautions: Tuberculosis. Latent amebiasis. Hypothyroidism. Cirrhosis. Ocular herpes simplex. If exposed to chickenpox or measles, consider prophylactic passive immune therapy. Renal insufficiency. Ulcerative colitis if perforation pending. Diverticulitis. Peptic ulcer. Hypertension. Osteoporosis. Diabetes. Supplement with additional steroids in physiologic stress. Avoid abrupt cessation. Alternate, intermittent or single-daily doses at 8AM minimize adrenal suppression. Monitor weight, growth, fluid and electrolyte balance. Pregnancy (Cat.C). Nursing mothers.

Interactions: Barbiturates, hydantoins, rifampin may decrease effects. Avoid aspirin in hypoprothrombinemia.

Adverse reactions: HPA axis suppression, masks infection, increased susceptibility to infection, glaucoma, cataracts, secondary infections, hypokalemia, hypocalcemia, hypernatremia, hypertension, psychic disorders, myopathy, osteoporosis, peptic ulcer, dermal atrophy, increased intracranial pressure, carbohydrate intolerance.

How supplied: Tabs 5mg–50; 10mg, 20mg–100; Solu-Cortef 100mg (2mL)–1, 25; 250mg (2mL)–1, 25; 500mg (4mL), 1g (8mL)–1

METHYLPREDNISOLONE

MEDROL Pfizer

Glucocorticoid. Methylprednisolone 8mg, 16mg, 32mg; scored tabs.

Also: Methylprednisolone

MEDROL DOSEPAK

Methylprednisolone 4mg; unit-of-use 21 scored tabs.

Indications: Steroid-responsive disorders.

Adults and Children: See literature. 4–48mg daily.

Also: Methylprednisolone

DEPO-MEDROL

Methylprednisolone acetate 20mg/mL, 40mg/mL, 80mg/mL; susp for IM or local inj; contains benzyl alcohol.

Indications: Steroid-responsive disorders when oral therapy not feasible. Local inflammation.

Adults and Children: See literature. 40–120mg IM/week for 1–4 weeks. Locally: 4–80mg.

Also: Methylprednisolone

SOLU-MEDROL

Methylprednisolone (as sodium succinate) 40mg, 125mg, 500mg, 1g; pld for IV or IM inj; contains benzyl alcohol except 500mg, 1g multi-dose vials.

Indications: Steroid-responsive disorders where oral therapy not feasible.

Adults: Initially 10–40mg IV; subsequent doses IV or IM.

Children: Infants: not recommended. Others: 0.5mg/kg per day or more IV or IM.

Contraindications: Systemic fungal infections.

Live vaccines. Depo-Medrol: also premature infants, intrathecal administration. Solu-Medrol: also premature infants.

Warnings/Precautions: Tuberculosis. Latent amebiasis. *Strongyloides* infestation.

Hypothyroidism. Ocular herpes simplex. Cirrhosis.

Renal insufficiency. If exposed to chickenpox or measles, consider prophylactic passive immune therapy.

Ulcerative colitis if perforation pending. Peptic ulcer. Diverticulitis. Intestinal anastomoses.

Myasthenia gravis. Hypertension. Osteoporosis.

Diabetes. Kaposi's sarcoma. Supplement with additional steroids in physiologic stress. Avoid abrupt cessation. May increase risk and mask signs of infection. May cause electrolyte imbalances, adrenocortical insufficiency, psychotic derangements. Alternate, intermittent, or single-daily doses at 8AM minimize adrenal suppression. Use lowest effective dose. Monitor weight, growth, fluid and electrolyte balance. Intravenous: avoid previously infected or unstable joints. Pregnancy. Nursing mothers.

Interactions: Potentiated by CYP3A4 inhibitors (eg, troleandomycin, ketoconazole). Antagonized by CYP3A4 inducers (eg, barbiturates, phenytoin, rifampin). Avoid cyclosporine and aspirin in hypoprothrombinemia. May antagonize anticoagulants (monitor). May need to adjust dose of antidiabetic agents.

Adverse reactions: HPA axis suppression, increased susceptibility to infection, glaucoma, cataracts, secondary infections, hypokalemia, hypocalcemia, hypernatremia, hypertension, CHF, psychic disorders, myopathy, osteoporosis, peptic ulcer, dermal atrophy, increased intracranial pressure, carbohydrate intolerance.

Parenteral: atrophy, flare at site; intravenous: septic arthritis.

How supplied: Tabs 2mg–100; 8mg, 32mg–25; 16mg–50; Dosepak–21; Depo-Medrol 20mg/mL (5mL)–1; 40mg/mL (5mL, 10mL)–1, 25; 80mg/mL (5mL)–1, 25; Solu-Medrol single-dose vial 40mg (1mL)–1, 25; 125mg (2mL)–25; 500mg (4mL), 1g (8mL)–1; Multi-dose vial 500mg (8mL), 1g (16mL)–1

PREDNISONE**PREDNISONE** (various)*Glucocorticoid.* Prednisone 1mg, 2.5mg, 5mg, 10mg, 20mg, 50mg; scored tabs.**Indications:** Corticosteroid-responsive disorders.**Adults and Children:** See literature. Initially 5–60mg daily.**Contraindications:** Systemic fungal infections. Live vaccines.**Warnings/Precautions:** Tuberculosis. Latent amebiasis. *Strongyloides* infestation. Hypothyroidism. Ocular herpes simplex. Cirrhosis. Renal insufficiency. If exposed to chickenpox or measles, consider prophylactic passive immune therapy. Ulcerative colitis if perforation pending. Peptic ulcer. Diverticulitis. Intestinal anastomoses. Myasthenia gravis. Hypertension. Osteoporosis. Diabetes. Kaposi's sarcoma. Supplement with additional steroids in physiologic stress. Avoid abrupt cessation. May increase risk and mask signs of infection. May cause electrolyte imbalances, adrenocortical insufficiency, psychotic derangements. Alternate, intermittent, or single-daily doses at 8AM minimize adrenal suppression. Use lowest effective dose. Monitor weight, growth, fluid and electrolyte balance. Pregnancy. Nursing mothers.**Interactions:** Barbiturates, hydantoins, rifampin, other hepatic enzyme inducers may decrease effects. Potentiated by ketoconazole, troleandomycin. Excretion of high-dose aspirin increased. Caution with diuretics, digoxin, aspirin in hypoprothrombinemia. Potentiated by oral contraceptives. Monitor oral anticoagulants.**Adverse reactions:** HPA axis suppression, increased susceptibility to infection, glaucoma, cataracts, secondary infections, hypokalemia, hypocalcemia, hypernatremia, hypertension, CHF, psychic disorders, myopathy, osteoporosis, peptic ulcer, dermal atrophy, increased intracranial pressure, carbohydrate intolerance.**How supplied:** Contact supplier.

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History of angioedema with other DPP-4 inhibitors. Discontinue if serious hypersensitivity reaction is suspected. Hepatic impairment. Obtain liver function tests before starting therapy; interrupt and evaluate if liver enzymes elevated or abnormal tests persist; do not restart if liver injury is confirmed and no other etiology can be found. Monitor renal function prior to therapy and periodically thereafter. Pregnancy (Cat.B). Nursing mothers.

Interactions: Concomitant sulfonylurea or insulin: may need lower dose of sulfonylurea or insulin to reduce risk of hypoglycemia.**Adverse reactions:** Nasopharyngitis, headache, upper respiratory tract infection.**How supplied:** 6.25mg–30, 90; 12.5mg, 25mg–30, 90, 500**ALOGLIPTIN + METFORMIN**

R

KAZANO Takeda*Dipeptidyl peptidase-4 (DPP-4) inhibitor + biguanide.*

Alogliptin, metformin (as HCl); 12.5mg/500mg, 12.5mg/1000mg; tabs.

Indications: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and metformin is appropriate. Limitations of use: not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.**Adults:** Individualize. Swallow whole; do not split tabs. Take twice daily with food; increase dose gradually to reduce GI effects. Max 25mg alogliptin/2000mg metformin per day.**Children:** Not established.**Contraindications:** Renal impairment (Scr ≥ 1.5 mg/dL [men], ≥ 1.4 mg/dL [women] or abnormal CrCl). Metabolic acidosis. Diabetic ketoacidosis.**Warnings/Precautions:** Confirm normal renal function before starting; monitor (esp. in elderly). Discontinue if lactic acidosis, ketoacidosis, renal impairment, shock, acute MI, acute CHF, hypoxemia, dehydration, sepsis, pancreatitis, or hypersensitivity reactions occur. Temporarily suspend during surgery; may restart when oral intake is resumed and renal function normalized. History of angioedema with other DPP-4 inhibitors. Obtain LFTs before starting therapy. Avoid if clinical or lab evidence of hepatic disease. Monitor hematology (esp. serum Vit. B₁₂ in susceptible patients). Elderly, debilitated, malnourished, adrenal or pituitary insufficiency, or alcohol intoxication: increased risk of hypoglycemia. Concomitant intravascular iodinated contrast agents (suspend during and for 48hrs after procedure). Pregnancy (Cat.B). Nursing mothers.**Interactions:** Cationic drugs eliminated by renal tubular secretion (eg, amiloride, digoxin, morphine, procainamide, quinidine, ranitidine, triamterene, trimethoprim, vancomycin), cimetidine: may increase metformin levels. Avoid excessive alcohol intake (potentiates effects of metformin on lactate). Caution with concomitant topiramate, or

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4B Diabetes**ALOGLIPTIN****NESINA** Takeda*Dipeptidyl peptidase-4 (DPP-4) inhibitor.* Alogliptin 6.25mg, 12.5mg, 25mg; tabs.**Indications:** As adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: not for treatment of type 1 diabetes or diabetic ketoacidosis.**Adults:** 25mg once daily. Renal impairment: moderate (CrCl ≥ 30 – <60 mL/min): 12.5mg once daily; severe (CrCl ≥ 15 – <30 mL/min) or ESRD (CrCl <15 mL/min or need hemodialysis): 6.25mg once daily.**Children:** Not established.**Warnings/Precautions:** Monitor for signs/symptoms of pancreatitis; discontinue if suspected.

other carbonic anhydrase inhibitors (eg, zonisamide, acetazolamide, dichlorophenamide); may induce metabolic acidosis. Diuretics, steroids, estrogens, oral contraceptives, phenothiazines, phenytoin, thyroid products, nicotinic acid, sympathomimetics, calcium channel blockers, isoniazid, others that may cause hyperglycemia. Concomitant sulfonylurea or insulin: may need lower dose of sulfonylurea or insulin to reduce risk of hypoglycemia. β -blockers may mask hypoglycemia.

Adverse reactions: Upper respiratory tract infection, nasopharyngitis, diarrhea, hypertension, headache, back pain, UTI.

How supplied: Tabs-60, 180, 500

ALOGLIPTIN + PIOGLITAZONE R

OSEN Takeda

Dipeptidyl peptidase-4 (DPP-4) inhibitor + thiazolidinedione. Alogliptin, pioglitazone; 12.5mg/15mg, 12.5mg/30mg, 12.5mg/45mg, 25mg/15mg, 25mg/30mg, 25mg/45mg; tabs.

Indications: As adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and pioglitazone is appropriate. Limitations of use: not for treatment of type 1 diabetes or diabetic ketoacidosis.

Adults: Swallow whole; do not split tabs. Take once daily with or without food. Inadequately controlled on diet/exercise, or on metformin or alogliptin monotherapy: initially 25mg/15mg or 25mg/30mg daily. Previously on pioglitazone alone: initially 25mg/15mg, 25mg/30mg, or 25mg/45mg daily. Switching from alogliptin with pioglitazone: start at dose based on current therapy. NYHA Class I or II HF: initially 25mg/15mg. All: max 25mg/45mg daily. Renal impairment: moderate (CrCl ≥ 30 –<60mL/min): 12.5mg/15mg, 12.5mg/30mg, or 12.5mg/45mg daily; severe or ESRD: not recommended. Concomitant gemfibrozil or other strong CYP2C8 inhibitors: max pioglitazone 15mg daily.

Children: Not recommended.

Contraindications: NYHA Class III or IV heart failure.

Warnings/Precautions: Symptomatic HF: not recommended. Risk of CHF; monitor after initiation and dose increases; consider discontinuation or reduce pioglitazone dose if occurs. Monitor for pancreatitis or serious hypersensitivity reaction; discontinue if suspected. History of angioedema with other DPP-4 inhibitors. Renal impairment; monitor prior to starting therapy and periodically thereafter. Hepatic impairment; obtain LFTs before starting therapy; interrupt and evaluate if liver enzymes elevated; do not restart if liver injury is confirmed and no other etiology can be found. Active bladder cancer: do not use. Do regular eye exams. Resumption of premenopausal ovulation in anovulatory women may occur (may result in unintended pregnancy). Pregnancy (Cat.C); use adequate contraception. Nursing mothers: not recommended.

Interactions: Concomitant insulin may cause fluid retention. Potentiated by strong CYP2C8 inhibitors (eg, gemfibrozil). Antagonized by CYP2C8 inducers (eg, rifampin). Concomitant sulfonylurea or insulin: may need lower dose of sulfonylurea or insulin to reduce risk of hypoglycemia.

Adverse reactions: Nasopharyngitis, back pain, upper respiratory tract infection; edema, fractures (esp. females), macular edema.

How supplied: Tabs-30, 90, 500

CANAGLIFLOZIN R

INVOKANA Janssen

Sodium-glucose co-transporter 2 (SGLT2) inhibitor. Canagliflozin 100mg, 300mg; tablets.

Indications: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of use: not for treating type 1 diabetes or diabetic ketoacidosis.

Adults: See full labeling. Take before first meal of the day. Initially 100mg once daily; if tolerated and with eGFR ≥ 60 mL/min/1.73m², and need additional glycemic control; may increase to 300mg once daily. Moderate renal impairment (eGFR 45–<60mL/min/1.73m²): 100mg once daily; if eGFR <45mL/min/1.73m²: do not initiate. Concomitant UGT inducers in patients with eGFR ≥ 60 mL/min/1.73m²: consider increase to 300mg once daily; if eGFR 45–<60mL/min/1.73m²: consider other antihyperglycemics.

Children: <18yrs: not established.

Contraindications: Severe renal impairment (eGFR <30mL/min/1.73m²), ESRD, or patients on dialysis.

Warnings/Precautions: Correct volume depletion before starting therapy. Monitor for symptomatic hypotension in patients with renal impairment (eGFR <30mL/min/1.73m²), elderly, low systolic BP, concomitant diuretics or drugs that interfere with the renin-angiotensin-aldosterone system (eg, ACEIs, ARBs). Monitor renal function before and during therapy; more frequently if eGFR <60mL/min/1.73m². Monitor K⁺ levels in patients with renal impairment and predisposed to hyperkalemia. Risk of genital mycotic infections; monitor and treat. Monitor LDL levels and treat per standard of care. Severe hepatic impairment: not recommended. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Antagonized by UGT inducers (eg, rifampin, phenytoin, phenobarbital, ritonavir); see Adults dose. Concomitant digoxin: monitor. Concomitant insulin or insulin secretagogue: consider a lower dose of insulin/insulin secretagogue to reduce risk of hypoglycemia.

Adverse reactions: Female genital mycotic infections, urinary tract infection, increased urination; hypersensitivity reactions (discontinue if occurs).

How supplied: Tabs-30, 90, (10×10 blister cards), 500

CAPTOPRIL**CAPOTEN** Par

ACE inhibitor. Captopril 12.5mg, 25mg, 50mg, 100mg; scored tabs.

Indications: Diabetic nephropathy (proteinuria >500mg/day) in type 1 diabetes with retinopathy.**Adults:** Take 1 hr before meals. 25mg 3 times daily. Renal impairment: see literature.**Children: Not recommended.****Contraindications:** History of ACEI-associated or other angioedema.**Warnings/Precautions:** Fetal toxicity may develop: discontinue if pregnancy is detected. Renal impairment. Salt/volume depletion. Dialysis (esp. high-flux membrane). CHF. Aortic stenosis. Monitor WBCs and renal function in renal and collagen vascular disease. Monitor for hyperkalemia in diabetics, blood pressure and renal insufficiency. Surgery. Discontinue if neutropenia, agranulocytosis, angioedema or laryngeal edema occurs. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.**Interactions:** Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or alkirens may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant alkirens in diabetics or renal impairment (CrCl <60mL/min); not recommended. Caution with K⁺-sparing diuretics, K⁺-containing supplements and K⁺-containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs (including COX-2 inhibitors); monitor renal function in elderly and/or volume depleted. Potentiated by diuretics, β -blockers, adrenergic antagonists. Discontinue nitroglycerin, other nitrates, or other vasodilators before starting therapy; if resumed, reduce dose and give cautiously. May increase lithium levels. May produce false (+) urinary acetone. Nitroide reactions with injectable gold (sodium aurothiomalate).**Adverse reactions:** Hypotension, headache, dysgeusia, rash, pruritus, dizziness, fatigue, cough, proteinuria, nephritis, GI upset, hyperkalemia, hyponatremia, tachycardia, dry mouth, jaundice, somnolence, impotence, angioedema.**How supplied:** Tabs 25mg, 50mg-100, 1000; 12.5mg, 100mg-100**COLESEVELAM****WELCHOL** Daiichi Sankyo

Bile acid sequestrant. Colesevelam HCl 625mg; tabs.

Also: Colesevelam**WELCHOL FOR ORAL SUSPENSION**

Colesevelam HCl 3.75g; pwd pkts; citrus flavored; contains phenylalanine 48mg/3.75g pkt.

Indications: Adjunct to diet and exercise in type 2 diabetes in combination with metformin, sulfonylureas, or insulin.**Adults:** Take with a meal and liquid. 3 tabs twice daily or 6 tabs once daily. Susp: one 3.75g pkt once

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daily. Empty contents into a glass or cup, add 4-8oz of water, fruit juice, or diet soft drinks; stir and drink. Do not take susp in its dry form.

Children: Not recommended.**Contraindications:** History of bowel obstruction. Serum TG >500mg/dL. History of hypertriglyceridemia-induced pancreatitis.**Warnings/Precautions:** Not for treating type 1 diabetes or diabetic ketoacidosis. TG levels >300mg/dL. Monitor lipids, TG, and non-HDL-C levels prior to therapy and periodically thereafter. Susceptibility to Vit. A, D, E, or K deficiencies. Risk of bowel obstruction (eg, gastroparesis, other GI motility disorders, or a history of major GI surgery). Dysphagia or swallowing disorders (esp. w/tab form). Pregnancy (Cat.B). Nursing mothers.**Interactions:** Monitor drugs with a narrow therapeutic index, glyburide, levothyroxine, oral contraceptives containing ethinyl estradiol and norethindrone, phenytoin, warfarin; give at least 4 hours prior to colesvelam. May potentiate metformin extended-release.**Adverse reactions:** Constipation, dyspepsia, nausea, dysphagia.**How supplied:** Tabs-180; Susp 3.75g-30 (single-dose pkt)**EXENATIDE**

R

BYDUREON Amylin

GLP-1 receptor antagonist. Exenatide ext-rel 2mg; pwd for SC inj after reconstitution.

Indications: As adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes. Not for first-line therapy in patients inadequately controlled on diet and exercise.**Adults:** Give by SC inj in abdomen, thigh, or upper arm. Inject immediately after mixing. 2mg once every 7 days (weekly). Changing from Byetta: discontinue, then start Bydureon.**Children: Not recommended.****Contraindications:** History (personal or family) of medullary thyroid carcinoma. Multiple endocrine neoplasia syndrome type 2.**Warnings/Precautions:** Not a substitute for insulin. Not for treating type 1 diabetes or diabetic ketoacidosis. Risk of thyroid C-cell tumors possible. History of pancreatitis; consider other antidiabetics.

Monitor for pancreatitis; if suspected, promptly discontinue; if confirmed, do not restart. Severe GI disorders, renal impairment (CrCl <30mL/min), end-stage renal disease: not recommended. Renal transplantation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concurrent insulin: not recommended. Increased risk of hypoglycemia with concomitant sulfonylurea, insulin, or other insulin secretagogues (eg, meglitinides); consider reducing dose of these. May delay absorption of oral drugs. Monitor warfarin.**Adverse reactions:** GI upset, constipation, headache, injection site reactions; possible antibody

formation (glycemic response may be attenuated), pancreatitis (may be fatal), hypersensitivity reactions.
How supplied: Single-dose trays—4 (each contains 1 vial, 1 prefilled syringe with diluent, vial connector and needles)

EXENATIDE

R

BYETTA Amylin and Lilly
Incretin mimetic. Exenatide 250mcg/mL; soln for SC inj; contains m-cresol and mannitol.

Indications: Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Adults: Give by SC inj into thigh, abdomen, or upper arm within 60 minutes before AM and PM meals (or before the 2 main meals of the day, approx. ≥ 6 hrs apart). Initially 5mcg twice daily; may increase to 10mcg twice daily after 1 month. Moderate renal impairment (CrCl 30–50mL/min): caution when initiating or escalating doses from 5mcg to 10mcg.

Children: Not recommended.

Warnings/Precautions: Not a substitute for insulin. Not for treating type 1 diabetes or diabetic ketoacidosis. History of pancreatitis; consider other antidiabetic therapies. Monitor for pancreatitis; if suspected, promptly discontinue; if confirmed, do not restart. Severe GI disorders, renal impairment (CrCl < 30 mL/min), end-stage renal disease: not recommended. Renal transplantation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concurrent prandial insulin: not recommended. Increased risk of hypoglycemia with concomitant sulfonylurea, insulin, or other insulin secretagogues (eg, meglitinides); consider reducing dose of these. May delay absorption of oral drugs (take these 1 hour before exenatide). Monitor warfarin.

Adverse reactions: GI upset, hypoglycemia, feeling jittery, dizziness, headache, dyspepsia, constipation, asthenia, reduced appetite, GERD, hyperhidrosis; antibody formation (glycemic response may be attenuated), pancreatitis (may be fatal), hypersensitivity reactions.

How supplied: Prefilled pen (needles not included): 5mcg/dose–1 (60 doses); 10mcg/dose–1 (60 doses)

GLIMEPIRIDE

R

AMARYL Sanofi Aventis
Sulfonylurea. Glimepiride 1mg, 2mg, 4mg; scored tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, alone or in combination with metformin. Secondary failure in combination with insulin.

Adults: Initially 1–2mg once daily with breakfast or first main meal; after reaching a dose of 2mg increase by up to 2mg at 1–2 week intervals if needed. Usual maintenance: 1–4mg once daily; max 8mg/day. Prior sensitivity to hypoglycemic agents or impaired renal function: initially 1mg once daily, titrate carefully. Secondary failure: initiate combination therapy for fasting blood glucose levels > 150 mg/dL.

Use 8mg glimepiride once daily with first main meal and titrate with low-dose insulin as needed.

Children: Not recommended.

Contraindications: Ketoacidosis.

Warnings/Precautions: Impaired renal or hepatic function. Adrenal or pituitary insufficiency. Stress. Secondary failure may occur with extended therapy. Discontinue if skin reactions persist. Elderly. Debilitated. Malnourished. Pregnancy (Cat.C): consider using insulin instead. Nursing mothers: not recommended.

Interactions: May be potentiated by alcohol, NSAIDs, highly protein bound drugs, miconazole, salicylates, sulfonamides, warfarin, chloramphenicol, probenecid, MAOIs, β -blockers. May be antagonized by diuretics, corticosteroids, phenothiazines, thyroid products, phenytoin, niacin, sympathomimetics, isoniazid, estrogens, oral contraceptives.

Disulfiram reactions have been reported with other sulfonylureas. Monitor for 1–2 weeks if transferring from long-acting sulfonylureas. Monitor for hypoglycemia if used with insulin or metformin.

Adverse reactions: Increased risk of cardiovascular mortality. Hypoglycemia, dizziness, asthenia, headache, nausea, allergic skin reactions, blood dyscrasias.

How supplied: Tabs—100

GLIPIZIDE

R

GLUCOTROL XL Pfizer
Sulfonylurea (2nd generation). Glipizide 2.5mg, 5mg, 10mg; ext-rel tabs.

Indications: Adjunct to diet in type 2 diabetes.

Adults: Do not crush, chew or divide. Initially 5mg with breakfast. Usual range: 5–10mg once daily; max 20mg daily.

Children: Not recommended.

Also: **Glipizide**
GLUCOTROL

R

Glipizide 5mg, 10mg; scored tabs.

Adults: Initially 5mg before breakfast. Elderly or debilitated: initially 2.5mg daily. Increase only if needed per blood glucose by 2.5–5mg every few days. Max 15mg once daily dose. Max 40mg daily in divided doses $\frac{1}{2}$ hour before meals.

Children: Not recommended.

Contraindications: Ketoacidosis.

Warnings/Precautions: Impaired renal or hepatic function. Adrenal or pituitary insufficiency. Stress. Secondary failure may occur with prolonged therapy. Monitor urine and blood glucose. Impaired GI function or GI narrowing (XL). Discontinue if jaundice or persistent rash occurs. Malnourished. Elderly. Debilitated. Pregnancy (Cat.C): consider using insulin instead. Nursing mothers: not recommended.

Interactions: Potentiated by NSAIDs, alcohol, highly protein bound drugs, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, MAOIs, β -blockers, possibly miconazole. Antagonized by diuretics, steroids, phenothiazines, phenytoin, niacin,

sympathomimetics, calcium channel blockers, isoniazid, others. Disulfiram-like reaction with alcohol (rare).

Adverse reactions: Increased risk of cardiovascular mortality. Hypoglycemia, cholestatic jaundice, GI disturbances, tremor, allergic skin reactions, photosensitivity, blood dyscrasias, hepatic porphyria, transient dizziness, drowsiness, headache.

How supplied: XL tabs 2.5mg–30; XL tabs 5mg, 10mg–100, 500; Tabs–100, 500

GLIPIZIDE + METFORMIN R

GLIPIZIDE/METFORMIN HCl TABLETS (various)
Sulfonylurea (2nd generation) + biguanide. Glipizide, metformin HCl; 2.5mg/250mg, 2.5mg/500mg, 5mg/500mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as initial therapy or as second-line therapy when response to a sulfonylurea or metformin is inadequate.

Adults: Take with meals. First-line: initially 2.5mg/250mg once daily; or, if fasting plasma glucose is 280–320mg/dL, may start at 2.5mg/500mg twice daily. May increase by 1 tab/day every 2 weeks; max 10mg/1000mg or 10mg/2000mg per day in divided doses. Second-line: (previously treated with sulfonylurea or metformin only): 2.5mg/500mg or 5mg/500mg twice daily (AM & PM) (initial dose should not exceed previous daily doses of individual components); may increase by increments of ≤5mg/500mg up to minimum effective dose or max 20mg/2000mg per day. Previously treated with combination therapy (sulfonylurea plus metformin): may be switched to 2.5mg/500mg or 5mg/500mg (initial dose should not exceed previous daily doses of individual components). Elderly: avoid max doses.

Children: Not recommended.

Contraindications: Renal disease or dysfunction. Metabolic acidosis, diabetic ketoacidosis. Concomitant intravascular iodinated contrast agents (suspend during and for 48 hours).

Warnings/Precautions: Increased risk of cardiovascular mortality. Confirm normal renal function before starting therapy (esp. in patients ≥80 years); monitor renal and hepatic function. Discontinue if lactic acidosis, shock, acute MI, acute CHF, stroke, sepsis, hypoxemia, or dehydration occurs. G6PD deficiency. Avoid in hepatic disease. Suspend before surgery that requires fasting. Monitor blood (esp. Vit. B₁₂ in susceptible patients). Stress. Elderly, debilitated, uncompensated strenuous exercise, malnourished or deficient caloric intake, adrenal or pituitary insufficiency, alcohol intoxication increases hypoglycemia risk. Pregnancy (Cat.C), nursing mothers: not recommended, consider using insulin instead.

Interactions: Cationic drugs eliminated by renal tubular secretion (eg, amiloride, cimetidine, digoxin, morphine, procainamide, quinidine, quinine, trimethoprim, ranitidine, triamterene, vancomycin), furosemide, nifedipine: may increase metformin levels. Glipizide potentiated by NSAIDs, highly

protein-bound drugs, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, MAOIs, β-blockers, azole antifungals. Excess alcohol potentiates metformin's effect on lactate. Diuretics, steroids, phenytoin, phenothiazines, nicotinic acid, sympathomimetics, calcium channel blockers, isoniazid, others may cause hyperglycemia. β-blockers may mask hypoglycemia.

Adverse reactions: Lactic acidosis (rare, ½ the cases are fatal), GI upset, abdominal pain, upper respiratory infection, headache, dizziness, hypertension, musculoskeletal pain, hypoglycemia. Oral hypoglycemic agents may increase cardiovascular mortality risk.

How supplied: Contact supplier.

GLUCAGON R

GLUCAGON Novo Nordisk
Antihypoglycemic. Glucagon (as HCl) (recombinant) 1mg; pwd for SC, IV, or IM inj after reconstitution.

Indications: Severe hypoglycemic episodes in diabetics treated with insulin.

Adults and Children: May give IV, IM, or SC. Hypoglycemia: <8yrs (<55 lbs): 0.5mg. >6yrs (>55 lbs): 1mg. Repeat if needed.

Contraindications: Pheochromocytoma. Insulinoma.

Warnings/Precautions: Instruct caregivers in proper use. If ineffective, give IV glucose. Give oral carbohydrates after treatment. Insufficient hepatic glycogen reserves (eg, prolonged fasting, starvation, adrenal insufficiency, chronic hypoglycemia). As a diagnostic aid in diabetes or elderly with cardiac disease. Pregnancy (Cat.B). Nursing mothers.

Interactions: β-blockers potentiate cardiac effects. Potentiates anticholinergics.

Adverse reactions: GI upset, tachycardia, transient increase in blood pressure, allergic reactions.

How supplied: HypoKit–1 (w. syringe + diluent) Vials–10

GLUCAGON R

GLUCAGON Lilly
Antihypoglycemic. Glucagon (recombinant) 1mg/mL; pwd for IM, IV, or SC inj after reconstitution.

Indications: Acute hypoglycemia.

Adults and Children: <20kg: 0.5mg or 20–30micrograms/kg. ≥20kg: 1mg. If patient does not respond in 15 minutes, may give 1–2 more doses.

Contraindications: Pheochromocytoma.

Warnings/Precautions: If ineffective, IV dextrose must be given. When patient responds, supplemental carbohydrate should be given (esp. children).

Type 1 diabetics may be less responsive. History of insulinoma or pheochromocytoma. Insufficient glycogen stores (eg, starvation, adrenal insufficiency, chronic hypoglycemia). Monitor serum potassium. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: GI upset, hypersensitivity reactions (urticaria, respiratory distress, hypotension).

How supplied: Emergency kit (1mg)–1 (w. diluent)

GLYBURIDE**DIABETA** Sanofi AventisSulfonylurea (2nd generation). Glyburide 1.25mg, 2.5mg, 5mg; scored tabs.**Indications:** Adjunct to diet in type 2 diabetes.**Adults:** Initially 2.5–5mg daily with breakfast.

Elderly or debilitated: initially 1.25mg daily. Increase by 2.5mg at weekly intervals if needed per blood glucose. Maintenance: 1.25–20mg daily in single or divided doses (consider divided doses above 10mg daily); max 20mg daily.

Children: Not recommended.**Contraindications:** Ketoacidosis.**Warnings/Precautions:** Impaired renal or hepatic function. Adrenal or pituitary insufficiency. Stress. Secondary failure may occur with extended therapy. Monitor urine and blood glucose. Discontinue if jaundice or persistent rash occurs. Malnourished. Elderly. Debilitated. Pregnancy (Cat.C): consider using insulin instead. Nursing mothers: not recommended.**Interactions:** Potentiated by NSAIDs, alcohol, highly protein bound drugs, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, MAOIs, β -blockers. Antagonized by diuretics, steroids, phenothiazines, thyroid products, phenytoin, niacin, sympathomimetics, calcium channel blockers and isoniazid. Disulfiram-like reaction with alcohol (rare). Monitor for 2 wks if transferring from chlorpropamide.**Adverse reactions:** Increased risk of cardiovascular mortality. Hypoglycemia, cholestatic jaundice, GI disturbances, allergic skin reactions, photosensitivity, blood dyscrasias, hepatic porphyria.**How supplied:** 1.25mg–50; 2.5mg–100, 500; 5mg–100, 500, 1000**GLYBURIDE + METFORMIN****GLUCOVANCE** Bristol-Myers Squibb

Sulfonylurea + biguanide. Glyburide, metformin HCl; 1.25mg/250mg, 2.5mg/500mg, 5mg/500mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as initial therapy or as second-line therapy when response to a sulfonylurea or metformin is inadequate; may add a thiazolidinedione.**Adults:** Take with meals. First-line: initially 1.25mg/250mg once daily; or, 1.25mg/250mg twice daily (AM & PM) if HbA_{1c} >9% or FPG >200mg/dL. May increase by 1.25mg/250mg per day every 2 weeks. Second-line (previously treated with sulfonylurea and/or metformin): 2.5mg/500mg or 5mg/500mg twice daily (AM & PM); (initial dose should not exceed previous daily doses of individual components); may increase by increments of up to 5mg/500mg; max 20mg/2000mg per day. May add a thiazolidinedione; see literature. Elderly: avoid max doses.**Children: Not recommended.****Contraindications:** Renal disease or dysfunction. CHF requiring drug treatment. Metabolic acidosis,

R

diabetic ketoacidosis. Concomitant intravascular iodinated contrast agents (suspend during and for 48 hours after use).

Warnings/Precautions: Confirm normal renal function before starting therapy (esp. in patients ≥ 80 ys); monitor renal and hepatic function.Discontinue if lactic acidosis, shock, acute MI, acute CHF, sepsis, hypoxemia or dehydration occurs. G6PD deficiency. Avoid in hepatic disease. Suspend before surgery that requires fasting. Monitor blood (esp. Vit. B₁₂ in susceptible patients). Stress. Elderly, debilitated, uncompensated strenuous exercise, malnourished or deficient caloric intake, adrenal or pituitary insufficiency, alcohol intoxication: increased risk of hypoglycemia. Pregnancy (Cat.B), nursing mothers: not recommended, consider using insulin instead.**Interactions:** Cationic drugs eliminated by renal tubular secretion (eg, amiloride, cimetidine, digoxin, procainamide, quinidine, trimethoprim, ranitidine), furosemide, nifedipine: may increase metformin levels. Glyburide potentiated by NSAIDs, highly protein-bound drugs, salicylates, sulfonamides, probenecid, coumarins, MAOIs, β -blockers. Disulfiram-like reaction with alcohol (rare). Excessive alcohol potentiates metformin's effect on lactate. Diuretics, steroids, phenothiazines, phenytoin, sympathomimetics, calcium channel blockers, isoniazid, niacin, others may cause hyperglycemia. β -blockers may mask hypoglycemia.**Adverse reactions:** Lactic acidosis (rare, $\frac{1}{2}$ the cases are fatal), GI upset, abdominal pain, upper respiratory infections, headache, dizziness, hypoglycemia. Oral hypoglycemic agents may increase risk of cardiovascular mortality. With rosiglitazone: edema, weight gain.**How supplied:** Tabs–100**GLYBURIDE, MICRONIZED**

R

GLYNASE PRESTAB PfizerSulfonylurea (2nd generation). Glyburide, micronized 1.5mg, 3mg, 6mg; scored tabs.**Indications:** Adjunct to diet in type 2 diabetes.**Adults:** Initially 1.5–3mg daily with breakfast.

Debilitated: initially 0.75mg daily with breakfast.

Increase by 1.5mg at weekly intervals if needed per blood glucose. Maintenance: 0.75–12mg daily in single or divided doses (consider divided doses above 6mg daily); max 12mg daily.

Children: Not recommended.**Elderly:** Initially 0.75mg daily with breakfast.**Contraindications:** Ketoacidosis. Type 1 diabetes, as sole therapy.**Warnings/Precautions:** Impaired renal or hepatic function. Adrenal or pituitary insufficiency. Stress. Secondary failure may occur with extended therapy. Monitor urine and blood glucose. Discontinue if jaundice or persistent rash occurs. Retire if transfer from other glyburide containing or hypoglycemic agents (see literature). Malnourished.

Elderly. Debilitated. Pregnancy (Cat.B): consider using insulin instead. Nursing mothers: not recommended.

Interactions: Potentiated by NSAIDs, alcohol, highly protein bound drugs, salicylates, sulfonamides, chloramphenicol, probenecid, coumarins, MAOIs, β -blockers. Antagonized by diuretics, steroids, phenothiazines, thyroid products, phenytoin, niacin, sympathomimetics, calcium channel blockers and isoniazid. Disulfiram-like reaction with alcohol (rare). Monitor for 2 weeks if transferring from chlorpropamide.

Adverse reactions: Increased risk of cardiovascular mortality. Hypoglycemia, cholestatic jaundice, GI disturbances, allergic skin reactions, photosensitivity, blood dyscrasias, hepatic porphyria.

How supplied: PresTab 1.5mg-100; 3mg-100, 500, 1000; 6mg-100, 500

INSULIN ASPART

Rx

NOVOLOG Novo Nordisk

Insulin aspart (recombinant) 100 Units/mL; soln for SC inj, continuous subcutaneous insulin infusion (CSII), IV infusion; contains zinc, m-cresol.

Indications: Diabetes.

Adults: For SC inj, CSII, or IV infusion: see literature. Onset approx ≤ 15 minutes, peak approx 1-3 hours, duration approx 3-5 hours.

Children: < 2 yrs: not recommended. 2-4 yrs: use SC inj only. ≥ 4 yrs: may use SC inj or CSII: see literature. Onset approx ≤ 15 minutes, peak approx 1-3 hours, duration approx 3-5 hours.

Contraindications: During episodes of hypoglycemia.

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by oral antidiabetic agents, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics.

Antagonized by corticosteroids, isoniazid, niacin, danazol, diuretics, thiazides, phenothiazines, sympathomimetics, somatropin, thyroid hormones, estrogens, progestogens, atypical antipsychotics. Variable effects with β -blockers, clonidine, lithium salts, alcohol, pentamidine. CSII: Do not mix with other insulins or diluent when pump is used.

Adverse reactions: Hypoglycemia, hypokalemia, local or systemic allergy, lipodystrophy, edema.

How supplied: Vials (10mL)-1; FlexPen (3mL prefilled syringe)-5; PenFill (3mL cartridges)-5; NovoPen 3 (inj device, uses PenFill cartridges)-1; NovoLog NovoPen Junior (inj device, uses PenFill cartridges)-1

INSULIN ASPART PROTAMINE + INSULIN ASPART

Rx

NOVOLOG MIX 70/30 Novo Nordisk

Insulin aspart protamine suspension 70% (recombinant), insulin aspart 30% (recombinant) 100 Units/mL; SC inj; contains zinc, m-cresol.

Indications: Diabetes.

Adults: For SC inj only. Onset approx ≤ 15 minutes, peak approx 2.4 hours, duration up to 24 hours.

Children: Not recommended.

Contraindications: During episodes of hypoglycemia.

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by oral antidiabetic agents, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics.

Antagonized by corticosteroids, isoniazid, niacin, danazol, diuretics, thiazides, phenothiazines, sympathomimetics, somatropin, thyroid hormones, estrogens, progestogens, atypical antipsychotics. Variable effects with β -blockers, clonidine, lithium salts, alcohol, pentamidine. Do not mix with other insulins.

Adverse reactions: Hypoglycemia, hypokalemia, local or systemic allergy, lipodystrophy, edema.

How supplied: Vials (10mL)-1
FlexPen (3mL prefilled syringe)-5

INSULIN DETEMIR

Rx

LEVEMIR Novo Nordisk

Insulin detemir (rDNA origin) 100 Units/mL; SC inj; contains zinc, m-cresol.

Indications: Type 1 diabetes (in adults and children) and type 2 diabetes (in adults) when basal (long-acting) insulin is needed.

Adults and Children: May be given once daily with evening meal or at bedtime or twice-daily (in the AM and PM). SC inj only into thigh, abdominal wall, or upper arm. < 2 yrs: not recommended. ≥ 2 yrs, type 1 diabetes: starting dose should be $\frac{1}{3}$ of total daily insulin requirements; rapid-acting or short-acting, pre-meal insulin should be used to satisfy remainder of daily insulin requirements. Insulin-naïve, type 2 diabetic adults inadequately controlled on oral antidiabetics: initially 10 Units (or 0.1-0.2 Units/kg) once daily in the evening or divided into twice daily regimen; inadequately controlled on GLP-1 receptor agonist: initially 10 Units once daily in the evening. Switching from another basal insulin: dose should be the same on a unit-to-unit basis; may need more insulin detemir when switching from NPH (see literature).

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction. Pregnancy (Cat.B). Nursing mothers.

Interactions: Do not mix or dilute with other insulins. Potentiated by oral antidiabetic agents, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics. Antagonized by corticosteroids, isoniazid, niacin, danazol, diuretics, thiazides, phenothiazines, sympathomimetics, somatropin, thyroid hormones, estrogens, progestogens, atypical antipsychotics. Variable effects with β -blockers, clonidine, lithium salts, alcohol, pentamidine.

Adverse reactions: Hypoglycemia, hypokalemia, local or systemic allergy, lipodystrophy, edema.

How supplied: Vials (10mL)-1; FlexPen (3mL)-5

INSULIN GLARGINE

R

LANTUS Sanofi Aventis
Insulin glargine (recombinant) 100 IU/mL; inj; contains m-cresol.

Indications: Type 1 diabetes (in adults and children) and type 2 diabetes (in adults) when basal (long-acting) insulin is needed.

Adults and Children: Give once daily at same time each day; SC inj only. Onset 1.1 hrs, no pronounced peak, duration 24 hrs or longer. <6yrs: not recommended. $\geq$ 6yrs: individualize; monitor and adjust as needed. Switching from once-daily NPH or ultralente insulin: initial dose should be the same on a unit-for-unit basis. Switching from twice-daily NPH: reduce initial insulin glargine dose by 20% from previous total NPH dose. Insulin-naïve, type 2 diabetics on oral antidiabetic: initially 10 IU; range 2-100 IU.

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction. Pregnancy (Cat.C). Nursing mothers.

Interactions: Do not mix or dilute with other insulins. Potentiated by oral antidiabetic agents, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics. Antagonized by corticosteroids, isoniazid, niacin, danazol, diuretics, thiazides, phenothiazines, sympathomimetics, somatropin, thyroid hormones, estrogens, progestogens, atypical antipsychotics. Variable effects with β -blockers, clonidine, lithium salts, alcohol, pentamidine.

Adverse reactions: Pain, other inj site reactions, pruritus, rash, hypoglycemia, hypokalemia, lipodystrophy, edema.

How supplied: Vials (10mL)-1; Lantus SoloStar pen (3mL)-5 (prefilled, disposable inj device)

INSULIN LISPRO PROTAMINE + INSULIN LISPRO

R

HUMALOG MIX75/25 Lilly
Insulin lispro protamine suspension 75% (recombinant), insulin lispro 25% (recombinant) 100 Units/mL; SC inj; contains zinc, m-cresol.

Indications: Diabetes.

Adults: $\geq$ 18yrs: SC injection only. Onset approx $\leq$ 15 minutes, peak approx 30-90 minutes, duration up to 24 hrs.

Children: <18yrs: not recommended.

Also: Insulin lispro protamine +

R

Insulin lispro

HUMALOG MIX50/50
Insulin lispro protamine suspension 50% (recombinant), insulin lispro 50% (recombinant) 100 Units/mL; SC inj; contains zinc, m-cresol.

Adults: $\geq$ 18yrs: SC injection only. Onset approx $\leq$ 15 minutes, peak approx 60 minutes, duration up to 16 hrs.

Children: <18yrs: not recommended.

Also: Insulin lispro

R

HUMALOG

Insulin lispro (recombinant) 100 Units/mL; soln for SC inj or continuous subcutaneous insulin infusion pump; contains zinc, m-cresol.

Adults and Children: <3yrs: not recommended.

Onset approx $\leq$ 15 minutes, peak approx 1 hr, duration approx 3.5-4.5 hrs. $\geq$ 3yrs: Give SC, either by injection or continuous infusion external pump. SC inj: give 15 minutes before meal or immediately after a meal; use with an intermediate or long-acting insulin. Rotate inj sites. Continuous SC infusion pump: do not use diluted or mixed insulins in external pumps; change the Humalog in the reservoir at least every 7 days, change the infusion sets and insertion site at least every 3 days.

Contraindications: During episodes of hypoglycemia.

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by oral antidiabetic agents, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics. Antagonized by corticosteroids, isoniazid, niacin, danazol, diuretics, thiazides, phenothiazines,

sympathomimetics, somatropin, thyroid hormones, estrogens, progestogens, atypical antipsychotics. Variable effects with β -blockers, clonidine, lithium salts, alcohol, pentamidine. When mixing insulin lispro with other insulins, draw insulin lispro into syringe first and inject mixture immediately.

Adverse reactions: Hypoglycemia, hypokalemia, local or systemic allergy, lipodystrophy, edema.

How supplied: Humalog Mix75/25, Humalog vials (10mL)-1; Humalog Mix, Humalog KwikPen (disposable insulin delivery device) (3mL)-5; Humalog cartridges (3mL)-5; HumaPen MEMOIR (inj device, uses Humalog cartridges)-1; HumaPen LUXURA HD (inj device, uses Humalog cartridges)-1

INSULIN, HUMAN

OTC

HUMULIN 70/30 Lilly

Insulin isophane suspension (NPH) 70% (human, recombinant), regular insulin 30% (human, recombinant) 100Units/mL; inj.

Indications: Diabetes.

Adults and Children: SC injection only. Onset approx 30 minutes, peak 2-12 hrs, duration up to 24 hrs.

Also: Insulin, human

OTC

HUMULIN R U-100

Regular insulin (human, recombinant) 100Units/mL; inj.

Adults and Children: SC, IV, or IM injection. SC: onset approx 30 minutes, peak 2-4 hrs, duration 6-8 hrs.

Also: Insulin, human

Rx

HUMULIN R U-500

Regular insulin (human, recombinant) 500Units/mL; inj; contains m-cresol.

Adults and Children: SC injection only. Onset approx 30 minutes, peak 1.75-4 hrs, duration up to 24 hrs.

Also: Insulin, human

OTC

HUMULIN N

Insulin isophane suspension (NPH) (human, recombinant) 100Units/mL; inj.

Adults and Children: SC injection only. Onset approx 1-2 hrs, peak 6-12 hrs, duration 18-24 hrs.

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction.

Interactions: Potentiated by oral antidiabetic agents, pramlintide, ACE inhibitors, disopyramide, fibrates, fluoxetine, MAOIs, propoxyphene, salicylates, somatostatin analog, sulfonamide antibiotics.

Antagonized by corticosteroids, isoniazid, niacin, danazol, diuretics, thiazides, phenothiazines, sympathomimetics, somatropin, thyroid hormones, estrogens, progestogens, atypical antipsychotics. Variable effects with β -blockers, clonidine, lithium

salts, alcohol, pentamidine. Onset may be delayed if regular insulin is mixed with zinc insulin. Regular and NPH insulins may be mixed and used immediately or stored for future use.

Adverse reactions: Hypoglycemia, hypokalemia, local or systemic allergy, lipodystrophy, edema.

How supplied: Vials 70/30, N, R (U-100)-10mL; R (U-500)-20mL; Prefilled disposable Pen (70/30, N)-5 $\times$ 3mL

INSULIN, HUMAN

OTC

NOVOLIN 70/30 Novo Nordisk

Insulin isophane suspension 70% (recombinant), regular insulin 30% (recombinant) 100Units/mL; inj.

Indications: Diabetes.

Adults and Children: SC injection only. Onset approx 30 minutes, peak 2-12 hrs, duration approx 24 hrs.

Also: Insulin, human

OTC

NOVOLIN R

Regular insulin (recombinant) 100Units/mL; inj.

Adults and Children: SC, IV, or IM injection. SC: onset approx 30 minutes, peak 2.5-5 hrs, duration approx 8 hrs.

Also: Insulin, human

OTC

NOVOLIN N

Insulin isophane suspension (recombinant) 100Units/mL; inj.

Adults and Children: SC injection only. Onset approx 1.5 hrs, peak 4-12 hrs, duration approx 24 hrs.

Warnings/Precautions: Instruct patients on diet, exercise, blood or urine testing, proper administration of insulin, change in species of origin, type or purity of insulin, and management of hypoglycemia. Dosage increase may be required during infection, illness, stress, trauma, and pregnancy. Dosage decrease may be needed with renal or hepatic dysfunction.

Interactions: Potentiated by salicylates, MAOIs, alcohol, sulfa drugs, some ACE inhibitors, drugs that inhibit pancreatic function (eg, octreotide), oral hypoglycemic agents, anabolic steroids, quinine, quinidine, alpha-adrenergic blocking agents.

Antagonized by corticosteroids, isoniazid, niacin, thiazides, phenothiazines, sympathomimetics, oral contraceptives, thyroid hormones, growth hormone, diazoxide, asparaginase, nicotinic acid. Variable effects with β -blockers, clonidine, lithium salts, alcohol.

Adverse reactions: Hypoglycemia, hypokalemia, local or systemic allergy, lipodystrophy, edema.

How supplied: Vials (10mL)-1

IRBESARTAN

Rx

AVAPRO Sanofi Aventis

Angiotensin II receptor blocker. Irbesartan 75mg, 150mg, 300mg; tabs.

Indications: Treatment of diabetic nephropathy in patients with type 2 diabetes and hypertension.

Adults: 300mg once daily.
Children: Not recommended.
Contraindications: Concomitant aliskiren in patients with diabetes.
Warnings/Precautions: Fetal toxicity may develop; discontinue if pregnancy is detected. Correct salt/volume depletion before beginning therapy, or reduce initial dose. Renal impairment. Severe CHF. Renal artery stenosis. Elderly. Neonates. Pregnancy (Cat.D); monitor. Nursing mothers: not recommended.
Interactions: Hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. May be antagonized by NSAIDs including COX-2 inhibitors. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.
Adverse reactions: Diarrhea, dyspepsia, fatigue, orthostatic hypotension, hyperkalemia; rhabdomyolysis (rare).
How supplied: Tabs 75mg–30, 90; 150mg, 300mg–30, 90, 500

LINAGLIPTIN

TRAJENTA Boehringer Ingelheim and Lilly
Dipeptidyl peptidase-4 inhibitor. Linagliptin 5mg; tabs.
Indications: Adjunct to diet and exercise in type 2 diabetes mellitus, as monotherapy or combination therapy.
Adults: 5mg once daily.
Children: Not recommended.
Warnings/Precautions: Not for the treatment of type 1 diabetes or diabetic ketoacidosis. Pregnancy (Cat.B). Nursing mothers.
Interactions: Antagonized by strong P-gp or CYP3A4 inducers (eg, rifampin); consider alternatives to linagliptin if used in combination. May need lower dose of concomitant sulfonylurea or insulin to reduce risk of hypoglycemia.
Adverse reactions: Nasopharyngitis, hypoglycemia, arthralgia, back pain, headache; hypersensitivity reactions (eg, urticaria, angioedema, localized skin exfoliation, bronchial hyperreactivity), myalgia, pancreatitis.
How supplied: Tabs 30, 90, 1000

LIRAGLUTIDE

VICTOZA Novo Nordisk
Glucagon-like peptide-1 [GLP-1] receptor agonist. Liraglutide [rDNA origin] 6mg/mL; soln for SC inj.
Indications: As adjunct to diet and exercise, to improve glycemic control in type 2 diabetes. Limitations of use: not recommended as first-line treatment for patients inadequately controlled on diet and exercise. Not a substitute for insulin. Not for treating type 1 diabetes or ketoacidosis. Not studied in combination with prandial insulin or with a history of pancreatitis.

Adults: Give by SC inj in abdomen, thigh, or upper arm once daily. Initially 0.6mg/day for 1 week, then 1.2mg/day; may increase to 1.8mg/day. If >3 days elapsed since last dose, reinitiate at 0.6mg/day, then titrate. Renal impairment: caution with initiating or escalating doses.
Children: <18yrs: not recommended.
Contraindications: History (personal or family) of medullary thyroid carcinoma. Multiple endocrine neoplasia syndrome type 2.
Warnings/Precautions: Inform patients of thyroid cancer risk and symptoms. Discontinue if pancreatitis is suspected; do not restart if confirmed. History of pancreatitis: consider other antidiabetic therapies. Renal or hepatic dysfunction. Gastroparesis. Pregnancy (Cat.C). Nursing mothers: not recommended.
Interactions: Concomitant insulin (insufficient data); administer as separate injections not adjacent to each other. Hypoglycemia with sulfonylureas or insulin (consider reducing their doses). May affect absorption of other drugs (delayed gastric emptying). Monitor digoxin.
Adverse reactions: Headache, nausea, diarrhea, antibody formation, immunogenicity reactions (eg, urticaria), constipation; rare: pancreatitis (discontinue if occurs), papillary thyroid carcinoma, anaphylactic reactions and angioedema (discontinue if occurs).
How supplied: Multi-dose, pre-filled pen (3mL)–2, 3

LOSARTAN

COZAAR Merck
Angiotensin II receptor blocker. Losartan potassium 25mg, 50mg, 100mg; tabs.
Indications: Treatment of diabetic nephropathy in type 2 diabetes with hypertension.
Adults: Initially 50mg once daily; may increase to 100mg once daily.
Children: Not established.
Contraindications: Concomitant aliskiren in patients with diabetes.
Warnings/Precautions: Fetal toxicity; discontinue as soon as pregnancy is detected. Correct salt/volume depletion before starting therapy, or reduce initial dose. Renal impairment: monitor for worsening renal function. Hepatic impairment. Severe CHF. Renal artery stenosis. Pregnancy (Cat.C in 1st trimester, Cat.D in 2nd and 3rd trimesters). Nursing mothers: not recommended.
Interactions: Hyperkalemia with K⁺ supplements, K⁺ sparing diuretics, K⁺ containing salt substitutes. May be antagonized by, and renal toxicity potentiated by NSAIDs, including selective COX-2 inhibitors (monitor renal function periodically in elderly and/or volume-depleted). Monitor lithium. Dual inhibition of the renin-angiotensin system with ARBs, ACEIs, or aliskiren may increase risk of hypotension, hyperkalemia, renal function changes; monitor closely. Concomitant aliskiren in renal impairment (CrCl <60mL/min): not recommended.

Adverse reactions: Dizziness, insomnia, muscle cramps, leg pain, hyperkalemia, angioedema, orthostatic hypotension, rhabdomyolysis (rare).

How supplied: Tabs 25mg–90, 1000; 50mg, 100mg–30, 90, 1000

METFORMIN

R

GLUCOPHAGE XR Bristol-Myers Squibb
Biguanide. Metformin HCl 500mg, 750mg; ext-rel tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes as monotherapy, or (in adults) with a sulfonylurea or insulin.

Adults: Swallow whole. Take with evening meal. ≥ 17 yrs: initially 500mg once daily; may increase by 500mg/day at 1-week intervals; max 2g once daily or in 2 divided doses. Reduce insulin dose by 10–25% as needed. Concomitant sulfonylureas: see literature.

Children: < 10 yrs: not recommended. 10–16 yrs: use immediate-release form.

Also: Metformin

R

GLUCOPHAGE

Metformin HCl 500mg, 850mg, 1g; tabs.

Adults: Take with meals. ≥ 17 yrs: Monotherapy: Initially 500mg twice daily or 850mg once daily; may increase by 500mg/day at 1-week intervals or by 850mg/day in divided doses at 2-week intervals. Or, may increase from 500mg twice daily to 850mg twice daily after 2 weeks. Max 2.5g/day in 2–3 divided doses. Adding to insulin: initially 500mg once daily; may increase by 500mg/day at 1-week intervals; max 2.5g/day. Reduce insulin dose by 10–25% as needed. Concomitant sulfonylureas: see literature.

Children: Take with meals. < 10 yrs: not recommended. ≥ 10 yrs: Monotherapy only: Initially 500mg twice daily; may increase by 500mg/day at 1-week intervals. Max 2g/day in divided doses.

Contraindications: Renal disease or dysfunction. Metabolic acidosis, ketoacidosis. Concomitant intravascular iodinated contrast agents (suspend during and for 48 hours after use).

Warnings/Precautions: Confirm normal renal function before starting and monitor (esp. in patients ≥ 80 yrs). Avoid in hepatic disease. Discontinue if lactic acidosis, shock, acute MI, sepsis, or hypoxemia occurs. Suspend therapy if dehydration occurs or before surgery. Monitor hepatic function, hematology (esp. serum Vit. B₁₂ in susceptible patients). Stress. Secondary failure. Elderly, debilitated, uncompensated strenuous exercise, malnourished or deficient caloric intake, adrenal or pituitary insufficiency, or alcohol intoxication: increased risk of hypoglycemia. Pregnancy (Cat.B), nursing mothers: not recommended; consider using insulin instead.

Interactions: Cationic drugs eliminated by renal tubular secretion (eg, amiloride, cimetidine, digoxin, procainamide, quinidine, trimethoprim, ranitidine), furosemide, nifedipine: may increase metformin levels. Avoid excessive alcohol intake (potentiates effects of metformin on lactate). Diuretics, steroids, phenothiazines, phenytoin, sympathomimetics,

calcium channel blockers, isoniazid, niacin, others may cause hyperglycemia. Increased risk of hypoglycemia with alcohol, sulfonylureas, insulin, repaglinide. β -blockers may mask hypoglycemia.

Adverse reactions: GI disturbances, transient taste disturbance, lactic acidosis (rare, half the cases are fatal).

How supplied: XR 500mg, 750mg–100; Tabs 500mg–100, 500; 850mg, 1g–100

PIOGLITAZONE

R

ACTOS Takeda

Thiazolidinedione. Pioglitazone (as HCl) 15mg, 30mg, 45mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as monotherapy or in combination with metformin, insulin, or a sulfonylurea.

Adults: ≥ 18 yrs: initially 15mg or 30mg once daily; max 45mg once daily. Reduce insulin or sulfonylurea dose if needed.

Children: < 18 yrs: not recommended.

Contraindications: NYHA Class III or IV heart failure.

Warnings/Precautions: Not for treating type 1 diabetes or diabetic ketoacidosis. Symptomatic HF: not recommended. CHF: if NYHA Class II: start at lowest approved dose and titrate carefully. Edema. May increase plasma volume (monitor for signs/symptoms of heart failure); discontinue if cardiac status deteriorates. Hepatic disease. Do not start therapy in active liver disease or if ALT $> 2.5 \times$ ULN. Monitor ALT at baseline, then periodically. If ALT $1.2\text{--}2.5 \times$ ULN, follow-up and monitor closely; discontinue if ALT $> 3 \times$ ULN persists or if jaundice occurs. Not for use in patients with history of troglitazone-associated jaundice. Resumption of premenopausal ovulation in anovulatory patients may occur (may result in unintended pregnancy). Pregnancy (Cat.C): consider using insulin instead. Nursing mothers: not recommended.

Interactions: Potentiated by CYP2C8 inhibitors (eg, gemfibrozil). Antagonized by CYP2C8 inducers (eg, rifampin). Antagonizes oral contraceptives, midazolam. Monitor glycemic control more frequently with ketoconazole. Monitor for heart failure with insulin.

Adverse reactions: Upper respiratory tract infection, headache, sinusitis, pharyngitis, myalgia, anemia, edema, weight gain, hypoglycemia, dyspnea; changes in serum lipids (may be beneficial); also women: risk of fracture.

How supplied: Tabs–30, 90, 500

PIOGLITAZONE + METFORMIN

R

ACTOPLUS MET Takeda

Thiazolidinedione + biguanide. Pioglitazone (as HCl), metformin HCl: 15mg/500mg, 15mg/850mg; tabs.

Indications: Adjunct to diet and exercise to improve glycemic control in type 2 diabetes in patients already on pioglitazone and metformin, or

when response to pioglitazone or metformin alone is inadequate.

Adults: Give in divided doses with meals. Individualize. Previously on pioglitazone and/or metformin: switch on a mg/mg basis. Initially 15mg/500mg or 15mg/850mg once or twice daily; may adjust after 8–12 weeks; max 45mg pioglitazone/2550mg metformin per day. Elderly, debilitated, malnourished: max doses not recommended.

Children: Not recommended.

Also: Pioglitazone + Metformin
ACTOPLUS MET XR

Pioglitazone (as HCl), metformin HCl extended-release; 15mg/1000mg, 30mg/1000mg; tabs.

Adults: Swallow whole. Give once daily with the evening meal. Individualize. Previously on pioglitazone and/or metformin: switch on a mg/mg basis. Initially 15mg/1000mg or 30mg/1000mg once daily; may adjust after 8–12 weeks; max 45mg pioglitazone/2000mg metformin per day. Elderly, debilitated, malnourished: max doses not recommended.

Children: Not recommended.

Contraindications: NYHA Class III or IV heart failure. Renal disease or dysfunction. Metabolic acidosis, ketoacidosis. Concomitant intravascular iodinated contrast agents (suspend during and for 48 hours after use).

Warnings/Precautions: Not for treating type 1 diabetes. Symptomatic HF: not recommended. CHF: NYHA Class II: start at lowest approved dose and titrate carefully. Edema. May increase plasma volume (monitor for signs/symptoms of heart failure); discontinue if cardiac status deteriorates, or if lactic acidosis, shock, acute MI, sepsis, or hypoxemia occurs. Confirm normal renal function before starting and monitor (esp. in patients ≥ 80 yrs). Avoid in hepatic disease. Do not start therapy in active liver disease or if ALT $> 2.5 \times$ ULN. Monitor ALT at baseline, then periodically. If ALT $1-2.5 \times$ ULN, follow-up and monitor closely; discontinue if ALT $> 3 \times$ ULN persists or if jaundice occurs. Not for use in patients with history of troglitazone-associated jaundice. Suspend therapy if dehydration occurs or before surgery. Monitor blood (esp. serum Vit. B₁₂ in susceptible patients). Stress. Elderly, debilitated, uncompensated strenuous exercise, malnourished or deficient caloric intake, adrenal or pituitary insufficiency, or alcohol intoxication: increased risk of hypoglycemia. Resumption of premenopausal ovulation in anovulatory patients may occur (may result in unintended pregnancy). Pregnancy (Cat.C; not recommended; consider using insulin instead). Nursing mothers: not recommended.

Interactions: See Contraindications. Potentiated by CYP2C8 inhibitors (eg, gemfibrozil). Antagonized by CYP2C8 inducers (eg, rifampin). Antagonizes oral contraceptives, midazolam. Monitor for heart failure with insulin. Avoid excessive alcohol intake

(potentiates effects of metformin on lactate). Cationic drugs eliminated by renal tubular secretion, furosemide, nifedipine: may increase metformin levels. Increased risk of hyperglycemia with diuretics, steroids, phenothiazines, phenytoin, sympathomimetics, calcium channel blockers, niacin, thyroid products, estrogens, oral contraceptives, isoniazid. β -blockers may mask hypoglycemia.

Adverse reactions: Upper respiratory tract infection, GI upset, edema, headache, urinary tract infection, dizziness, weight gain, lactic acidosis (rare, half the cases are fatal); also women: risk of fracture.

How supplied: Tabs–60, 180; XR tabs–30, 60, 90

PRAMLINTIDE

SYMLIN Amylin

Amylin analogue/amylinomimetic. Pramlintide (as acetate) 0.6mg/mL; soln for SC inj; contains m-cresol, mannitol.

Indications: Type 1 diabetes as adjunct to mealtime insulin, or type 2 diabetes as adjunct to mealtime insulin with or without sulfonylurea and/or metformin, in patients without optimal blood glucose control despite optimal insulin therapy.

Adults: Do not mix with insulin. Reduce preprandial, short/rapid-acting insulin dose by 50% when starting pramlintide. Monitor blood glucose frequently (pre- and post-meals, and at bedtime). Adjust insulin dose after target pramlintide dose is achieved and any nausea subsides. Give by SC inj into abdomen or thigh immediately before major meals (≥ 250 kcal or ≥ 30 g carbohydrates); rotate inj sites (use different site for insulin). Type 1: initially 15mcg; titrate in 15mcg increments if no significant nausea occurs for at least 3 days; maintenance: 60mcg (30mcg only if 60mcg is not tolerated). If nausea occurs at 45 or 60mcg dose, reduce to 30mcg; if not tolerated, consider discontinuing therapy. Type 2: initially 60mcg; may increase to 120mcg if no significant nausea occurs for 3–7 days; if nausea occurs at 120mcg reduce to 60mcg.

Children: Not recommended.

Contraindications: Gastroparesis. Hypoglycemia unawareness. Do not use in patients with poor compliance, HbA_{1c} $> 9\%$, recurrent hypoglycemia needing assistance in the past 6 months, or if on prokinetic drugs.

Warnings/Precautions: Dialysis. Pregnancy (Cat.C). Nursing mothers.

Interactions: Drugs that alter GI motility (eg, anticholinergics) and those that slow intestinal absorption (eg, α -glucosidase inhibitors) not recommended. May delay absorption of oral drugs (give these 1 hr before or 2 hrs after pramlintide).

Adverse reactions: GI upset, anorexia, headache, allergy, insulin-dependent hypoglycemia (may be severe).

How supplied: SymlinPen 60–1 (pre-filled inj device); SymlinPen 120–1 (pre-filled inj device)

REPAGLINIDE**PRANDIN** Novo Nordisk

Meglitinide analogue. Repaglinide 0.5mg, 1mg, 2mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as monotherapy or with metformin or thiazolidinediones.**Adults:** Take within 30 minutes before meals (skip dose if meal is skipped; add dose if meal is added). Treatment-naïve, or HbA1c <8%, or severe renal dysfunction (CrCl 20–40mL/min): initially 0.5mg with 2–4 meals daily. Previously treated with antidiabetic agents and HbA1c ≥8%: initially 1–2mg with 2–4 meals daily. For both: titrate by doubling dose at intervals of at least 1 week; range 0.5–4mg with 2–4 meals daily; max 16mg/day. Hemodialysis or CrCl <20mL/min: not recommended.**Children: Not recommended.****Contraindications:** Type 1 diabetes. Diabetic ketoacidosis. Concomitant gemfibrozil.**Warnings/Precautions:** Not for use with NPH-insulin (serious cardiovascular events possible). Elderly, debilitated, malnourished, or adrenal, pituitary, hepatic or severe renal insufficiency: increased risk of hypoglycemia; titrate more slowly. Stress. Monitor for initial effect and for secondary failure. Pregnancy (Cat.C): consider using insulin instead. Nursing mothers: not recommended.**Interactions:** See Contraindications. Potentiated by gemfibrozil. β -blockers, alcohol, other antidiabetic agents increase risk of hypoglycemia. May be potentiated by CYP3A4 inhibitors (eg, ketoconazole, itraconazole, erythromycin, clarithromycin), CYP2C8 inhibitors (eg, trimethoprim, montelukast, deferasirox), OATP1B1 inhibitors (eg, cyclosporine), and by other highly protein-bound drugs (eg, NSAIDs, salicylates, sulfonamides), chloramphenicol, coumarins, probenecid, MAOIs. May be antagonized by other CYP3A4 inducers (eg, carbamazepine, rifampin, barbiturates), isoniazid, nicotinic acid, phenytoin, diuretics, corticosteroids, phenothiazines, sympathomimetics, calcium channel blockers, estrogens, oral contraceptives, thyroid drugs, others. β -blockers may mask hypoglycemia.**Adverse reactions:** Hypoglycemia, upper respiratory infection, headache, diarrhea, constipation, arthralgia, back or chest pain. Oral antidiabetics may increase risk of cardiovascular mortality; myocardial ischemia (w. NPH-insulin).**How supplied:** Tabs–100, 500, 1000**ROSIGLITAZONE****AVANDIA** GlaxoSmithKline

Thiazolidinedione. Rosiglitazone (as maleate) 2mg, 4mg, 8mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as monotherapy, or in combination with metformin and/or a sulfonylurea.**Adults:** ≥18yrs: Give once daily or in two divided doses (AM & PM). Initially 4mg/day. Monotherapy or

R

with metformin and/or sulfonylurea: may increase after 8–12 weeks; max 8mg/day.

Children: <18yrs: not recommended.**Contraindications:** Concomitant metformin in renal impairment. NYHA Class III or IV heart failure.**Warnings/Precautions:** Not for treating type 1 diabetes or diabetic ketoacidosis. Symptomatic HF or acute coronary syndromes: not recommended; discontinue if occurs. CHF: NYHA Class I or II: increased risk of cardiovascular events (monitor). Edema. May increase plasma volume (monitor for heart failure); discontinue if cardiac status deteriorates. Hepatic disease. Do not start therapy in active liver disease or if ALT >2.5×ULN. Monitor transaminases at baseline, then periodically. If ALT is mildly elevated (≤2.5×ULN), follow-up and monitor closely; discontinue if ALT >3×ULN or jaundice occurs. Not for use in patients with history of troglitazone-associated jaundice. Resumption of premenopausal ovulation in anovulatory patients may occur (may result in unintended pregnancy). Reevaluate if menstrual dysfunction occurs. Labor & delivery. Pregnancy (Cat.C): consider using insulin instead. Nursing mothers: not recommended.**Interactions:** Concomitant insulin or nitrates: not recommended. Potentiated by CYP2C8 inhibitors (eg, gemfibrozil). Antagonized by CYP2C8 inducers (eg, rifampin).**Adverse reactions:** Upper respiratory tract infection, injury, headache, edema, weight gain, anemia, changes in serum lipids, macular edema (possible); also women: risk of fracture. See literature re: risk of myocardial ischemic events.**How supplied:** Tabs 2mg–60; 4mg, 8mg–30, 90**SAXAGLIPTIN**

R

ONGLYZA Bristol-Myers Squibb

Dipeptidyl peptidase-4 inhibitor. Saxagliptin 2.5mg, 5mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as monotherapy or combination therapy. Limitations of use: not for treating type 1 diabetes or diabetic ketoacidosis. Not studied in patients with history of pancreatitis.**Adults:** 2.5mg or 5mg once daily. Moderate-severe renal impairment or ESRD requiring hemodialysis (CrCl ≤50mL/min), or concomitant strong CYP3A4/5 inhibitors: 2.5mg once daily. Give dose after hemodialysis.**Children: <18yrs: not established.****Contraindications:** History of serious hypersensitivity reactions (eg, anaphylaxis, angioedema, exfoliative skin conditions).**Warnings/Precautions:** Monitor for signs/symptoms of pancreatitis; discontinue if suspected. Monitor renal function before starting therapy and periodically thereafter. History of angioedema to other DPP4 inhibitors. Pregnancy (Cat.B). Nursing mothers.**Interactions:** Potentiated by strong CYP3A4/5 inhibitors (eg, ketoconazole, atazanavir,

clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin). Concomitant sulfonylurea: may need lower dose of sulfonylurea to reduce risk of hypoglycemia.

Adverse reactions: Upper respiratory tract infection, UTI, headache, abdominal pain, gastroenteritis, vomiting; peripheral edema (with thiazolidinediones); hypoglycemia (with sulfonylureas), hypersensitivity reactions (discontinue if suspected).

How supplied: Tabs 2.5mg–30, 90; 5mg–30, 90, 500

SITAGLIPTIN

R

JANUVIA Merck

Dipeptidyl peptidase-4 inhibitor. Sitagliptin (as phosphate) 25mg, 50mg, 100mg; tabs.

Indications: Adjunct to diet and exercise in type 2 diabetes, as monotherapy or combination therapy (see literature).

Adults: 100mg once daily. Renal insufficiency: CrCl ≥ 30 –50mL/min: 50mg once daily; CrCl < 30mL/min or on dialysis: 25mg once daily.

Children: < 18yrs: not recommended.

Warnings/Precautions: Not for the treatment of type 1 diabetes or diabetic ketoacidosis. Monitor renal function before starting therapy, then periodically. Monitor for pancreatitis; discontinue if it occurs. Severe hepatic insufficiency. Pregnancy (Cat.B). Nursing mothers.

Interactions: Concomitant sulfonylurea or insulin: may need lower dose of sulfonylurea or insulin to reduce risk of hypoglycemia. Monitor digoxin.

Adverse reactions: Nasopharyngitis, upper respiratory tract infection, headache; hypersensitivity reactions (eg, anaphylaxis, angioedema, Stevens-Johnson syndrome), discontinue if occur.

How supplied: Tabs 25mg, 50mg–30, 90; 100mg–30, 90, 1000

4C Hypogonadism

OXANDROLONE

CIII

OXANDRIN Savient

Androgen. Oxandrolone 2.5mg+, 10mg; tabs (+ scored).

Indications: As an adjunct to promote weight gain after extensive surgery, chronic infections, severe trauma, and without definite cause, to offset protein catabolism associated with prolonged corticosteroid administration, and for relief of osteoporotic bone pain.

Contraindications: Male breast or prostate carcinoma. Nephrosis. Hypercalcemia. Pregnancy (Cat.X).

Warnings/Precautions: Discontinue if jaundice, abnormal liver function, hypercalcemia, or edema occurs. Cardiac, hepatic, or renal dysfunction. Monitor hepatic function, blood, and bone age. Elderly. Young children. Nursing mothers: not recommended.

Interactions: May potentiate oral anticoagulants, oxphenbutazone. May alter insulin needs. Increased risk of edema with ACTH, corticosteroids.

Adverse reactions: Peliosis hepatis, premature epiphyseal closure in adolescents, edema, hepatic carcinoma, prostatic hypertrophy or carcinoma, gynecomastia, priapism, oligospermia, nausea, jaundice, hirsutism, virilization, male pattern baldness, acne, polycythemia, headache, anxiety, depression, paresthesias, altered libido, fluid and electrolyte disturbances, suppression of clotting factors, increased serum cholesterol.

How supplied: Tabs 2.5mg–100 10mg–60

TESTOSTERONE

CIII

ANDROGEL 1% AbbVie

Androgen. Testosterone 1%; gel.

Indications: Testosterone replacement therapy.

Adults: Advise patients to strictly adhere to recommended instructions. Apply to clean, intact, dry skin of the shoulders, upper arms, and/or abdomen; do not apply to scrotum. ≥ 18 yrs: 5g (50mg of testosterone) once daily in the AM; check serum testosterone level at intervals until normal range; may increase to 7.5g/day (75mg of testosterone), then to 10g/day (100mg of testosterone) if needed. Wash hands after application. Allow gel to dry before it touches clothing.

Children: < 18yrs: not recommended.

Also: Testosterone

CIII

ANDROGEL 1.62%

Testosterone 1.62% (20.25mg of testosterone per one pump actuation); gel.

Adults: Advise patients to strictly adhere to recommended instructions. Apply to clean, intact, dry skin of the shoulders and upper arms; do not apply to abdomen or genitals. ≥ 18 yrs: 2.5g (40.5mg of testosterone [2 pump actuations]) once daily in the AM. May adjust dose between minimum of 20.25mg (1 pump actuation) and a maximum of 81mg (4 pump actuations) based on the pre-dose morning serum testosterone concentration at approx. 14 days and 28 days after starting treatment or following dose adjustment. See literature. Check additional serum testosterone levels periodically thereafter. Wash hands after application. Allow gel to dry before it touches clothing.

Children: < 18yrs: not recommended.

Contraindications: Male breast or prostate cancer. Not for use in women. Pregnant women must avoid skin contact with application sites in men. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Not interchangeable with other topical testosterone products. Other persons (esp. children) must avoid contact with application site. Secondary exposure to testosterone; promptly discontinue if signs of virilization in children and women occurs, until cause is identified. Increased risk for worsening BPH; monitor for signs/symptoms. Evaluate for prostate cancer before starting therapy. Cardiac, renal, or hepatic disease (discontinue if edema occurs). May worsen sleep apnea. Monitor

hemoglobin, hematocrit, liver function, PSA, cholesterol, lipid profile, serum testosterone; calcium (in cancer patients at risk for hypercalcemia). Elderly.

Interactions: Monitor antidiabetic drugs. ACTH, corticosteroids may increase edema. Monitor INR, PT with anticoagulants.

Adverse reactions: Increased PSA, local reactions, lab abnormalities, acne, prostate disorders, emotional lability, hypertension, breast pain, gynecomastia, nervousness, testis disorders, edema; virilization in children.

How supplied: Gel 1% (2.5g, 5g)–30 packets; Pump 1% 75g (60 metered 1.25g doses)–2; Gel 1.62% (1.25g, 2.5g)–30 packets; Pump 1.62% 75g (60 metered 1.25g doses)–1

TESTOSTERONE CYPIONATE CIII

DEPO-TESTOSTERONE Pfizer

Androgen. Testosterone cypionate 100mg/mL, 200mg/mL; IM inj in cottonseed oil; contains benzyl alcohol.

Indications: Testosterone replacement therapy.

Adults: Give by deep IM inj into gluteal muscle once every 2 to 4 weeks. 50–400mg; max 400mg/month.

Children: Not recommended.

Contraindications: Serious cardiac, hepatic, or renal disease. Male breast or prostate cancer. Use in women. Pregnancy (Cat.X).

Warnings/Precautions: Discontinue if jaundice, abnormal liver function, hypercalcemia, or edema occurs. Monitor liver function, hemoglobin, hematocrit, prostate specific antigen (PSA), cholesterol, bone age. Cardiac, hepatic, or renal dysfunction. May increase risk of prostatic hyperplasia in elderly. May increase growth of subclinical prostatic carcinoma. Elderly. Young children. Nursing mothers: not recommended.

Interactions: May potentiate oral anticoagulants, oxyphenbutazone. May alter insulin effects. Increased risk of edema with ACTH, corticosteroids.

Adverse reactions: Inj site reactions, peliosis hepatis, premature epiphyseal closure in adolescents, edema, hepatic carcinoma, prostatic hypertrophy or carcinoma, gynecomastia, priapism, oligospermia, nausea, jaundice, hirsutism, virilization, male pattern baldness, acne, polycythemia, headache, anxiety, depression, paresthesias, altered libido, fluid and electrolyte disturbances, suppression of clotting factors, increased serum cholesterol.

How supplied: Vial 100mg/mL (10mL)–1
Vial 200mg/mL (1mL, 10mL)–1

4D Pituitary disorders

CABERGOLINE R

CABERGOLINE (various)

Dopamine agonist. Cabergoline 0.5mg; scored tabs.

Indications: Hyperprolactinemic disorders, either idiopathic or due to pituitary tumors.

Adults: Initially 0.25mg twice weekly. Dose may be increased at 4-week intervals by 0.25mg twice weekly. Max: 1mg twice weekly.

Children: Not recommended.

Contraindications: Uncontrolled hypertension. Sensitivity to ergot alkaloids.

Warnings/Precautions: Not for pregnancy-induced hypertension or postpartum lactation inhibition or suppression. Respiratory or cardiac disease due to fibrosis. Hepatic dysfunction. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent dopamine D₂ antagonists (eg, phenothiazines, butyrophenones, thioxanthenes, metoclopramide); not recommended. Hypertension may be potentiated by antihypertensives.

Adverse reactions: GI upset, dizziness, fatigue, postural hypotension, nervousness, breast pain, dysmenorrhea, vision abnormalities; rare: fibrosis, valvulopathy.

How supplied: Contact supplier.

DESMOPRESSIN R

DDAVP Sanofi Aventis

Vasopressin (synthetic). Desmopressin acetate 0.1mg, 0.2mg; scored tabs.

Indications: Central (cranial) diabetes insipidus. Temporary polyuria and polydipsia following head trauma or surgery in the pituitary region.

Adults: When switching to tabs give 1st oral dose 12hrs after last intranasal dose. Initially 0.05mg twice daily; individualize, usual range: 0.1–1.2mg/day in 2–3 divided doses.

Children: <4yrs: not recommended. ≥4yrs: initially 0.05mg once daily; individualize.

Also: Desmopressin
DDAVP NASAL SPRAY

Desmopressin acetate 10mcg/spray; nasal spray; contains benzalkonium chloride.

Adults: 10–40mcg daily intranasally in 1–3 divided doses; usually 20mcg in two divided doses. Use rhinal tube for doses <10mcg or doses other than multiples of 10mcg.

Children: <3months: not recommended. ≥3months: 5–30mcg daily intranasally in 1–2 divided doses. Use rhinal tube for doses <10mcg or doses other than multiples of 10mcg.

Also: Desmopressin
DDAVP RHINAL TUBE

Desmopressin acetate 10mcg/0.1mL; intranasal soln.

Adults: 10–40mcg intranasally in 1–3 divided doses; usually 20mcg in two divided doses. Use rhinal tube for doses <10mcg or doses other than multiples of 10mcg.

Children: <3months: not recommended. ≥3months: 5–30mcg daily intranasally in 1–2 divided doses. Use rhinal tube for doses <10mcg or doses other than multiples of 10mcg.

Also: Desmopressin

DDAVP INJECTION

Desmopressin acetate 4mcg/mL; soln for inj or IV infusion after dilution.

Adults: 2–4mcg/day SC or IV in 2 divided doses. If switching stabilized patient, use one-tenth of intranasal dose.

Children: Not recommended.

Contraindications: Moderate to severe renal impairment (CrCl <50mL/min). Hyponatremia, or history of.

Warnings/Precautions: Monitor fluid intake, urine volume and osmolality. Fluid/electrolyte imbalance (eg, cystic fibrosis). Habitual or psychogenic polydipsia. Coronary artery insufficiency. Hypertension. Inj: Predisposition to thrombosis. Nasal mucosal changes (nasal forms). Young children. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with other pressor agents, drugs that may increase the risk of water intoxication with hyponatremia (eg, tricyclic antidepressants, SSRIs, chlorpromazine, opiates, NSAIDs, lamotrigine, carbamazepine). Possible convulsions with oxybutynin, imipramine.

Adverse reactions: Headache, nausea, flushing, abdominal cramps, vulval pain, water intoxication, hyponatremia, nasal congestion or rhinitis (nasal forms), inj site reaction; rare: changes in BP, severe allergic reactions, seizures in children from plasma hyposmolality, thrombotic events (inj).

How supplied: Tabs–100; Nasal spray–5mL (50 sprays); Rhinal tube–2.5mL (w. 2 rhinal tubes); Amp (1mL)–10; Multi-dose vial (10mL)–1

R

effects after 1–2 months of starting therapy, with dose changes and during treatment. Depot 3-Month: monitor at months 2–3, month 6 and as needed thereafter. Measure height and bone age velocity every 6–12 months. Exclude pregnancy before treatment. Nursing mothers: not recommended.

Interactions: Caution with concomitant drugs that are associated with convulsions (eg, bupropion, SSRIs).

Adverse reactions: Transient exacerbation of symptoms, inj site reactions, pain, headache, emotional lability, hot flushes/sweating, acne/seborrhea, rash, vaginitis, vaginal discharge, syncope, GI upset, gynecomastia, weight increased, mood altered; convulsions.

How supplied: Depot-PED kit–1 (prefilled dual-chamber syringe w. diluent); Depot-PED 3 Month kit–1 (prefilled dual-chamber syringe w. diluent)

OCTREOTIDE

R

SANDOSTATIN Novartis

Somatostatin analogue. Octreotide acetate 50mcg, 100mcg, 500mcg, 200mcg, 1000mcg; soln for IV or SC inj; contains mannitol, phenol (vials).

Indications: Acromegaly unresponsive to or that cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses.

Adults: Give by IV infusion over 15–30 minutes, IV push over 3 minutes, or deep SC (intrafat) inj. Initially 50mcg 3 times daily. Usual maintenance: 100micrograms 3 times daily; max 500mcg 3 times daily. Reevaluate every 6 months. Pituitary irradiation recipients: withdraw therapy for 4 weeks once yearly to assess disease activity; resume if GH or IGF-1 levels increase or signs/symptoms recur.

Children: Not recommended.

Also: Octreotide

SANDOSTATIN LAR DEPOT

R

Octreotide acetate 10mg, 20mg, 30mg; susp for IM inj after dilution; contains mannitol.

Indications: Long-term maintenance therapy of acromegaly in patients who have had an inadequate response or cannot be treated with surgery and/or radiotherapy and in whom immediate-release (IR) octreotide acetate is effective and tolerated.

Adults: Give by intragluteal IM inj. Not currently receiving octreotide: initiate therapy with immediate-release octreotide SC inj for at least 2 weeks. Switching from octreotide IR: initially 20mg every 4 weeks for 3months. After 3months, adjust as follows: GH≤2.5ng/mL, IGF-1 normal and clinical symptoms controlled: maintain dosage at 20mg every 4 weeks; GH≤1ng/mL, IGF-1 normal and clinical symptoms controlled: reduce to 10mg every 4 weeks; GH>2.5ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled: increase to 30mg every 4 weeks; may increase to max 40mg every 4 weeks. Pituitary irradiation recipients: withdraw therapy for 8 weeks once yearly to assess disease activity; resume

R

LEUPROLIDE

LUPRON DEPOT-PED AbbVie

GnRH analogue. Leuprolide acetate 7.5mg, 11.25mg or 15mg; per kit; depot sup for IM inj; preservative-free.

Indications: Central precocious puberty.

Adults: Not applicable.

Children: <2yrs: not recommended. ≥2yrs: Individualize. Give by single IM inj once a month. ≤25kg: 7.5mg; 25–37.5kg: 11.25mg; >37.5kg: 15mg; if inadequate response with starting dose, may increase to next available higher dose. Also, dose may be adjusted with changes in body weight.

Also: Leuprolide

LUPRON DEPOT-PED 3 MONTH

Leuprolide acetate 11.25mg, 30mg; per kit; depot sup for IM inj; preservative-free.

Adults: Not applicable.

Children: <2yrs: not recommended. ≥2yrs: 11.25mg or 30mg as a single IM inj once every 3 months. If inadequate response, consider other alternative treatments.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: Confirm diagnosis.

History of seizures. Epilepsy. Cerebrovascular disorders. CNS anomalies/tumors. Monitor hormonal

R

if GH or IGF-1 levels increase or signs/symptoms recur.

Children: Not recommended.

Warnings/Precautions: Diabetes. Hypothyroidism. Cardiovascular disease. Renal or hepatic impairment. Monitor growth hormone, IGF-1 levels, thyroid function, gallbladder, glucose, vitamin B₁₂. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiates bromocriptine, CYP450 substrates (eg, quinidine, terfenadine), bradycardia-inducing drugs (eg, β -blockers, calcium channel blockers). Antagonizes cyclosporine. Not compatible with TPN solutions. May need to adjust antidiabetic agents. May affect agents used to control fluid and electrolyte balance.

Adverse reactions: Gallbladder abnormalities (eg, gallstones, biliary sludge), GI upset, bradycardia, conduction abnormalities, arrhythmias, hyperglycemia, hypoglycemia, hypothyroidism, injection site pain, headache, dizziness, pancreatitis, altered dietary fat absorption.

How supplied: Ampules 50mcg/mL, 100mcg/mL, 500mcg/mL (1mL)–10
Multi-dose vials 200mcg/mL, 1000mcg/mL (5mL)–1 LAR kit–1 (5mL vial w. supplies)

SOMATROPIN

R

GENOTROPIN Pfizer

Growth hormone (GH). Somatropin (rDNA origin) lyophilized pwd 1.5mg (1.3mg/mL after reconstitution, preservative-free), 5.8mg (5mg/mL after reconstitution, preserved with m-Cresol), 13.8mg (12mg/mL after reconstitution, preserved with m-Cresol); for SC inj.

Also: Somatropin

GENOTROPIN MINIQUICK

R

Somatropin (rDNA origin) 0.2mg, 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg; per 0.25mL; lyophilized pwd for SC inj after reconstitution; preservative-free.

Indications: Long-term treatment of growth failure in children, due to inadequate GH secretion or Prader-Willi Syndrome (PWS), or in those born small for gestational age (SGA) who do not manifest catch-up growth by 2 years of age. Long-term replacement therapy in adults with GH deficiency (GHD) confirmed by appropriate GH stimulation test.

Adults: Give by SC inj into thigh, buttocks, or abdomen; rotate inj site. Individualize; give weekly dose in 6 or 7 divided doses. Initially up to 0.04mg/kg per week, may increase at 4–8 week intervals to max 0.08mg/kg per week.

Children: Give by SC inj into thigh, buttocks, or abdomen; rotate inj site. Individualize; give weekly dose in 6 or 7 divided doses. GHD: 0.16–0.24mg/kg per week. PWS: 0.24mg/kg per week. SGA: 0.48mg/kg per week.

Contraindications: Children with fused epiphyses. Active neoplasia. Acute critical illness due to surgical complications or multiple trauma. Acute respiratory

failure. Severe obesity or severe respiratory impairment in PWS patients.

Warnings/Precautions: Monitor gait, thyroid function, glucose tolerance, and for leukemia, scoliosis progression, malignant transformation of skin lesions, intracranial lesion progression or recurrence or intracranial hypertension (do fundoscopic exam at baseline then periodically). PWS: evaluate for upper airway obstruction before starting; monitor weight, for sleep apnea, respiratory impairment/obstruction (eg, snoring; suspend therapy if occurs) or respiratory infection (treat aggressively if occurs). Pregnancy (Cat.B). Nursing mothers.

Interactions: May be antagonized by glucocorticoids. Monitor drugs metabolized by CYP450 (eg, steroids, anticonvulsants, cyclosporine).

Adverse reactions: Antibody formation, local reactions. Pediatric GHD: headache, hematuria, hypothyroidism. PWS: edema, aggressiveness, arthralgia, hair loss, headache, myalgia. SGA: jaw prominence, progression of pigmented nevi. Adult GHD: edema, arthralgia, extremity pain/stiffness, paresthesia, myalgia.

How supplied: Intra-Mix Device (1.5mg)–5

Intra-Mix Device (5.8mg)–1, 5

Pen or Mixer device (5.8mg, 13.8mg)–1, 5

MiniQuick (0.25mL)–7

All: as two-chambered cartridge w. diluent

SOMATROPIN

R

HUMATROPE Lilly

Growth hormone (GH). Somatropin 5mg (rDNA origin); pwd for SC or IM inj after reconstitution; diluent contains m-cresol.

Indications: Long-term treatment of growth failure in children due to GH deficiency (GHD). Treatment of short stature associated with Turner syndrome in children whose epiphyses are not closed. Long-term treatment of idiopathic short stature. Replacement therapy in adults.

Adults: Give by SC inj once daily; rotate inj site. <65 years: Initially up to 0.006mg/kg per day, may increase to max 0.0125mg/kg per day.

Children: GHD: 0.18mg/kg per week SC or IM divided into equal doses on 3 alternate days or 6 times per week or daily; max 0.3mg/kg per week. Turner syndrome: up to 0.375mg/kg per week SC divided into equal doses daily or on 3 alternate days. Idiopathic short stature: up to 0.37mg/kg per week SC divided into equal doses given 6 to 7 times per week.

Contraindications: Children with fused epiphyses. Active neoplasias. Acute critical illness due to surgical complications or multiple trauma. Acute respiratory failure. Diabetic retinopathy. Prader-Willi syndrome (severely obese or w. respiratory impairment); see literature.

Warnings/Precautions: Monitor gait, thyroid function, glucose tolerance (esp. in diabetes), and for leukemia, scoliosis progression, malignant transformation of skin lesions, intracranial lesion

progression or recurrence or intracranial hypertension (do funduscopic exam at baseline then periodically). Prader-Willi syndrome: evaluate baseline respiratory function; monitor weight and for respiratory infection. Discontinue if signs of upper airway obstruction or sleep apnea occur. Monitor Turner syndrome patients for ear or cardiovascular disorders. Pregnancy (Cat.C). Nursing mothers.

Interactions: May be antagonized by glucocorticoids. May affect CYP3A4 substrates.

Adverse reactions: Edema, ear disorders, myalgia, arthralgia, hyperlipidemia, gynecomastia, headache, weakness, glucosuria, antibody formation, elevated serum phosphate. Long-term overdose may cause gigantism and/or acromegaly.

How supplied: Vials (5 mg)–6 (w. diluent) Cartridge kit (6 mg, 12 mg, 24 mg)–1 (w. diluent in prefilled syringe) HumatroPen (device for use with cartridge)–1

SOMATROPIN

NUTROPIN Genentech

Growth hormone (GH). Somatropin (rDNA origin) 10mg per vial; pwd for SC inj after reconstitution; diluent contains benzyl alcohol.

Also: Somatropin

NUTROPIN AQ

Somatropin (rDNA origin) 2.5mg/mL, 5mg/mL, 10mg/mL; liq for SC inj; contains phenol.

Indications: Treatment of children with growth failure due to growth hormone deficiency (GHD), idiopathic short stature (ISS), Turner syndrome (TS), and chronic kidney disease (CKD) up to the time of renal transplantation. Treatment of adults with childhood-onset or adult-onset GHD.

Adults: Individualize. Rotate inj site. Weight-based regimen: initially not more than 0.006mg/kg SC daily, may increase to max 0.025mg/kg daily in adults ≤35yrs or 0.0125mg/kg daily in adults >35yrs. Non weight-based regimen: initially 0.2mg/day SC (range: 0.15–0.3mg/day); may increase gradually every 1–2 months by increments of approximately 0.1–0.2mg/day. Elderly or obese: may need lower dose.

Children: Individualize. Rotate inj site. Give in daily divided doses by SC inj. GHD: up to 0.3mg/kg/week. Pubertal patients: up to 0.7mg/kg/week. ISS: up to 0.3mg/kg/week. CKD: up to 0.35mg/kg/week. Dialysis: see literature. TS: up to 0.375mg/kg/week divided into equal doses 3–7 times per week.

Contraindications: Acute critical illness. Acute respiratory failure. Children with closed epiphysis. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy. Prader-Willi syndrome (severely obese or w. respiratory impairment): see literature.

Warnings/Precautions: Monitor gait, thyroid function, glucose tolerance, and for malignant transformation of skin lesions or for intracranial hypertension (do baseline and periodic funduscopic exams). Discontinue if signs of neoplasia, upper

airway obstruction or sleep apnea occur. Not for use in patients with functioning renal allografts. History of intracranial lesions: monitor for lesion progression or recurrence. Hypopituitarism. Preexisting scoliosis. Obtain baseline hip X-ray and monitor for renal osteodystrophy in renal failure. Monitor for otitis media, other ear disorders, and cardiovascular disorders in Turner syndrome. May elevate serum phosphate, alkaline phosphatase, parathyroid hormone. Elderly. Newborns. Pregnancy (Cat.C). Nursing mothers.

Interactions: May be antagonized by glucocorticoids; adjust doses. May affect CYP450 substrates (eg, corticosteroids, sex steroids, anticonvulsants, cyclosporine); monitor. Concomitant oral estrogens: may require larger somatropin doses. Insulin and/or oral/IV hypoglycemic agents may require adjustment before starting therapy.

Adverse reactions: Local reactions, progression of scoliosis, intracranial hypertension, slipped capital epiphysis, edema, arthralgia, carpal tunnel syndrome, gynecomastia, antibody formation; rare: pancreatitis (monitor).

How supplied: Nutropin vial–1 (w. diluent)

Nutropin AQ (2mL) vial–1

Nutropin AQ (2mL) pen–1

Nutropin AQ (2mL) NuSpin–1

SOMATROPIN

TEV-TROPIN Teva US Generics

Growth hormone (GH). Somatropin (rDNA origin) 5mg (15 IU); pwd for SC inj after reconstitution; contains mannitol; diluent contains benzyl alcohol.

Indications: Growth failure in children due to inadequate endogenous GH secretion.

Adults: Not recommended.

Children: Individualize. Give by SC inj up to 0.1mg/kg 3 times per week; rotate inj site.

Contraindications: Acute critical illness. Acute respiratory failure. Closed epiphyses. Active malignancy or growing intracranial tumors. Diabetic retinopathy. Prader-Willi syndrome (severely obese or w. respiratory impairment); see literature.

Warnings/Precautions: Monitor gait, thyroid function, glucose tolerance, for malignant transformation of skin lesions, and for intracranial hypertension (do baseline and periodic funduscopic exams). History of intracranial lesions: monitor for lesion progression or recurrence. Prader-Willi syndrome: evaluate baseline respiratory function; monitor weight and for respiratory infection. Discontinue if signs of upper airway obstruction or sleep apnea occurs. Diabetes. Hypothyroidism. Scoliosis. Turner syndrome: evaluate for ear disorders (eg, otitis media); monitor for cardiovascular disorders (eg, stroke, aortic aneurysm/dissection, hypertension). Pregnancy (Cat.C). Nursing mothers.

Interactions: Antagonized by glucocorticoids. Antidiabetic medications may need to be adjusted. May affect CYP3A4 substrates.

Adverse reactions: Headache, inj site reactions, localized muscle pain, weakness, hypothyroidism, mild hyperglycemia, glucosuria, arthralgia, myalgia, fluid retention, edema, elevated serum phosphate, antibody formation, pancreatitis; also children: slipped capital femoral epiphysis. Long-term overdose may cause gigantism and/or acromegaly.

How supplied: Vials (5mg)-1 (w. diluent)

4E Thyroid disease

LEVOTHYROXINE

SYNTHROID AbbVie

T₄ (synthetic). Levothyroxine sodium 25mcg, 50mcg (dye-free), 75mcg, 88mcg, 100mcg, 112mcg, 125mcg, 137mcg, 150mcg, 175mcg, 200mcg, 300mcg; scored tabs.

Indications: Hypothyroidism.

Adults: Take in AM on empty stomach.

Hypothyroidism: 1.7mcg/kg once daily. >50yrs, or <50yrs with cardiovascular disease: initially 25-50mcg once daily; titrate in increments of 12.5-25mcg every 6-8 weeks. Elderly with cardiovascular disease: initially 12.5-25mcg once daily; titrate in increments of 12.5-25mcg every 4-6 weeks. Usual max 200mcg/day. Severe hypothyroidism: initially 12.5-25mcg once daily; titrate in increments of 25mcg/day every 4 weeks. Subclinical hypothyroidism, secondary or tertiary hypothyroidism: see literature.

Children: Give once daily on empty stomach. May crush tabs and mix in 5-10mL water. Hypothyroidism: 0-3months: 10-15mcg/kg per day; 3-6months: 8-10mcg/kg per day; 6-12months: 6-8mcg/kg per day; 1-5yrs: 5-6mcg/kg per day; 6-12yrs: 4-5mcg/kg per day; >12yrs: 2-3mcg/kg per day; growth and puberty complete: as adult. Chronic or severe hypothyroidism: initially 25mcg/day; titrate in increments of 25mcg every 4weeks. Infants with serum *T₄* <5mcg/dL: initially 50mcg/day.

Also: Levothyroxine

SYNTHROID INJECTION

Levothyroxine sodium 200mcg, 500mcg; pwd for IV or IM inj after reconstitution.

Indications: Rapid induction in hypothyroidism or myxedema coma, if oral route not feasible.

Adults: Myxedema coma: 200-500mcg IV once (may reduce dose in cardiovascular disease), may give 100-300mcg (or more) IV on second day if needed, then 50-100mcg IV daily; switch to oral form and dose as soon as feasible. Hypothyroidism: ½ oral dose by IV or IM inj; titrate.

Children: Consult manufacturer.

Contraindications: Uncorrected adrenal insufficiency. Untreated thyrotoxicosis. Acute MI.

Warnings/Precautions: Not for treatment of obesity or infertility. Cardiovascular disease. Seizures. Adrenocortical insufficiency. Increased sensitivity in severe hypothyroidism. Autonomous thyroid tissue.

Elderly. Pregnancy (Cat.A); do not discontinue due to pregnancy. Nursing mothers.

Interactions: See literature. Absorption reduced by some foods (eg, soy, fiber), aluminum and magnesium hydroxide, simethicone, calcium carbonate, sodium polystyrene sulfonate, bile acid sequestrants, iron, sucralate (give at least 4 hrs apart). Potentiates, and is potentiated by, tri- and tetracyclol antidepressants, sympathomimetics. Antagonized by hepatic enzyme inducers (eg, carbamazepine, phenytoin, phenobarbital, rifampin), sertraline. Antagonizes digoxin. Marked hypertension and tachycardia with ketamine. Estrogens affect thyroid function tests. Monitor oral anticoagulants, antidiabetic agents, theophylline.

Adverse reactions: Hyperthyroidism, decreased bone mineral density, transient alopecia; seizures (rare); pseudotumor cerebri in children.

How supplied: Tabs-90, 1000; Single dose vials (10mL)-1

PROPYLTHIOURACIL

PROPYLTHIOURACIL (various)

Antithyroid. Propylthiouracil 50mg; scored tabs; contains docusate sodium.

Indications: Hyperthyroidism.

Adults: Give in 3 equally divided doses every 8 hrs. Initially 300mg/day. Severe conditions: initially 400mg/day; max 900mg/day. Maintenance: 100-150mg/day.

Children: Give in 3 equally divided doses every 8 hrs. <6yrs: not recommended. 6-10yrs: initially 50-150mg/day. ≥10yrs: initially 150-300mg/day.

Contraindications: Nursing mothers.

Warnings/Precautions: Monitor blood.

Discontinue if hepatic dysfunction, agranulocytosis, aplastic anemia, fever, or exfoliative dermatitis occurs. Pregnancy (Cat.D).

Interactions: May potentiate anticoagulants. Caution with other drugs that may cause agranulocytosis.

Adverse reactions: Rash, urticaria, GI upset, arthralgia, paresthesia, taste loss/perversion, hair loss, myalgia, headache, drowsiness, edema, vertigo, jaundice, blood dyscrasias, lupus-like syndrome, drug fever, hepatitis, hypoprothrombinemia.

How supplied: Tabs-100, 1000

SECTION 5:

GASTROHEPATIC DISORDERS 5A Colorectal disorders

ADALIMUMAB

HUMIRA AbbVie

Tumor necrosis factor-α blocker. Adalimumab 20mg/0.4mL, 40mg/0.8mL; soln for SC inj; preservative-free.

Indications: In moderately-to-severely active Crohn's disease (CD): to reduce signs/symptoms

and to induce and maintain clinical remission in adult patients with inadequate response to conventional therapy; and to reduce signs/symptoms and to induce clinical remission in these patients who have also lost response to or are intolerant to infliximab. In moderately-to-severely active ulcerative colitis (UC); for inducing and sustaining clinical remission in adults who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-MP.

Adults: Inject SC into thigh or abdomen; rotate inj sites; supervise 1st dose. ≥ 18 yrs: 160mg (as 4 injections in 1 day or divided over 2 days) at week 0, then 80mg at week 2. At week 4, start maintenance of 40mg every other week. May continue aminosaliclates, corticosteroids, or immunomodulatory agents. CD: use beyond 1 year has not been evaluated. UC: only continue if evidence of clinical remission by 8 weeks.

Children: <18yrs: not recommended.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Lymphoma and other malignancies. Active infections: do not initiate therapy. Chronic or history of recurring infections. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. CHF (monitor). Immunosuppression. Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs. CNS demyelinating disorders. Juvenile arthritis: follow up on current immunizations before starting therapy. Latex allergy. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent abatacept, anakinra, live vaccines, or other TNF blockers: not recommended. Immunosuppressants increase risk of infection.

Adverse reactions: Inj site reactions, infections (may be serious), headache, nausea, rash, abdominal pain; rare: malignancies (eg, lymphoma; esp children), blood dyscrasias, hypertension, neurological events, antibody formation, lupus-like syndrome.

How supplied: Single-dose prefilled syringe-2; Single-dose prefilled pen-2, 6 (Starter Package)

ALVIMOPAN

ENTEREG Cubist

Opioid antagonist (peripheral). Alvimopan 12mg; caps.

Indications: To accelerate the time to upper and lower gastrointestinal recovery after partial large or small bowel resection surgery with primary anastomosis.

Adults: 12mg orally 30min to 5 hours before surgery, then 12mg twice daily starting on 1st

post-op day for up to 7 days or until hospital discharge (max 15 doses).

Children: Not recommended.

Contraindications: Opioid use, at therapeutic doses, for >7 consecutive days prior.

Warnings/Precautions: For hospital use only. Severe hepatic impairment or end stage renal disease: not recommended. Mild-to-severe renal dysfunction or mild-to-moderate hepatic impairment (monitor; discontinue if adverse reactions occur). Recent (within 1 week) use of more than 3 doses of opioids. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Dyspepsia, constipation, flatulence, back pain, urinary retention.

Note: Available only to hospitals that enroll in Entereg Access and Support Program (EASE). For more information, and to enroll, call (866) 4ADOLOR.

How supplied: Caps-30

BALSALAZIDE

GAZO Salix

Aminosaliclate. Balsalazide disodium 1.1g; tabs; contains sodium 126mg/tab.

Indications: Treatment of mildly-to-moderately active ulcerative colitis in male patients. Limitations of use: effectiveness in treatment of female patients was not demonstrated. Safety and effectiveness of therapy beyond 8 weeks have not been established.

Adults: ≥ 18 yrs: 3 tabs twice daily; max 8 weeks.

Children: <18yrs: not established.

Warnings/Precautions: Monitor for worsening symptoms of ulcerative colitis. Discontinue if acute intolerance syndrome is suspected. Known or history of renal impairment. Monitor renal function prior to initiating and periodically during therapy. Hepatic impairment; consider monitoring LFTs during therapy. Elderly. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: In male patients: anemia, diarrhea, pharyngolaryngeal pain, UTI.

How supplied: Tabs-180

BUDESONIDE

ENTOCORT EC AstraZeneca

Steroid. Budesonide (micronized) 3mg; e-c granules in caps.

Indications: Mild to moderate Crohn's disease of the ileum and/or ascending colon: to treat and to maintain clinical remission for up to 3 months.

Adults: Swallow whole. Treatment: 9mg once daily in the AM for up to 8 weeks; may repeat an 8-week course. Maintenance of remission: 6mg once daily for up to 3 months. Taper other systemic steroids when transferring to budesonide.

Children: Not recommended.

Warnings/Precautions: Systemic fungal, viral, or mycobacterial infections. Live vaccines. Hypertension. Diabetes. Osteoporosis. Peptic ulcer. Glaucoma. Cataracts. If exposed to chickenpox or measles, consider prophylactic passive immune therapy. Supplement with more steroids in physiologic stress.

Caution when transferring from steroids with high systemic availability. Monitor for hypercorticism in moderate to severe liver disease; consider reducing dose. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid grapefruit juice. Systemic effects may be potentiated by CYP3A4 inhibitors (eg, ketoconazole, ritonavir, erythromycin); consider reducing budesonide dose. Drug release characteristics may be affected by drugs that affect gastrointestinal pH.

Adverse reactions: Headache, infection, sinusitis, nausea, arthralgia, hypercorticism (eg, acne, bruising, face edema, hirsutism).

How supplied: Caps-100

CERTOLIZUMAB PEGOL

R

CIMZIA UCB

Tumor necrosis factor blocker. Certolizumab pegol 200mg/mL soln for SC inj; or per vial (pwd for SC inj after reconstitution); preservative-free.

Indications: In moderately to severely active Crohn's disease: to reduce signs and symptoms and to maintain clinical response in adult patients with inadequate response to conventional therapy.

Adults: Rotate inj site. Give by SC inj in abdomen or thigh. 400mg (two 200mg inj at separate sites) on day 1, then at weeks 2 and 4; maintenance 400mg every 4 weeks.

Children: Not recommended.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. History of histoplasmosis exposure. Malignancies. Skin cancer risk factors: perform periodic skin exams. Immunosuppressed. Pre-existing or recent-onset demyelinating disorders (eg, multiple sclerosis, Guillain-Barré syndrome). CHF (monitor). Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent anakinra, abatacept, rituximab, natalizumab, live or attenuated vaccines, or other TNF blockers: not recommended. Immunosuppressants increase risk of infection. May interfere with coagulation tests (eg, aPTT).

Adverse reactions: Upper respiratory infections, rash, UTI, arthralgia, other infections; rare: TB, HBV reactivation, hypertension, heart failure, back

pain, hypersensitivity reactions, malignancies (eg, lymphoma; esp. children), neurological disorders (seizures, optic neuritis, peripheral neuropathy), antibody formation, lupus-like syndrome.

How supplied: Kit-1 (2 single-dose vials w. syringes, needles, supplies); Single-use prefilled syringes-2 (w. supplies); Prefilled Syringe Starter Kit-6 (w. supplies)

GOLIMUMAB

R

SIMPONI Janssen Biotech

TNF blocker. Golimumab 50mg/0.5mL; soln for SC inj; preservative-free.

Indications: In moderately-to-severely active ulcerative colitis (UC) adult patients who have demonstrated corticosteroid dependence or have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine or 6-MP for: inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, achieving and sustaining clinical remission in induction responders.

Adults: Initially 200mg by SC inj at Week 0, followed by 100mg at Week 2, and then 100mg every 4 weeks. Rotate inj sites.

Children: <18yrs: not established.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring or opportunistic infections. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, new or worsening CHF, hematological abnormality (eg, cytopenias), or serious hypersensitivity reaction develops. Malignancies. Prior history of dysplasia. CHF (monitor). Immunosuppression. CNS demyelinating disorders. Latex allergy. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent abatacept, anakinra, live vaccines, or other TNF blockers: not recommended. Immunosuppressants increase risk of infection. Monitor CYP450 substrates with narrow therapeutic index.

Adverse reactions: Inj site reactions, infections (may be serious), upper respiratory tract infection, nasopharyngitis, hypertension; rare: malignancies (eg, skin, lymphoma; monitor), blood dyscrasias, new or worsening CHF, elevated liver enzymes, antibody formation, exacerbation or new onset of psoriasis.

How supplied: Single-dose SmartJect autoinjector-1; Single-dose prefilled syringe-1

INFLIXIMAB**REMICADE** Janssen Biotech*Tumor necrosis factor- α blocker.* Infliximab 100mg/vial; lyophilized powder for IV infusion after reconstitution and dilution; preservative-free.**Indications:** In moderately-to-severely active Crohn's disease: to reduce signs/symptoms and to induce and maintain clinical remission in adult and pediatric patients with inadequate response to conventional therapy. In fistulizing Crohn's disease: to reduce number of draining enterocutaneous and rectovaginal fistula(s); and maintain fistula closure in adults. In moderately-to-severely active ulcerative colitis (UC): to reduce signs/symptoms, to induce and maintain clinical remission and mucosal healing, and to eliminate corticosteroid use in adults with inadequate response to conventional therapy. In moderately-to-severely active UC: to reduce signs/symptoms and to induce and maintain clinical remission in pediatric patients with inadequate response to conventional therapy.**Adults:** Give by IV infusion over at least 2 hours. Crohn's disease: 5mg/kg at weeks 0, 2, 6, then once every 8 weeks; if relapse, may increase to 10mg/kg; discontinue if no response by week 14. UC: 5mg/kg at weeks 0, 2, 6, then once every 8 weeks. Both: max 5mg/kg in heart failure.**Children:** <6yrs: not recommended. $\geq$ 6yrs: Give by IV infusion over at least 2 hours. Active Crohn's disease or UC: 5mg/kg at weeks 0, 2, 6, then once every 8 weeks.**Contraindications:** Moderate to severe heart failure (doses >5mg/kg). Allergy to murine proteins.**Warnings/Precautions:** Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, viral, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections or hematological abnormalities. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. Discontinue if lupus-like syndrome with autoantibody formation, severe hypersensitivity reactions, or jaundice with liver enzymes $\geq$ 5 $\times$ ULN occurs. Pre-existing heart failure; closely monitor and discontinue if new or worsening symptoms occur. CNS demyelinating or seizure disorders; discontinue if significant CNS effects occur. Malignancies (eg, melanoma; perform periodic skin exams). Children: complete vaccinations before starting therapy (see literature). Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.**Interactions:** Concurrent anakinra, abatacept, tocilizumab, live vaccines, other TNF blockers or biological therapeutics: not recommended.

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Concomitant immunosuppressants (eg, corticosteroids, methotrexate) may increase risk of infection. May be potentiated by methotrexate. Concomitant CYP450 substrates with narrow therapeutic index (eg, warfarin, cyclosporine, theophylline): monitor and may need to adjust dose of these drugs. Caution with switching between DMARDs; overlapping may further increase the risk of infection.

Adverse reactions: Infections, infusion reactions (esp. after a period of no treatment), headache, abdominal pain, GI upset, fatigue, cough, fever, pain, dizziness, rash, pruritus, CHF, autoantibody formation; malignancies (eg, skin, lymphoma; esp children), optic neuritis, seizures, lupus-like syndrome, blood dyscrasias, hepatotoxicity.**How supplied:** Single-use vials-1**LINACLOTIDE**

R

LINZESS Forest*Guanylate cyclase-C agonist.* Linacotide 145mcg, 290mcg; capsules.**Indications:** Irritable bowel syndrome with constipation (IBS-C).**Adults:** Swallow whole. Take on empty stomach, at least 30 minutes before first meal of the day. 290mcg once daily.**Children:** <6yrs: contraindicated. 6-17yrs: avoid.**Contraindications:** Children up to 6 years old. Known or suspected mechanical GI obstruction.**Warnings/Precautions:** Hold or stop if severe diarrhea occurs. Pregnancy (Cat.C). Nursing mothers.**Adverse reactions:** Diarrhea, abdominal pain, flatulence, abdominal distention.**How supplied:** Caps-30**LUBIPROSTONE**

R

AMITIZA Sucampo and Takeda*GI motility enhancer (chloride channel activator).*

Lubiprostone 8mcg, 24mcg; caps.

Indications: Irritable bowel syndrome with constipation (IBS-C) in women.**Adults:** Swallow whole. Take with food and water. $\geq$ 18yrs: 8mcg twice daily. Severe hepatic impairment (Child-Pugh Class C): 8mcg once daily.**Children:** <18yrs: not recommended.**Contraindications:** Known or suspected mechanical GI obstruction.**Warnings/Precautions:** Confirm absence of GI obstruction before starting therapy. Severe diarrhea: not recommended. Renal or hepatic impairment. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers; monitor infants for diarrhea.**Interactions:** Possibly antagonized by diphenylheptane opioids (eg, methadone).**Adverse reactions:** Nausea, headache, diarrhea (suspend therapy if occurs), abdominal pain, abdominal distension, flatulence, dyspnea, vomiting, syncope, asthenia, others.**How supplied:** 8mcg-60; 24mcg-60, 100

MESALAMINE

R

ASACOL HD Warner Chilcott*Salicylate. Mesalamine 800mg; delayed release tabs.***Indications:** Moderately active ulcerative colitis.**Adults:** Swallow whole; do not crush or chew.

Treatment: 1600mg 3 times daily for 6 weeks.

Children: Not recommended.**Warnings/Precautions:** History of renal disease; monitor renal function before and during therapy. Pyloric stenosis. Pre-existing liver disease. Reevaluate periodically. Elderly (monitor CBCs). Pregnancy (Cat.B). Nursing mothers.**Adverse reactions:** Headache, GI upset or pain, constipation, eructation, nasopharyngitis, exacerbation of colitis symptoms (discontinue if occurs), dizziness, asthenia; renal impairment (eg, interstitial nephritis, minimal change nephropathy, renal failure [rare]).**How supplied:** Tabs-180**NATALIZUMAB**

R

TYSABRI Biogen Idec*Immunomodulator (integrin receptor antagonist).*

Natalizumab 300mg/15mL; soln; for IV infusion after dilution; preservative-free.

Indications: In moderately-to-severely active Crohn's disease; to induce and maintain clinical response and remission in adult patients with evidence of inflammation who have had inadequate response to or are intolerant to conventional therapy and TNF- α inhibitors.**Adults:** ≥ 18 yrs: Give by IV infusion over 1 hour; monitor during and for 1 hour post-infusion. 300mg every 4 weeks. Discontinue after 12 weeks of induction therapy if no therapeutic response, or if unable to taper off chronic concomitant steroids within 6 mos of starting therapy. May continue with aminosaliclates.**Children: < 18 yrs: not recommended.****Contraindications:** Progressive multifocal leukoencephalopathy (PML).**Warnings/Precautions:** Renal or hepatic insufficiency. Monitor for signs and symptoms of PML; discontinue if occurs. Test patients for anti-JVC antibody status prior to or during treatment if status unknown; patients with negative status should be retested periodically. Increased risk of PML with longer treatment duration, prior treatment with immunosuppressant, and/or presence of anti-JVC antibodies. Reevaluate periodically (at 3 months and 6 months post-infusion, then every 6 months thereafter). Immunosuppression. Vaccinations. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** Concomitant other immunosuppressants or TNF- α inhibitors: not recommended.**Adverse reactions:** Headache, fatigue, arthralgia, infections, allergic reactions (discontinue if occurs; do not restart), hepatotoxicity (monitor and discontinue

if occurs), nausea, cholelithiasis, urticaria, inj site reactions; antibody formation (if persistent, may substantially reduce efficacy); changes in blood cell counts; intestinal obstruction or stenosis, abdominal adhesions.

Note: This product is only available through the TOUCH prescribing program. For more information call (800) 456-2255.**How supplied:** Single-use vial (300mg)-1**TEDUGLUTIDE**

R

GATTEX NPS*Glucagon-like peptide-2 analog. Teduglutide 5mg; per vial; lyophilized pwd for SC inj after reconstitution.***Indications:** Treatment of adult patients with short bowel syndrome (SBS) who are dependent on parenteral support.**Adults:** Administer by SC inj only; alternate sites between 1 of the 4 quadrants of the abdomen, or into alternating thighs or arms. 0.05mg/kg once daily. Do not take 2 doses on the same day. Moderate-to-severe renal impairment, and ESRD: reduce dose by 50%.**Children: Not established.****Warnings/Precautions:** Risk of neoplastic growth acceleration. Discontinue in active GI malignancy (eg, GI tract, hepatobiliary, pancreatic), colorectal or small bowel cancer. Perform colonoscopy with removal of polyps within 6 months before starting; repeat at end of 1 year therapy and every 5 years or more as needed. Temporarily discontinue if intestinal or stomal bstruction develops; may restart if resolves. Monitor for biliary and pancreatic disease; assess bilirubin, alkaline phosphatase, lipase, amylase within 6 months before starting and at least every 6 months during treatment, or more if needed. Risk of fluid overload; if occurs, adjust parenteral support and reassess treatment (esp. in underlying cardiovascular disease). Reevaluate treatment if significant cardiac deterioration develops. Pregnancy (Cat.B). Nursing mothers: not recommended.**Interactions:** Concomitant oral drugs requiring titration or with a narrow therapeutic index (eg, benzodiazepines, phenothiazines): may require dose adjustment and monitor.**Adverse reactions:** Abdominal pain, inj site reactions, nausea, headaches, abdominal distension, upper respiratory tract infection, vomiting, fluid overload.**How supplied:** Single-use vial-1; one-vial kit (w. supplies); 30-vial kit (w. supplies)**ADVERSE REACTIONS**

Those adverse reactions listed within product monographs represent the potential for adverse effects based upon the active ingredient(s) and/or the drug class. It is not meant to be an inclusive list of responses.

5B Constipation and bowel cleansers

PEG 3350

GoLYTELY Baintree
Isoosmotic bowel cleanser. Polyethylene glycol 3350 236g, sodium chloride 5.86g, potassium chloride 2.97g, sodium bicarbonate 6.74g, sodium sulfate 22.74g; per 4 liters of soln; pwd for reconstitution; original or pineapple flavor.

Indications: Bowel cleansing before GI examination.

Adults: No solid food for at least 2 hrs, then 240mL orally every 10 minutes or 20–30mL/minute by NG tube until rectal effluent is clear or 4 liters consumed. May interrupt if severe GI disturbances occur. Only clear liquids until exam.

Children: Not recommended.

Contraindications: GI obstruction or perforation. Gastric retention. Toxic colitis. Toxic megacolon or ileus.

Warnings/Precautions: Severe ulcerative colitis. Impaired gag reflex. Semi- or unconsciousness. Risk of aspiration or regurgitation. Pregnancy (Cat.C).

Interactions: Drugs administered within 1 hr of start of Golytely may not be absorbed.

Adverse reactions: Nausea, abdominal fullness and bloating, cramps, vomiting, anal irritation.

How supplied: Disposable jug (4L)–1 Packets (to make 4L)–1

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PEG 3350

MIRALAX Merck
Osmotic. Polyethylene glycol (PEG) 3350; pwd for solution.

Indications: Occasional constipation.

Adults: ≥ 17 yrs: Dissolve 17g in 4–8oz liquid and drink once daily for up to 7 days. May need 1–3 days for results.

Children: < 17 yrs: not recommended.

Contraindications: Bowel obstruction (known or suspected).

Warnings/Precautions: Renal impairment: not recommended. Nausea, vomiting, abdominal pain or IBS: exclude bowel obstruction. Avoid prolonged, frequent, or excessive use. Pregnancy. Nursing mothers.

Adverse reactions: Loose, watery, frequent stools.

How supplied: Powder–119g, 238g, 510g (w. measuring cap); Single-dose packets (17g)–10

OTC

5C Diarrhea

CROFELEMER

FULYZAQ Salix
Antidiarrheal. Crofelemer 125mg; delayed-release tablets; enteric-coated.

Indications: Symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on antiretroviral therapy.

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Adults: Swallow whole. One tab twice daily.

Children: < 18 yrs: not established.

Warnings/Precautions: Rule out infectious etiologies of diarrhea before starting. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Upper respiratory tract infection, bronchitis, cough, flatulence, increased bilirubin.

How supplied: Tabs–60

DIPHENOXYLATE + ATROPINE CV

LOMOTIL Pfizer

Opioid + anticholinergic. Diphenoxylate HCl 2.5mg, atropine sulfate 0.025mg; tabs.

Also: **Diphenoxylate + Atropine** CV

DIPHENOXYLATE HCl/ATROPINE SULFATE ORAL

SOLUTION Roxane

Diphenoxylate HCl 2.5mg, atropine sulfate 0.025mg; per 5mL liq; alcohol 15%.

Indications: Adjunct to fluid and electrolyte replacement in diarrhea.

Adults: 2 tabs or 10mL 4 times daily until diarrhea is controlled. Maintenance: 2 tabs or 10mL daily.

Children: < 2 yrs: not recommended. 2–12 yrs:

initially 0.3–0.4mg/kg in 4 divided doses until diarrhea is controlled. Maintenance: 25% initial dose; max 48hrs.

Contraindications: Pseudomembranous enterocolitis. Obstructive jaundice. Diarrhea caused by organisms that penetrate intestinal mucosa. Age < 2 yrs.

Warnings/Precautions: Dehydration. Acute ulcerative colitis; discontinue if toxic megacolon occurs. Hepatic or renal disease. Abnormal liver function tests. Drug abusers. Pregnancy (Cat.C). Nursing mothers.

Interactions: MAOIs may cause hypertensive crisis. Antimuscarinics may cause paralytic ileus. Potentiates sedation with alcohol, CNS depressants. May delay elimination of other drugs metabolized by CYP450.

Adverse reactions: Nausea, vomiting, abdominal discomfort, paralytic ileus, toxic megacolon, dizziness, drowsiness, headache, euphoria, tachycardia, numbness of extremities, pruritus, urticaria, angioneurotic edema, anticholinergic effects; respiratory depression (overdosage), atropinism.

How supplied: Tabs–100, 500, 1000, 2500; Soln–60mL

FIDAXOMICIN

DIFICID Optimer

Macrolide antibiotic. Fidaxomicin 200mg; tabs.

Indications: For the treatment of *Clostridium difficile*-associated diarrhea.

Adults: ≥ 18 yrs: 200mg twice daily for 10 days.

Children: < 18 yrs: not established.

Warnings/Precautions: Not for treating systemic infections (minimal systemic absorption). Known macrolide allergy. Discontinue if severe

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hypersensitivity reactions occur. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Nausea, vomiting, abdominal pain, GI hemorrhage, anemia, neutropenia.

How supplied: Tabs—20, 60, 100 (10×10 blister cards)

LOPERAMIDE

IMODIUM McNeil Cons & Specialty
Opioid. Loperamide HCl 2mg; caps.

Also: Loperamide

IMODIUM A-D CAPLETS

Loperamide 2mg.

Also: Loperamide

IMODIUM A-D LIQUID

Loperamide HCl 1mg/5mL; cherry-mint flavor; contains alcohol 0.5%.

Indications: Diarrhea.

Adults: Acute: Initially 4mg, then 2mg after each loose stool; max 16mg/day. Stop after 48 hours if ineffective. Chronic: initially 4mg; maintenance 4–8mg/day. Reevaluate if no improvement after 10 days at 16mg/day.

Children: <2yrs: not recommended. 24–47lbs (2–5yrs): 1mg up to 3 times daily for 2 days (use liq). 48–59lbs (6–8yrs): initially 2mg, then 1mg after each loose stool; max 4mg/day for 2 days. 60–95lbs (9–11yrs): initially 2mg, then 1mg after each loose stool; max 6mg/day for 2 days.

Also: Loperamide

IMODIUM MULTI-SYMPTOM RELIEF

Opioid + antispasmodic.

Loperamide HCl 2mg, simethicone 125mg; chew tabs; caplets; mint flavored; contains calcium.

Indications: Diarrhea with gas.

Adults: Chew tabs: take with 4–8oz of water after each dose. Initially 2 chew tabs or caplets, then 1 chew tab or caplet after each loose stool; max 4 tabs or caplets per day for 2 days.

Children: <6yrs: consult physician. Chew tabs: take with 4–8oz of water after each dose. ≥6yrs: initially 1 chew tab or caplet, then ½ chew tab or caplet after each loose stool. 48–59lbs (6–8yrs): max 2 tabs or caplets per day for 2 days. 60–95lbs (9–11yrs): max 3 tabs or caplets per day for 2 days.

Contraindications: If constipation must be avoided. Acute dysentery.

Warnings/Precautions: Acute ulcerative colitis and antibiotic induced pseudomembranous colitis; discontinue if abdominal distention occurs. In dehydration, use fluid and electrolyte replacement. Hepatic dysfunction; monitor for CNS toxicity. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Abdominal pain, distention, constipation, dry mouth, nausea, drowsiness, dizziness, fatigue, rash.

How supplied: Caps—30; A-D Caplets—6, 12, 18, 24; A-D Liq—2oz, 4oz; Multi-Symptom Caplets—12, 42; Multi-Symptom Chew tabs—18, 42

RIFAXIMIN

XIFAXAN 200MG Salix

Rifaximin. Rifaximin 200mg; tabs.

Indications: Travelers' diarrhea due to noninvasive *E. coli*.

Adults: 200mg 3 times daily for 3 days.

Children: Not recommended.

Warnings/Precautions: Not for use if diarrhea is accompanied by fever or blood in stool, or if causative agent other than *E. coli* may be suspected (eg, *C. jejuni*, *Shigella* spp., *Salmonella* spp.). Discontinue and reevaluate if diarrhea worsens or persists >24 hours. Not for treating systemic infections. Severe hepatic impairment. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Flatulence, headache, abdominal pain, rectal tenesmus, defecation urgency, nausea; pseudomembranous colitis.

How supplied: Tabs—30, 100

VANCOMYCIN

VANCOCIN ViroPharma

Antibiotic. Vancomycin (as HCl) 125mg, 250mg; caps.

Indications: Enterocolitis due to *S. aureus*.

Antibiotic-associated pseudomembranous colitis due to *C. difficile*.

Adults: ≥18yrs: 500mg–2g per day in 3–4 divided doses for 7–10 days. *C. difficile*-associated diarrhea: 125mg 4 times a day for 10 days.

Children: 40mg/kg per day in 3–4 divided doses for 7–10 days; max 2g/day.

Warnings/Precautions: Renal insufficiency and/or colitis. Inflammatory bowel disorders. Underlying hearing loss. Monitor hearing, blood, renal function. Consider monitoring vancomycin serum concentrations. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Monitor with aminoglycosides, other neurotoxic, nephrotoxic, or ototoxic drugs.

Adverse reactions: Nausea, abdominal pain, hypokalemia, drug fever, urticaria, rash (may be serious, eg, Stevens-Johnson syndrome), ototoxicity, nephrotoxicity, eosinophilia, anaphylaxis, superinfection, blood dyscrasias; rare: interstitial nephritis, vertigo.

How supplied: Caps—20

VANCOMYCIN

VANCOMYCIN INJECTION (various)

Antibiotic. Vancomycin (as HCl) 500mg/vial, 1g/vial; lyophilized pld for IV infusion after reconstitution and dilution.

Indications: Antibiotic-associated pseudomembranous colitis due to *C. difficile*.

Adults: Dilute dose in 1oz of water and drink or give via nasogastric tube; 500mg–2g per day in 3–4 divided doses for 7–10 days. Renal impairment: adjust or reduce dose, obesity; see literature.

Children: Dilute dose in 1 oz of water and drink or give via nasogastric tube; 40mg/kg per day in 3–4

divided doses for 7–10 days; max 2g/day. Renal impairment: adjust or reduce dose, obesity; see literature.

Warnings/Precautions: Renal insufficiency. Monitor hearing, blood, renal function. Monitor vancomycin serum concentrations closely. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Monitor with other ototoxic, nephrotoxic, neurotoxic drugs (eg, aminoglycosides, amphotericin B, bacitracin, polymyxin B, colistin, viomycin, cisplatin). Erythema, histamine-like flushing, anaphylactoid reactions may occur with concomitant anesthetic agents.

Adverse reactions: Nausea, drug fever, rash (may be serious, eg, Stevens-Johnson syndrome), ototoxicity, nephrotoxicity, blood dyscrasias; rare: interstitial nephritis, vertigo.

How supplied: Contact supplier.

5D Digestive and biliary disorders

LIPASE + PROTEASE + AMYLASE

CREON AbbVie

Pancreatic enzymes. Lipase/protease/amylase:

3000Units/9500Units/15000Units;
6000Units/19000Units/30000Units;
12000Units/38000Units/60000Units;
24000Units/76000Units/120000Units;
36000Units/114000Units/180000Units;
del-rel caps containing e-c spheres.

Indications: Treatment of exocrine pancreatic insufficiency due to cystic fibrosis, chronic pancreatitis, pancreatectomy, or other conditions.

Adults and Children: See literature. Start at the lowest recommended dose and increase gradually. Individualize based on clinical symptoms, the degree of steatorrhea present, and the fat content of the diet. Infants: May sprinkle directly into mouth or into a small amount of applesauce; do not mix directly into formula or breastmilk. ≤ 12 months: 3000 lipase units per 120mL of formula or per breastfeeding. Children and adults: Do not crush or chew caps; swallow whole, or may open and sprinkle contents into small amount of acidic food ($\text{pH} \leq 4$) and swallow mixture immediately. > 12 months– < 4 ys: 1000 lipase units/kg per meal; ≥ 4 ys: 500 lipase units/kg per meal. Max (for children and adults): 2500 lipase units/kg per meal (or ≤ 10000 lipase units/kg per day), or < 4000 lipase units/g fat ingested per day. Adults with exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy: individualize; in one study, patients received 72,000 lipase units per meal while consuming 100g of fat per day; lower starting doses are consistent with the 500 lipase units/kg per meal lowest starting dose recommended for adults in the guidelines.

Warnings/Precautions: Not interchangeable with any other pancrelipase products. Pork allergy. Potential viral transmission. Gout. Renal impairment. Hyperuricemia. Contents irritating to mucosa. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Abdominal pain, abnormal feces, cough, dizziness, flatulence, headache, weight decreased; hyperuricemia, fibrosing colonopathy (with high doses), allergic reactions.

How supplied: Caps 3000–70; 6000, 12000, 24000, 36000–100, 250

URSODIOL

R

ACTIGALL Actavis

Bile acid. Ursodiol 300 mg; caps.

Indications: Dissolution of radiolucent, noncalcified gallstones < 20 mm in diameter in patients who refuse cholecystectomy or are at increased risk during surgery. Prevention of gallstone formation in obese patients experiencing rapid weight loss.

Adults: Dissolution: 8–10mg/kg per day in 2–3 divided doses. Prevention: 300mg twice daily.

Children: Not recommended.

Contraindications: Not for calcified, radio-opaque, or radiolucent bile pigment stones. Compelling need for cholecystectomy.

Warnings/Precautions: Obtain sonogram at 6 and 12 months. After complete dissolution, repeat sonogram in 1–3 months and then discontinue. Gallstones can recur. Measure SGOT (AST) and SGPT (ALT) at start, 1 and 3 months later, and then every 6 months; monitor frequently if levels increase, and discontinue if elevations persist. Pregnancy (Cat.B): not recommended. Nursing mothers.

Interactions: Reduced absorption with bile acid sequestrants, aluminum-containing antacids. Estrogens, oral contraceptives, clofibrate, other lipid lowering drugs may reduce effectiveness by increasing hepatic cholesterol secretion.

Adverse reactions: Diarrhea.

How supplied: Caps–100

URSODIOL

R

URSO Aptalis

Bile acid. Ursodiol 250mg; tabs.

Also: Ursodiol

R

URSO FORTE

Ursodiol 500mg; scored tabs.

Indications: Primary biliary cirrhosis.

Adults: Take with food. 13–15mg/kg per day in 2–4 divided doses.

Children: Not recommended.

Warnings/Precautions: Variceal bleeding, hepatic encephalopathy, ascites, and/or need for an urgent liver transplant: give appropriate specific treatment. Pregnancy (Cat.B). Nursing mothers.

Interactions: Reduced absorption with bile acid sequestrants (eg, cholestyramine, colestipol), and aluminum-containing antacids. Estrogens, oral

contraceptives, clofibrate, other lipid-lowering drugs may reduce effectiveness of ursodiol by increasing hepatic cholesterol secretion.

Adverse reactions: Leukopenia, rash, GI effects, elevated creatinine or blood glucose, thrombocytopenia.

How supplied: Tabs-100, 500; Forte-100

5E Hyperacidity, GERD, and ulcers

AMOXICILLIN

R

AMOXIL Dr. Reddy's

Broad-spectrum penicillin antibiotic. Amoxicillin (as trihydrate) 500mg; caps.

Indications: In combination with lansoprazole and/or clarithromycin to eradicate *H. pylori* in adults with duodenal ulcer disease.

Adults: Triple therapy: amoxicillin 1g + clarithromycin 500mg + lansoprazole 30mg, all every 12 hrs for 14 days. Dual therapy (if allergic or resistant to clarithromycin): amoxicillin 1g + lansoprazole 30mg, both every 8 hrs for 14 days.

Children: Not recommended.

Warnings/Precautions: Cephalosporin, imipenem, other allergy or mononucleosis: not recommended. Monitor blood, renal, and hepatic function in long-term use. Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by probenecid. May cause false (+) glucose test with Clinitest, Benedict's or Fehling's soln.

Adverse reactions: Diarrhea, headache, hypersensitivity reactions (eg, urticaria, rash, Stevens-Johnson syndrome, anaphylaxis), blood dyscrasias. Triple therapy: taste perversion.

Note: See clarithromycin entry for more information. See lansoprazole entry for more information.

How supplied: Caps-500

CIMETIDINE

R

TAGAMET GlaxoSmithKline

H₂ blocker. Cimetidine 300mg, 400mg; tabs.

Indications: Active duodenal or benign gastric ulcer. Maintenance of healed duodenal ulcers. Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome). GERD.

Adults: Active duodenal ulcer: 800mg at bedtime for 4-8 wks. Maintenance: 400mg at bedtime. Active benign gastric ulcer: 800mg at bedtime or 300mg 4 times daily with meals and at bedtime for 6 wks. Hypersecretory conditions: 300mg 4 times daily with meals and at bedtime; max 2.4g/day. GERD: 800mg 2 times daily or 400mg 4 times daily for max 12 weeks; see literature. For difficult to heal ulcers: see literature.

Children: <16 yrs: not recommended; see literature. Doses of 20-40mg/kg per day have been used.

Warnings/Precautions: Impaired renal or hepatic function. Elderly. Debilitated. Immunocompromised. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid antacids within 1 hour of dosing. May potentiate anticoagulants, phenytoin, theophylline, lidocaine, and others (see literature) by inhibition of hepatic microsomal enzymes. May alter absorption of drugs affected by gastric pH (eg, ketoconazole), give 2 hours before cimetidine.

Adverse reactions: Headache, diarrhea, dizziness, somnolence, CNS disturbances, gynecomastia, rash (maybe serious eg, Stevens-Johnson syndrome); rare: arthralgia, myalgia, blood dyscrasias, nephritis, increased serum transaminases, pancreatitis, bradycardia, tachycardia; increased risk of community-acquired pneumonia (see literature).

How supplied: Tabs 300mg-100; 400mg-60

CLARITHROMYCIN

R

BIAXIN AbbVie

Macrolide. Clarithromycin 250mg, 500mg; tabs.

Indications: Triple therapy (w. amoxicillin + lansoprazole or omeprazole) for treating patients with *H. pylori* infection and duodenal ulcer disease. Dual therapy (w. omeprazole) for treating active duodenal ulcer associated with *H. pylori* infection.

Adults: Triple therapy: clarithromycin 500mg + lansoprazole 30mg + amoxicillin 1g, all every 12 hours for 10 or 14 days. Or, clarithromycin 500mg + omeprazole 20mg + amoxicillin 1g, all every 12 hours for 10 days; may continue omeprazole for days 11-28 if ulcer was present at start. Dual therapy: clarithromycin 500mg 3 times daily + omeprazole 40mg once daily in the AM on days 1-14, then omeprazole 20mg once daily in the AM on days 15-28. CrCl <30mL/min: reduce clarithromycin dose by 1/2.

Children: Not recommended.

Contraindications: Concomitant cisapride, pimozide, ergots, HMG-CoA reductase inhibitors extensively metabolized by CYP3A4 (lovastatin or simvastatin). History of QT prolongation or ventricular cardiac arrhythmia (including torsades de pointes). Concomitant colchicine (in renal or hepatic impairment). Cholestatic jaundice/hepatic dysfunction with prior clarithromycin use.

Warnings/Precautions: Discontinue immediately if hepatitis occurs. Severe renal impairment. Proarrhythmic conditions (eg, hypokalemia, hypomagnesemia, bradycardia); avoid. Myasthenia gravis. Elderly. Pregnancy (Cat.C): usually not recommended. Nursing mothers.

Interactions: See Contraindications. Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmics: not recommended. Sildenafil, tadalafil, vardenafil: not recommended. Antagonized by CYP3A inducers (eg, efavirenz, nevirapine, rifampicin, rifapentine); use alternative antibacterial treatment. Doses >1000mg/day should not be coadministered with

protease inhibitors. Concomitant atazanavir: reduce clarithromycin dose by 50%. Potentiated by CYP3A inhibitors (eg, itraconazole, phenytoin). May potentiate theophylline, omeprazole, phenytoin, digoxin, midazolam, alprazolam, triazolam, cyclosporine, hexobarbital, tacrolimus, alfentanil, disopyramide, bromocriptine, valproate, carbamazepine, tolterodine, itraconazole, methylprednisolone, cimetidine, vinblastine; monitor these and other drugs metabolized by CYP3A. Myopathy/rhabdomyolysis with statins; max 20mg atorvastatin/day, 40mg pravastatin/day; consider use of statin not dependent on CYP3A metabolism (eg, fluvastatin). Reduce colchicine dose if coadministration is necessary. Hypoglycemia with oral hypoglycemics/insulin; carefully monitor glucose. Oral anticoagulants: frequently monitor INR and prothrombin times. Hypotension with calcium channel blockers metabolized by CYP3A4 (eg, verapamil, amlodipine, diltiazem).

Adverse reactions: GI upset, abnormal taste, headache, rash, increased BUN; hepatotoxicity, QT prolongation, *C. difficile* associated diarrhea, hypersensitivity reactions.

Notes: See omeprazole entry for more information. See lansoprazole entry for more information. See amoxicillin entry for more information.

How supplied: Tabs-60

DEXLANSOPRAZOLE

DEXILANT Takeda

Proton pump inhibitor. Dexlansoprazole 30mg, 60mg; delayed-release caps.

Indications: Healing of all grades of erosive esophagitis (EE). Treatment of heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD). Maintenance of healing of EE and relief of heartburn.

Adults: ≥ 18 yrs: Swallow whole, or sprinkle granules on 1 tablespoon of applesauce and swallow immediately. EE healing: 60mg once daily for up to 8 weeks. Maintenance of healed EE and relief of heartburn: 30mg once daily for up to 6 months. Symptomatic GERD: 30mg once daily for 4 weeks. Moderate hepatic impairment (Child-Pugh Class B): max 30mg/day.

Children: < 18 yrs: not established.

Warnings/Precautions: Gastric malignancy. Use lowest dose for shortest duration appropriate to condition. If diarrhea occurs that does not improve, consider *C. difficile* diagnosis. Increased risk of osteoporosis-related fractures of the hip, wrist or spine with long-term and multiple daily dose PPI therapy. Severe hepatic impairment. Monitor magnesium levels with long-term therapy. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant atazanavir: not recommended (may decrease atazanavir levels). May alter absorption of pH-dependent drugs (eg, ketoconazole, digoxin, iron, ampicillin). Monitor warfarin. May increase tacrolimus, methotrexate levels.

Adverse reactions: Diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, flatulence; rare: hypomagnesemia (w. prolonged PPI therapy).

Notes: Formerly marketed as Kapidex.

How supplied: Caps-30, 90, 1000

DICYCLOMINE

BENTYL Aptalis

Anticholinergic. Dicyclomine HCl 10mg caps; 20mg tabs.

Also: Dicyclomine

DICYCLOMINE HCl SYRUP (various)

Dicyclomine HCl 10mg/5mL.

Indications: Irritable bowel syndrome.

Adults: Initially 20mg 4 times daily; after 1 week may increase to 40mg 4 times daily if tolerated. Discontinue if not effective within 2 weeks or daily doses ≥ 80 mg are not tolerated.

Children: < 6 months: see Contraindications. ≥ 6 months: consult manufacturer.

Also: Dicyclomine

BENTYL INJECTION

Dicyclomine HCl 10mg/mL; soln for IM inj.

Adults: Give by IM route only. 10-20mg four times daily for max 1-2 days when oral therapy is not feasible.

Children: < 6 months: see Contraindications. ≥ 6 months: consult manufacturer.

Contraindications: Glaucoma. Unstable cardiovascular status. GI or urinary tract obstruction. Severe ulcerative colitis. Myasthenia gravis. Reflux esophagitis. Children < 6 months of age. Nursing mothers.

Warnings/Precautions: Inj: avoid IV administration (may cause thrombosis, inj site reactions). Autonomic neuropathy. Hepatic or renal impairment. Cardiovascular disease. Hypertension. Hyperthyroidism. Salmonella dysentery. Toxic megacolon. Ulcerative colitis. GI or GU obstruction. High environmental temperature. Diarrhea. Elderly. Dehydrated. Pregnancy (Cat.B).

Interactions: Antacids may inhibit absorption; avoid. May antagonize anti-glaucoma agents or drugs that alter GI motility (eg, metoclopramide). Antagonized by agents used to treat achlorhydria and those used to test gastric secretion. Additive anticholinergic effects with other anticholinergics, narcotic analgesics, type I antiarrhythmics, antihistamines, antipsychotics, tricyclics, amantadine, benzodiazepines, MAOIs, nitrites, nitrates, sympathomimetics. May affect absorption of sust-rel dosage forms.

Adverse reactions: Dizziness, dry mouth, blurred vision, nausea, somnolence, asthenia, and nervousness; cardiovascular and CNS symptoms (eg, psychosis, delirium). Fatal reactions have occurred in infants.

How supplied: Caps, tabs-100; Syrup-contact supplier; Amps (2mL)-5

ESOMEPRAZOLE**NEXIUM** AstraZeneca

Proton pump inhibitor. Esomeprazole (as magnesium trihydrate) 20mg, 40mg; caps containing e-c delayed-release pellets.

Also: Esomeprazole**NEXIUM FOR ORAL SUSPENSION**

Esomeprazole (as magnesium trihydrate) 10mg, 20mg, 40mg; per packet; e-c delayed release granules.

Indications: Triple therapy (w. amoxicillin + clarithromycin) for *H. pylori* eradication in duodenal ulcer disease. Short-term treatment and maintenance of healing of erosive esophagitis (EE), symptomatic GERD. Short-term treatment of EE due to acid-mediated GERD in infants 1month to <1year. To reduce risk of NSAID-associated gastric ulcer. Long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome).

Adults: Take 1 hour before food. Caps: swallow whole or may open caps and sprinkle pellets on 1 tablespoon applesauce and take immediately. May open caps and mix granules in 50mL of water and give via NG tube; flush tube with more water. Susp: mix contents of packet in 15mL of water, leave 2–3 minutes, then drink within 30 minutes. May give via NG or gastric tube (see literature). Triple therapy: esomeprazole 40mg once daily + amoxicillin 1g twice daily + clarithromycin 500mg twice daily; all for 10 days. EE: 20 or 40mg once daily for 4–8 weeks, may continue 4–8 more weeks. Maintenance of healing of EE: 20mg once daily. Symptomatic GERD: 20mg once daily for 4 weeks, may continue 4 more weeks. NSAID-associated ulcer risk reduction: 20mg or 40mg once daily for up to 6 months. Hypersecretory conditions: initially 40mg twice daily, adjust if needed; doses up to 240mg daily have been used. Severe hepatic impairment: max 20mg/day.

Children: EE due to acid-mediated GERD:

<1month: not established. 1month–<1yr: 3kg–5kg: 2.5mg. >5kg–7.5kg: 5mg. >7.5kg–12kg: 10mg; for all: give once daily for up to 6 weeks. Healing of EE: <1yr: not established. 1–11yrs: <20kg: 10mg; ≥20kg: 10 or 20mg; 12–17yrs: 20 or 40mg; for all: give once daily for up to 8 weeks. Symptomatic GERD: 1–11yrs: 10mg once daily for up to 8 weeks; 12–17yrs: 20mg once daily for 4 weeks.

Also: Esomeprazole**NEXIUM IV**

Esomeprazole (as sodium) 20mg, 40mg; per vial; pwd for IV inj after reconstitution or for infusion after reconstitution and dilution.

Indications: Short-term (up to 10 days) alternative to oral therapy for GERD with erosive esophagitis.

Adults: Inject IV over ≥ 3 minutes or infuse IV over 10–30 minutes. ≥18yrs: 20–40mg once daily for ≤10 days; switch to oral form when feasible. Severe hepatic impairment: max 20mg/day.

Children: Infuse IV over 10–30 minutes. <1month: not recommended. 1month–<1yr: 0.5mg/kg. 1yr–17yrs: <55kg: 10mg; ≥55kg: 20mg.

R

Warnings/Precautions: Long term and multiple daily dose therapy: increased risk of osteoporosis-related fractures. Monitor magnesium levels with long-term therapy. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant atazanavir, nelfinavir: not recommended. May potentiate saquinavir; monitor and consider reducing saquinavir dose. May alter absorption of gastric pH-dependent drugs (eg, ketoconazole, iron salts, digoxin). Antagonizes clopidogrel; consider alternative anti-platelet therapy. May affect drugs metabolized by CYP2C19. Avoid concomitant with St. John's Wort, rifampin. May potentiate tacrolimus, cilostazol (consider temporary withdrawal of PPI). Monitor warfarin. May give antacids concomitantly. May cause false (+) results in diagnostic investigations for neuroendocrine tumors.

Adverse reactions: Headache, diarrhea, abdominal pain, nausea, flatulence, constipation, dry mouth, inj site reactions; rare: rash, allergic reactions, hypomagnesemia, possible *C. difficile* associated diarrhea. Children: Also, somnolence, regurgitation, tachypnea, increased ALT.

Note: See clarithromycin for more information. See amoxicillin for more information.

How supplied: Caps–30, 90, 1000; Susp–30 packets/box; IV soln (single-use vial)–10

FAMOTIDINE

R

PEPCID Marathon

H₂ blocker. Famotidine 20mg, 40mg; tabs.

Also: Famotidine

R

PEPCID SUSPENSION Salix

Famotidine 40mg/5mL; pwd for reconstitution; cherry-banana-mint flavor.

Indications: Active duodenal ulcer. Maintenance of healed duodenal ulcer. Active benign gastric ulcer. Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome). Gastroesophageal reflux disease (GERD). Esophagitis due to GERD.

Adults: Duodenal ulcer: 40mg once daily at bedtime or 20mg twice daily for 4–8 wks. Maintenance: 20mg once daily at bedtime. Benign gastric ulcer: 40mg once daily at bedtime for up to 8 wks. Hypersecretory conditions: Initially 20mg every 6 hrs; individualize. GERD symptoms: 20mg twice daily for up to 6 wks. Esophagitis: 20–40mg twice daily for up to 12 wks (see literature).

Children: Individualize; adjust based on response. <1yr: not recommended. 1–16yrs: Peptic ulcer: Initially 0.5mg/kg per day at bedtime or in 2 divided doses; max 40mg/day. GERD: Initially 1mg/kg per day divided in 2 doses; max 40mg twice daily.

Also: Famotidine

R

FAMOTIDINE INJECTION (various)

Famotidine 10mg/mL; soln for IV inj or infusion after dilution; multidose vials contain benzyl alcohol.

Also: Famotidine *R*

FAMOTIDINE INJECTION PRESERVATIVE-FREE (various)
Famotidine 20mg/50mL; soln for IV infusion;
preservative-free.

Indications: Hospitalized patients with pathological hypersecretory conditions, intractable ulcers, or as a short-term alternative to oral dosage forms.

Adults: Give by IV inj over 2 minutes or infuse over 15–30 minutes. 20mg every 12 hrs.

Children: See literature. Give by IV inj over 2 minutes or infuse over 15 minutes. <1yr: not recommended. 1–16yrs: initially 0.25mg/kg every 12hrs; max 40mg/day.

Warnings/Precautions: Moderate to severe renal insufficiency (CrCl <50mL/min): reduce dose or prolong dosing interval. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May give antacids concomitantly.

Adverse reactions: Headache, dizziness, constipation, diarrhea, somnolence, seizures, palpitations, depression, inj site reactions.

How supplied: Tabs–30, 100; Susp–50mL; Inj–contact supplier

GLYCOPYRROLATE *R*

ROBINUL Shionogi

Anticholinergic. Glycopyrrolate 1mg; dye-free tabs.

Also: Glycopyrrolate *R*

ROBINUL FORTE

Glycopyrrolate 2mg; dye-free tabs.

Indications: Adjunct in peptic ulcer.

Adults: 1–2mg 2–3 times daily; max 8mg daily.

Children: Not recommended.

Also: Glycopyrrolate *R*

ROBINUL INJECTION Pfizer

Glycopyrrolate 0.2mg/mL; IM or IV inj; contains benzyl alcohol 0.9%.

Indications: Adjunct in peptic ulcer where oral therapy not tolerated.

Adults: 0.1–0.2mg IV or IM every 4 hrs 1–4 times daily.

Children: Not recommended.

Contraindications: Glaucoma. Unstable cardiovascular status. Asthma. GI or urinary tract obstruction. Paralytic ileus or intestinal atony. Toxic megacolon. Severe ulcerative colitis. Myasthenia gravis.

Warnings/Precautions: Reflux esophagitis. Autonomic neuropathy. Impaired hepatic or renal function. Cardiovascular disease. Tachycardia. Hypertension. Hyperthyroidism. High environmental temperature. Diarrhea. Elderly. Debilitated. Pregnancy (Cat.B). Nursing mothers.

Interactions: Concomitant antacids may inhibit absorption. Cyclopropane anesthetics may cause arrhythmias. Additive anticholinergic effects with other anticholinergics, narcotic analgesics, type I antiarrhythmics, antihistamines, phenothiazines, tricyclics.

Adverse reactions: Anticholinergic effects (eg, dry mouth, blurred vision, constipation).

How supplied: Tabs–100

Inj (vials) Single dose 1mL–25

2mL–25

Multidose 5mL–25

20mL–1

LANSOPRAZOLE *R*

PREVACID Takeda

Proton pump inhibitor. Lansoprazole 15mg, 30mg; e-c delayed-release granules in caps.

Also: Lansoprazole *R*

PREVACID SOLUTAB

Lansoprazole 15mg, 30mg; e-c delayed-release microgranules in orally-disintegrating tabs; strawberry flavor; contains phenylalanine.

Indications: Triple therapy (w. amoxicillin + clarithromycin) or dual therapy (w. amoxicillin; use only if allergic, intolerant, or resistant to clarithromycin) for *H. pylori* eradication in duodenal ulcer disease. Short-term treatment of active duodenal ulcer, active benign gastric ulcer, erosive esophagitis (EE), symptomatic GERD, and NSAID-associated gastric ulcers when NSAID use is continued. To reduce risk of NSAID-associated gastric ulcer in patients with history of gastric ulcer who need an NSAID. Maintenance of healing of duodenal ulcer, EE. Long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome).

Adults: Take before eating. Do not crush or chew granules. Caps: swallow whole, or sprinkle granules and mix contents with food or juice (see full labeling) and take immediately. May open caps and mix granules in 40mL apple juice and give via NG tube; flush tube with more juice. SoluTabs: dissolve on tongue; swallow with or without water. May give via oral syringe or NG tube (see full labeling). ≥18yrs: Triple therapy: lansoprazole 30mg + amoxicillin 1g + clarithromycin 500mg, all every 12 hours for 10 or 14 days. Dual therapy: lansoprazole 30mg + amoxicillin 1g, both every 8 hours for 14 days. Duodenal ulcer: 15mg once daily for 4 weeks. Gastric ulcer treatment: 30mg once daily for up to 8 weeks. EE treatment: 30mg once daily for up to 8 weeks; may repeat for 8 more weeks. If relapse occurs, may repeat 8-week course. GERD: 15mg once daily for up to 8 weeks. Maintenance of healing of duodenal ulcer or EE: 15mg once daily. Healing of NSAID-associated gastric ulcer: 30mg once daily for 8 weeks; NSAID ulcer risk reduction: 15mg once daily for up to 12 weeks. Hypersecretory conditions: Initially 60mg once daily, adjust as needed; give daily doses >120mg in divided doses.

Children: Take before eating. Do not crush or chew granules. Caps: swallow whole, or sprinkle granules and mix contents with food or juice (see full labeling) and take immediately. May open caps and mix granules in 40mL apple juice and give via NG tube; flush tube with more juice. SoluTabs: dissolve on

tongue; swallow with or without water. May give via oral syringe or NG tube (see literature). GERD or EE: ≤ 1 yr: not recommended. 1–11yrs: ≤ 30 kg: 15mg once daily; >30 kg: 30mg once daily. For both: give for up to 12 weeks; doses up to 30mg twice daily have been used.

Warnings/Precautions: Symptomatic response does not preclude gastric malignancy. Increased risk of osteoporosis-related fractures of the hip, wrist or spine with long-term and multiple daily dose PPI therapy. Monitor magnesium levels with long-term therapy. Severe hepatic impairment (consider dose reduction). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May antagonize atazanavir: not recommended. May alter absorption of pH-dependent drugs (eg, ketoconazole, digoxin, iron, ampicillin). Concomitant digoxin, diuretics may predispose patients to hypomagnesemia. Monitor theophylline, warfarin. May potentiate tacrolimus, methotrexate. Give at least 30 minutes before sucralfate. May give antacids concomitantly.

Adverse reactions: Diarrhea, abdominal pain, nausea, constipation, headache, bone fracture; hypomagnesemia (w. prolonged PPI therapy), possible *C. difficile* associated diarrhea.

Note: See amoxicillin entry for more information. See clarithromycin entry for more information.

How supplied: Caps 15mg–30, 100, 1000; 30mg–100, 1000; SoluTabs–100

LANSOPRAZOLE + AMOXICILLIN + CLARITHROMYCIN R

PREVPAC Takeda

Proton pump inhibitor + antibiotics (penicillin + macrolide). Lansoprazole 30mg (2 caps containing e-c granules), amoxicillin 500mg (4 caps), clarithromycin 500mg (2 tabs); per pack.

Indications: To eradicate *H. pylori* to reduce risk of duodenal ulcer recurrence.

Adults: Lansoprazole 30mg + amoxicillin 1g + clarithromycin 500mg, all twice daily for 10 or 14 days. Renal dysfunction (CrCl <30 mL/min): not recommended.

Children: Not recommended.

Note: For contraindications, precautions, interactions, and adverse reactions see entries for lansoprazole, amoxicillin, and clarithromycin.

How supplied: Prevpac–1

METOCLOPRAMIDE R

REGLAN Ani

Prokinetic. Metoclopramide (as HCl) 5mg, +10mg; +scored tabs.

Indications: Symptomatic refractory GERD.

Adults: 10–15mg 4 times daily 30 minutes before meals and at bedtime. Intermittent symptoms, up to 20mg prior to provoking situation; max 12 weeks per therapeutic course. Renal impairment: reduce dose.

Children: Not recommended.

Contraindications: When stimulation of GI motility may be dangerous (eg, obstruction, perforation, or hemorrhage). Pheochromocytoma. Epilepsy. Concomitant drugs which may cause extrapyramidal reactions (eg, phenothiazines, haloperidol).

Warnings/Precautions: Parkinsonism. Tardive dyskinesia. History of breast cancer or depression. Cirrhosis. CHF. Hypertension. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Hypertensive crisis with MAOIs.

Additive sedation with alcohol, other CNS depressants. Antagonized by anticholinergics and narcotics. Monitor insulin use; may diminish gastric and accelerate intestinal absorption of drugs or food.

Adverse reactions: Restlessness, drowsiness, fatigue, extrapyramidal effects, parkinsonism, tardive dyskinesia, neuroleptic malignant syndrome, dizziness, endocrine disturbances, hypo- or hypertension, fluid retention, GI or GU disturbances; rare: hepatotoxicity.

How supplied: Tabs–100

MISOPROSTOL R

CYTOTEC Pfizer

Prostaglandin E_1 analogue. Misoprostol 100mcg, 200mcg; tabs.

Indications: Prevention of NSAID-induced gastric ulcers.

Adults: Take with food. 200mcg 4 times daily with meals (last dose at bedtime). May reduce dose if not tolerated.

Children: Not recommended.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: For women of childbearing potential: negative serum pregnancy test within 2 weeks before starting therapy; begin on 2nd or 3rd day of next menstrual period; maintain contraception during therapy; give oral and written warnings on risks in pregnancy. Cardiovascular disease. Inflammatory bowel disease. Dehydration. Labor & delivery. Nursing mothers: not recommended.

Interactions: Avoid magnesium-containing antacids (to reduce diarrhea risk). Concomitant oxytocic agents: not recommended.

Adverse reactions: Diarrhea, abdominal pain, headache, gynecological effects (eg, spotting, cramps), abortion, premature birth, birth defects, uterine rupture.

How supplied: Tabs 100mcg–60, 120; 200mcg–60, 100

NIZATIDINE R

AXID (various)

H_2 blocker. Nizatidine 150mg; caps.

Also: Nizatidine R

AXID ORAL SOLUTION Baintree

Nizatidine 15mg/mL; bubble gum flavor.

Indications: Active duodenal ulcer. Maintenance of healed duodenal ulcer. Benign gastric ulcer. Gastroesophageal reflux disease (GERD); including heartburn and erosive and ulcerative esophagitis.

Adults: Active duodenal or benign gastric ulcer: 300mg daily at bedtime or 150mg twice daily, both for up to 8 weeks. Maintenance: 150mg daily at bedtime. GERD: 150mg twice daily for up to 12 weeks. Renal impairment: see literature.

Children: Not recommended.

Warnings/Precautions: Rule out malignant gastric ulceration. Renal insufficiency, reduce dose (see literature). Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May elevate serum salicylate levels in high-dose aspirin patients.

Adverse reactions: Headache, anemia, diarrhea, dizziness, sweating, rhinitis, urticaria.

How supplied: Caps-contact supplier; Soln-480mL

OMEPRAZOLE

PRIOSEC AstraZeneca

Proton pump inhibitor. Omeprazole 10mg, 20mg, 40mg; caps containing e-c delayed release granules.

Also: Omeprazole

PRIOSEC FOR ORAL SUSPENSION

Omeprazole 2.5mg, 10mg; per packet; e-c delayed-release granules.

Indications: Triple therapy (w. amoxicillin + clarithromycin) or dual therapy (w. clarithromycin) for *H. pylori* eradication in duodenal ulcer disease. Short-term treatment of active benign gastric ulcer, active duodenal ulcer, erosive esophagitis (EE), symptomatic GERD. Maintenance of healing of EE. Pathological hypersecretory conditions.

Adults: Take before eating. Caps: swallow whole, or may mix contents of caps in applesauce and take immediately; do not crush or chew granules; follow with water. Susp: Mix 2.5mg packet with 5mL of water; mix 10mg packet with 15mL of water. Leave 2-3 minutes to thicken, stir and drink within 30 minutes. NG or gastric tube: see full labeling. Triple therapy: omeprazole 20mg + clarithromycin 500mg + amoxicillin 1g, all every 12 hrs for 10 days; then (if ulcer was present at start): omeprazole 20mg once daily in the AM on days 11-28. Dual therapy (clarithromycin resistance more likely to develop than with triple therapy): omeprazole 40mg once daily in the AM + clarithromycin 500mg three times daily on days 1-14; then (if ulcer was present at start) omeprazole 20mg once daily in the AM on days 15-28. Active duodenal ulcer: 20mg once daily for 4 wks; may continue 4 more wks. Gastric ulcer: 40mg once daily for 4-8 weeks. GERD (no esophageal lesions): 20mg once daily for up to 4 weeks. EE with GERD symptoms: 20mg once daily for 4-8 wks; may give up to 4 more wks (if relapse of erosive esophagitis or GERD symptoms occurs may give additional 4-8 wk course). Maintenance of healing of EE: 20mg once daily. Hypersecretory conditions: initially 60mg once daily, then adjust; doses up to 120mg 3 times daily have been used; give doses >80mg/day in divided doses. Hepatic impairment or Asian: consider reducing dose (esp. for maintenance of healing of EE).

Children: Take before eating. Caps: swallow whole, or may mix contents of caps in applesauce and take immediately; do not crush or chew granules; follow with water. Susp: Mix 2.5mg packet with 5mL of water; mix 10mg packet with 15mL of water. Leave 2-3 minutes to thicken, stir and drink within 30 minutes. NG or gastric tube: see full labeling. <1yr: not recommended. 1-16yrs: GERD, EE: 5<10kg: 5mg daily. 10<20kg: 10mg daily; ≥20kg: 20mg daily.

Warnings/Precautions: Gastric malignancy. Increased risk of osteoporosis-related fractures of the hip, wrist or spine with long-term and multiple daily dose PPI therapy. Monitor magnesium levels with long-term therapy. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant St. John's wort, rifampin, atazanavir, nelfinavir: not recommended. Potentiates saquinavir, cimetidine; consider dose reduction of these drugs. May potentiate diazepam, phenytoin, warfarin, tacrolimus, methotrexate. Potentiated by voriconazole; may need to adjust omeprazole dose in Zollinger-Ellison syndrome. Antagonizes clopidogrel; consider alternative anti-platelet therapy. May alter absorption of pH-dependent drugs (eg, ketoconazole, digoxin, iron salts, ampicillin). Monitor drugs metabolized by CYP450 (eg, cyclosporine, disulfiram, benzodiazepines). May give antacids concomitantly. May interfere with neuroendocrine diagnostic tests. **Adverse reactions:** Headache, abdominal pain, GI upset, flatulence; bone fracture, hypomagnesemia (w. prolonged PPI therapy), possible *C. difficile* associated diarrhea. Children: also, respiratory system events, fever.

Note: See amoxicillin entry for more information.

See clarithromycin entry for more information.

How supplied: Caps 10mg-30; 20mg-30, 1000; 40mg-30, 100; packets-30

PANTOPRAZOLE

PROTONIX TABLETS Pfizer

Proton pump inhibitor. Pantoprazole (as sodium) 20mg, 40mg; e-c delayed-release tabs.

Also: Pantoprazole

PROTONIX FOR ORAL SUSPENSION

Pantoprazole (as sodium) 40mg; per packet; e-c delayed-release granules.

Indications: Short-term treatment and maintenance of healing of erosive esophagitis (EE). Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome).

Adults: Swallow whole. Do not crush or chew granules. Susp: Take 30mins before a meal. Mix contents of packet in 5mL of apple juice or applesauce (do not mix in water, other liquids or foods); then swallow. May give via NG tube (see literature). Treatment of EE: 40mg once daily for ≤8 weeks; if not healed, may repeat for 8 more weeks. Maintenance of EE healing: 40mg once daily.

Pathological hypersecretory conditions: initially 40mg twice daily; max 240mg/day.

Children: Swallow whole. Do not crush or chew granules. Susp: Take 30mins before a meal. Mix contents of packet in 5mL of apple juice or applesauce (do not mix in water, other liquids or foods); then swallow. May give via NG tube (see literature). <5yrs: not recommended. Treatment of EE: Give once daily for up to 8 weeks. ≥5yrs: (≥15kg to <40kg): 20mg; (≥40kg): 40mg.

Also: Pantoprazole
PROTONIX I.V.

Pantoprazole (as sodium) 40mg; per vial; pwd for IV infusion after reconstitution and dilution; contains edetate disodium.

Indications: Short-term treatment (7–10 days) of GERD associated with a history of erosive esophagitis. Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome).

Adults: ≥18yrs: GERD: 40mg once daily for 7–10 days; switch to tabs or oral suspension as soon as possible. Pathological hypersecretory conditions: 80mg every 8–12 hours; usual max 240mg/day or 6 days' treatment.

Children: <18yrs: not established.

Warnings/Precautions: Gastric malignancy. Increased risk of osteoporosis-related fractures of the hip, wrist or spine with long-term and multiple daily dose PPI therapy. Monitor magnesium levels with long-term therapy. Reevaluate periodically. IV: consider zinc supplementation in those prone to zinc deficiency. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant atazanavir or nelfinavir: not recommended. May alter absorption of gastric pH-dependent drugs (eg, ketoconazole, iron, ampicillin). Concomitant digoxin or drugs that may cause hypomagnesemia (eg, diuretics); consider monitoring magnesium levels. Monitor warfarin. May give antacids concomitantly. IV: caution with concomitant other EDTA-containing products. May potentiate methotrexate. May cause false (+) urine THC test.

Adverse reactions: Headache, GI upset, dizziness, arthralgia, inj site reactions; also children: upper respiratory infection, fever, rash, abdominal pain; rare: cyanocobalamin deficiency, hypomagnesemia (w. prolonged PPI therapy), possible *C. difficile* associated diarrhea.

How supplied: Tabs–90; Susp–30 packets/box; Vials (40mg)–10, 25

RABEPRAZOLE

ACIPHEX Eisai and Janssen
Proton pump inhibitor. Rabeprazole sodium 20mg; delayed-release, e-c tabs.

Also: Rabeprazole
ACIPHEX SPRINKLE

Rabeprazole sodium 5mg, 10mg; delayed-release, caps
Indications: Triple therapy (w. amoxicillin + clarithromycin) for *H. pylori* eradication in duodenal

ulcer disease. Short-term treatment of erosive or ulcerative gastroesophageal reflux disease (GERD) or duodenal ulcers. Short-term treatment of symptomatic GERD in patients ≥12 years of age. Maintenance of healing and reduction in relapse rates of heartburn symptoms in erosive or ulcerative GERD. Long-term treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome). Treatment of GERD in pediatric patients 1–11 years of age.

Adults: Swallow tabs whole. ≥18yrs: Triple therapy: rabeprazole 20mg + amoxicillin 1g + clarithromycin 500mg, all twice daily (w. AM and PM meals) for 7 days. GERD healing: 20mg once daily for 4–8 weeks; may repeat for 8 more weeks. GERD symptoms: 20mg once daily for 4 weeks; may repeat for 4 more weeks. GERD maintenance: 20mg once daily. Duodenal ulcer healing: 20mg once daily after breakfast for up to 4 weeks. Hypersecretory conditions: initially 60mg once daily; titrate; doses up to 100mg once daily or 60mg twice daily have been used.

Children: Sprinkle caps: take 30 minutes before meal. Open capsule and sprinkle contents on a small amount of soft food (eg, applesauce, fruit or vegetable based baby food, yogurt) or into a small amount of liquid (eg, infant formula, apple juice, pediatric electrolyte solution). <1yr: not recommended. Treatment of GERD: 1–11yrs (<15kg): 5mg once daily for up to 12 weeks; may increase to 10mg if inadequate response; (≥15kg): 10mg once daily for up to 12 weeks. Tabs: swallow whole. Treatment of symptomatic GERD: ≥12yrs: 20mg tab once daily for up to 8 weeks.

Warnings/Precautions: Gastric malignancy. Increased risk of osteoporosis-related fractures of the hip, wrist or spine with long-term and multiple daily dose PPI therapy. Severe hepatic impairment. Monitor magnesium levels with long-term therapy. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May alter absorption of gastric pH-dependent drugs (eg, ketoconazole, digoxin). Concomitant digoxin or drugs that cause may hypomagnesemia (eg, diuretics); consider monitoring magnesium levels. May give antacids concomitantly. May antagonize atazanavir (not recommended). Monitor warfarin, cyclosporine. May potentiate methotrexate (see literature).

Adverse reactions: Headache, pain, pharyngitis, flatulence, infection, constipation; rare: hypomagnesemia (w. prolonged PPI therapy), possible *C. difficile* associated diarrhea.

Note: See amoxicillin entry for more information. See clarithromycin entry for more information.

How supplied: Tabs–30, 90; Caps–30

RANITIDINE

ZANTAC GlaxoSmithKline
H₂ blocker. Ranitidine (as HCl) 150mg, 300mg; tabs.

Also: Ranitidine
ZANTAC EFFERDOSE

Ranitidine (as HCl) 25mg; effervescent tabs; contains phenylalanine, sodium (30.52mg per tab).

Also: Ranitidine**ZANTAC SYRUP**

Ranitidine (as HCl) 15mg/mL; peppermint flavor; contains alcohol 7.5%.

Indications: Active duodenal or benign gastric ulcer. Maintenance of healing of duodenal or gastric ulcer. Pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome and systemic mastocytosis). GERD. Erosive esophagitis. Maintenance of healing of erosive esophagitis.

Adults: Efferdose: dissolve 1 tab in 5mL of water. >16yrs: Active duodenal ulcer: 150mg twice daily or 300mg once daily after evening meal or at bedtime for up to 8wks; maintenance: 150mg at bedtime. Active benign gastric ulcer, hypersecretory conditions or GERD: 150mg twice daily; max 6g daily in hypersecretory conditions. Maintenance of healing of gastric ulcer: 150mg at bedtime. Limit to 6wks in benign gastric ulcer. Esophagitis: 150mg 4 times daily; reevaluate after 12wks; maintenance of healing of erosive esophagitis: 150mg twice daily. Renal impairment (CrCl <50mL/min): 150mg every 24hrs or more often if needed. Coincide a dose for end of hemodialysis. May give antacids concomitantly.

Children: Efferdose: dissolve 1 tab in 5mL of water. <1month: not recommended. ≥1month–16yrs: Treatment of duodenal or gastric ulcers: 2–4mg/kg per day in two divided doses; max 300mg/day. Maintenance of healing of duodenal or gastric ulcers: 2–4mg/kg per day once daily; max 150mg/day. GERD, erosive esophagitis: 5–10mg/kg per day usually in two divided doses. Renal impairment (CrCl <50mL/min): reduce dose; see literature.

Also: Ranitidine**ZANTAC INJECTION** Covis

Ranitidine (as HCl) 25mg/mL; IM or IV inj; contains phenol.

Indications: Hospitalized patients with pathological hypersecretory conditions, intractable duodenal ulcer. Short-term alternative to oral therapy.

Adults: >16yrs: 50mg every 6–8 hrs by IM inj, or intermittent IV bolus (dilute; give over 5 min), or intermittent IV (dilute; give over 15–20 min); usual max 400mg/day. Continuous IV infusion, or for Zollinger-Ellison: see literature. Renal impairment (CrCl <50mL/min): 50mg every 18–24hrs or more often if needed (intermittent only). Coincide a dose for end of hemodialysis.

Children: <1month: not recommended.

≥1month–16yrs: Treatment of duodenal ulcer: 2–4mg/kg per day in divided doses every 6–8hrs; max 50mg every 6–8hrs.

Also: Ranitidine**ZANTAC INJECTION PREMIXED** Covis

Ranitidine (as HCl) 1mg/mL in sodium chloride 0.45%; IV infusion; preservative-free.

Adults: For slow IV drip only. >16yrs: Intermittent infusion: 50mg every 6–8hrs (infuse over 15–20min);

usual max 400mg/day. Continuous IV infusion, or for Zollinger-Ellison: see literature. Renal impairment (CrCl <50mL/min): 50mg every 18–24hrs or more often if needed (intermittent only). Coincide a dose for end of hemodialysis.

Children: <1month: not recommended.

≥1month–16yrs: Treatment of duodenal ulcer: 2–4mg/kg per day in divided doses every 6–8hrs; max 50mg every 6–8hrs.

Warnings/Precautions: History of acute porphyria: not recommended. Renal impairment: reduce dose. Hepatic dysfunction. Discontinue if hepatic disorders occur. Monitor SGPT if on high-dose IV therapy for ≥5 days. Pregnancy (Cat.B). Nursing mothers.

Interactions: May increase triazolam, midazolam, glipizide, procainamide levels. May decrease ketoconazole, atazanavir, delaviridine, gefitinib levels. Monitor anticoagulants. May cause false (+) urine protein test with Multistix.

Adverse reactions: Headache, GI disturbances, jaundice, hepatitis, rash; rare: CNS disturbances, arrhythmias, blurred vision, arthralgia, myalgia, inj site reactions, blood dyscrasias, anaphylaxis, angioneurotic edema, acute interstitial nephritis, bradycardia with rapid administration (IV); increased risk of pneumonia (see literature).

How supplied: Tabs 150mg–60, 180, 500; 300mg–30; EFFERdose tabs–60; Syrup–pt; Inj single dose 2mL–10; Multidose 6mL–1; Premixed 50mL–24

SUCRALFATE**CARAFATE** Aptalis

Cytoprotectant. Sucralfate 1g; scored tabs.

Also: Sucralfate**CARAFATE SUSPENSION**

Sucralfate 1g/10mL.

Indications: Short-term (up to 8 weeks) treatment of active duodenal ulcer. Maintenance of healed duodenal ulcers (tabs only).

Adults: Active: 1g 4 times daily on an empty stomach for 4–8 weeks. Maintenance: 1g 2 times daily.

Children: Not established.

Warnings/Precautions: Monitor for glycemia in diabetic patients. Chronic renal failure. Dialysis. Tabs: swallowing impairment (eg, recent or prolonged intubation, tracheostomy, history of aspiration, dysphagia, others). Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid antacids within 30mins of dosing. May reduce absorption of tetracyclines, quinidine, levofloxacin, phenytoin, cimetidine, digoxin, ciprofloxacin, norfloxacin, ketoconazole, ranitidine, theophylline; dose concomitant drugs 2hrs before sucralfate. Additive aluminum load with aluminum-containing antacids. Monitor warfarin.

Adverse reactions: Constipation.

How supplied: Tabs–100; Susp–14oz

5F Nausea

APREPITANT

EMEND Merck

Substance P/neurokinin 1 receptor antagonist.

Aprepitant 40mg, 80mg, 125mg; caps.

Indications: In combination with other antiemetic agents to prevent acute and delayed nausea and vomiting associated with initial and repeat courses of moderately to highly emetogenic cancer chemotherapy, including high-dose cisplatin. Prevention of post-op nausea and vomiting.

Adults: ≥18yrs: Chemotherapy: Give with corticosteroid and 5-HT₃ antagonist. Day 1 of chemotherapy cycle: 125mg 1 hour before chemotherapy; Days 2 and 3: 80mg once daily in the AM. Post-op prophylaxis: 40mg within 3hrs prior to anesthesia.

Children: <18yrs: not recommended.

Also: Aprepitant

EMEND INJECTION

Fosaprepitant dimeglumine (prodrug of aprepitant) 115mg/vial, 150mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; contains polysorbate 80.

Indications: In combination with other antiemetic agents to prevent acute and delayed nausea and vomiting associated with initial and repeat courses of moderately to highly emetogenic cancer chemotherapy, including high-dose cisplatin.

Adults: ≥18yrs: Give with corticosteroid and 5-HT₃ antagonist (see literature). Give approx. 30min prior to chemotherapy. Highly emetogenic: Single-dose regimen: 150mg IV over 20–30min on Day 1. Moderately or highly emetogenic: 3-Day regimen: 115mg IV over 15 min on Day 1, then Days 2 and 3: 80mg orally once daily in the AM.

Children: <18yrs: not recommended.

Contraindications: Concomitant pimozide, cisapride.

Warnings/Precautions: Not for chronic continuous use. Severe hepatic insufficiency. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Monitor, and caution with, CYP3A4 substrates, including chemotherapy agents (eg, ifosfamide, vinblastine, vincristine); CYP3A4 inhibitors (eg, azole antifungals, macrolides, nefazodone, ritonavir, nelfinavir, diltiazem); and with CYP3A4 inducers (eg, carbamazepine, phenytoin, rifampin). Potentiates dexamethasone (reduce its dose by 50%), methylprednisolone (reduce its IV dose by 25% and its oral dose by 50%), midazolam, alprazolam, triazolam. May antagonize warfarin (closely monitor INR for 2 weeks after starting each regimen); phenytoin, tolbutamide, other CYP2C9 substrates; paroxetine, oral contraceptives (use alternative or backup method during and for 1 month after last dose).

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Adverse reactions: Asthenia, fatigue, hiccups, ALT/AST increased, headache, constipation, anorexia, GI upset, eructation, hypotension, pruritus, pyrexia.

Injection: inj site pain.

How supplied: Caps 40mg–1; Bi-fold pack (2 × 80mg)–1; Tri-fold pack (1 × 125mg + 2 × 80mg)–1; Vial–1

CHLORPROMAZINE

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CHLORPROMAZINE (various)

Phenothiazine. Chlorpromazine HCl 10mg, 25mg, 50mg, 100mg, 200mg; tabs; contains parabens.

Indications: Nausea and vomiting.

Adults: 10–25mg every 4–6 hrs as needed.

Children: <6months: not recommended.

≥6months: 0.25mg/lb every 4–6 hrs.

Also: Chlorpromazine

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CHLORPROMAZINE INJECTION

Chlorpromazine HCl 25mg/mL; for IV inj after dilution or IM inj; contains sulfites; multidose vials contain benzyl alcohol.

Adults: 25–50mg IM every 3–4 hrs if needed.

Children: <6months: not recommended.

≥6months: 0.25mg/lb IM every 6–8 hours if needed. <5yrs or <50lbs: max 40mg/day; ≥5yrs or 50–100lbs: usual max 75mg/day.

Contraindications: Coma. CNS or bone marrow depression. Reye's syndrome.

Warnings/Precautions: Discontinue 48 hrs before to 24 hrs after myelography. Cardiovascular, respiratory, renal, or liver disease. Epilepsy.

Glaucoma. History of breast cancer. Exposure to extreme heat or organophosphates. Asthma (inj). Monitor blood, liver, and ocular function. Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates phenytoin, alcohol, other CNS depressants, propranolol. Potentiated by propranolol. Antagonized by anticholinergics. Atropine. Decreased guanethidine, anticoagulant effects.

Adverse reactions: Tardive dyskinesia, drowsiness, jaundice, blood dyscrasias, hypotension, retinopathy, may mask emetic signs of disease, lowered seizure threshold, rash, skin pigmentation, anticholinergic effects, insomnia, extrapyramidal reactions, neuroleptic malignant syndrome.

How supplied: Contact supplier.

DIPHENHYDRAMINE

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BENADRYL INJECTION Pfizer

Antihistamine. Diphenhydramine HCl 50mg/mL; for IV or IM inj.

Indications: Motion sickness.

Adults: 10–50mg IV or deep IM; max 400mg/day.

Children: Neonates: not recommended. Others: 5mg/kg per day in 4 divided doses IV or deep IM; max 300mg daily in 4 divided doses.

Contraindications: Neonates. Premature infants. Nursing mothers.

Warnings/Precautions: Asthma. Lower respiratory disorders. Glaucoma. Hyperthyroidism.

Hypertension. Cardiovascular disease. GI or urinary obstruction. Children. Pregnancy (Cat.B).

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Potentiates anticholinergic effects with MAOIs.

Adverse reactions: Drowsiness, dizziness, anticholinergic effects, gastritis, paradoxical excitement, blood dyscrasias, hypotension.

How supplied: Vial (10 mL)–1 Amp or syringe (1 mL)–10

DOLASETRON

ANZEMET Sanofi Aventis

Selective 5-HT₃ receptor antagonist. Dolasetron mesylate 50mg, 100mg; tabs.

Indications: Prevention of nausea & vomiting associated with emetogenic cancer chemotherapy, including initial and repeat courses. Prevention of post-op nausea & vomiting.

Adults: ≥16yrs: 100mg within 1 hr before chemotherapy or within 2 hrs before surgery.

Children: <2yrs: not recommended. 2–16yrs: Chemotherapy-induced: 1.8mg/kg (max 100mg) within 1 hr before chemotherapy; or, may give IV soln and mix 1.8mg/kg (max 100mg) into apple or apple-grape juice and taken orally within 1 hour before chemotherapy. Post-op N/V: 1.2mg/kg (max 100mg) within 2 hrs before surgery; or may give IV soln and mix 1.2mg/kg (max 100mg) into apple or apple-grape juice and taken orally within 2 hrs before surgery.

Also: Dolasetron

ANZEMET INJECTION

Dolasetron mesylate 20mg/mL; IV inj.

Indications: Prevention and treatment of post-op nausea & vomiting.

Adults: Give by IV inj, either undiluted 100mg over 30 seconds or diluted to 50mL and infused over up to 15 minutes. ≥16yrs: Prevention: 12.5mg given as a single dose about 15 minutes before stopping anesthesia. Treatment: 12.5mg as soon as needed.

Children: May give by IV inj as in adult dose, or may be mixed into apple or apple-grape juice and taken orally (timing and doses are different; see literature). <2yrs: not recommended. 2–16yrs: Prevention: 0.35mg/kg IV (max 12.5mg) given as single dose about 15 minutes before stopping anesthesia; or, 1.2mg/kg (max 100mg) mixed into apple or apple-grape juice and taken orally within 2 hrs before surgery. Treatment: 0.35mg/kg IV as soon as needed.

Contraindications: Inj soln administered by IV: Prevention of nausea & vomiting associated with emetogenic cancer chemotherapy, including initial and repeat courses in adults and children.

Warnings/Precautions: Increased risk of developing QTc, PR and QRS interval prolongation. Avoid in patients with congenital QT syndrome, hypokalemia, hypomagnesemia, complete heart block or risk of (unless paced). Correct electrolyte imbalances prior to therapy. Monitor ECG periodically. CHF. Bradycardia. Pre-existing conduction

abnormalities and underlying structural heart disease. Sick sinus syndrome. Atrial fibrillation with slow ventricular response. Recent MI. Renal impairment. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with drugs which can prolong ECG intervals (eg, verapamil, flecainide, quinidine), diuretics, and with cumulative high-dose anthracycline therapy. Potentiated by cimetidine, atenolol (IV dolasetron). Antagonized by rifampin.

Adverse reactions: Headache, dizziness, pain, fatigue, diarrhea, bradycardia, tachycardia, ECG changes, 2nd or 3rd-degree AV block.

How supplied: Tabs–5; Single-use vials (100mg/5mL)–1; Single-use vials (12.5mg/0.625mL)–6; Single-use carpuject (12.5mg/0.625mL)–10; Multidose vial (500mg/25mL)–1

GRANISETRON

GRANISETRON HCl INJECTION (various)

Selective 5-HT₃ receptor antagonist. Granisetron (as HCl) 1mg/mL (contains benzyl alcohol); 0.1mg/mL (preservative-free); IV inj.

Indications: Prevention of nausea and vomiting associated with chemotherapy (including high-dose cisplatin). Prevention and treatment of post-op nausea and vomiting.

Adults and Children: Chemotherapy: give as an undiluted IV injection over 30 seconds or as a diluted IV infusion over 5 minutes. <2 years: not recommended; ≥2 years: 10micrograms/kg starting within 30 minutes of initiating chemotherapy, only on the days chemotherapy is given. Post-op (adults): infuse 1mg undiluted IV over 30 seconds. For prevention, give before induction of anesthesia or immediately before reversal of anesthesia. Post-op (children): not recommended.

Also: Granisetron

GRANISETRON HCl TABLETS

Granisetron HCl 1mg.

Indications: Prevention of nausea and vomiting associated with chemotherapy (including high-dose cisplatin), and with radiation (including total body irradiation and fractionated abdominal radiation).

Adults: Chemotherapy: give only on the days chemotherapy is given. 2mg up to 1 hour before chemotherapy; or, 1mg up to 1 hour before chemotherapy, then 1mg 12 hours after initial dose. Radiation: 2mg within 1 hour of radiation.

Children: Use IV form.

Warnings/Precautions: Abdominal surgery. May mask progressive ileus and/or gastric distention. Pre-existing arrhythmias or cardiac conduction disorders. Cardiac disease, concomitant cardio-toxic chemotherapy or electrolyte abnormalities: increased risk of QT prolongation. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with drugs that affect CYP450 or prolong the QT interval.

Adverse reactions: Headache, asthenia, diarrhea, constipation; QT prolongation.

How supplied: Contact supplier.

METOCLOPRAMIDE**REGLAN** Ani

Antidopaminergic. Metoclopramide (as HCl) 5mg, +10mg; +scored tabs.

Indications: Nausea and vomiting associated with diabetic gastroparesis.**Adults:** 10mg 30 minutes before each meal and at bedtime for 2–8 weeks. Renal impairment: reduce dose.**Children: Not recommended.****Contraindications:** When stimulation of GI motility may be dangerous (eg, obstruction, perforation, or hemorrhage). Pheochromocytoma. Epilepsy. Concomitant drugs which may cause extrapyramidal reactions (eg, phenothiazines, haloperidol).**Warnings/Precautions:** Parkinsonism. Tardive dyskinesia. History of breast cancer or depression. Cirrhosis. CHF. Hypertension. Elderly. Pregnancy (Cat.B). Nursing mothers.**Interactions:** Hypertensive crisis with MAOIs. Additive sedation with alcohol, other CNS depressants. Antagonized by anticholinergics and narcotics. Monitor insulin use; may diminish gastric and accelerate intestinal absorption of drugs or food.**Adverse reactions:** Restlessness, drowsiness, fatigue, extrapyramidal effects, parkinsonism, tardive dyskinesia, neuroleptic malignant syndrome, dizziness, endocrine disturbances, hypo- or hypertension, fluid retention, GI or GU disturbances; rare: hepatotoxicity.**How supplied:** Tabs–100**ONDANSETRON****ZOFTRAN** GlaxoSmithKlineSelective 5-HT₃ receptor antagonist. Ondansetron (as HCl dihydrate) 4mg, 8mg; tabs.**Also: Ondansetron****ZOFTRAN ODT**

Ondansetron (as base) 4mg, 8mg; orally disintegrating tabs; strawberry flavor; contains phenylalanine.

Also: Ondansetron**ZOFTRAN ORAL SOLUTION**

Ondansetron (as HCl dihydrate) 4mg/5mL; strawberry flavor.

Indications: Prevention of nausea and vomiting associated with highly emetogenic chemotherapy, including cisplatin $\geq 50\text{mg/m}^2$. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy. Prevention of nausea and vomiting associated with radiotherapy in patients receiving total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen. Prevention of post-op nausea and vomiting.**Adults:** See full labeling. Highly emetogenic chemotherapy: 24mg once 30 minutes before start of single-day chemotherapy (multi-day, single-dose not studied). Moderately emetogenic chemotherapy:

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8mg every 8 hours for 2 doses beginning 30 minutes before chemotherapy, then 8mg every 12 hours for 1–2 days after chemotherapy completed. Total body irradiation: 8mg 1–2 hours before each fraction of radiotherapy administered each day. Single high-dose fraction radiotherapy to abdomen: 8mg 1–2 hours before radiotherapy, then 8mg every 8 hours after 1st dose for 1–2 days after radiation completed. Daily fractionated radiotherapy to abdomen: 8mg 1–2 hours before radiotherapy, then 8mg every 8 hours after 1st dose for each day of radiotherapy. Post-op prophylaxis: 16mg 1 hour before induction of anesthesia. For all: severe hepatic dysfunction: max 8mg/day.**Children:** Highly emetogenic chemotherapy, radiotherapy, or <4yrs of age: not recommended (see IV form). 4–11yrs: moderately emetogenic chemotherapy: 4mg every 4 hours for 3 doses beginning 30 minutes before chemotherapy, then 4mg every 8 hours for 1–2 days after chemotherapy completed. Post-op prophylaxis: see IV form.**Also: Ondansetron****ZOFTRAN INJECTION**

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Ondansetron (as HCl dihydrate) 2mg/mL; IV or IM inj.

Indications: Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin. Prevention of post-op nausea and vomiting.**Adults:** Chemotherapy (vials must be diluted; see full labeling): >18yrs: Infuse over 15 minutes.

0.15mg/kg (max 16mg/dose) IV every 4 hours for 3 doses beginning 30 minutes before chemotherapy. Severe hepatic dysfunction: max 8mg/day. Post-op (do not dilute): Infuse in not less than 30 seconds, preferably over 2–5 minutes: 4mg IV as single dose immediately before induction of anesthesia; or shortly post-op if nausea or vomiting occurs. Or, may use 4mg IM undiluted as a single injection.

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Children: Chemotherapy (vials must be diluted; see full labeling): Infuse over 15 minutes. <6months: see full labeling. 6months–18yrs: 0.15mg/kg (max 16mg/dose) IV for 3 doses every 4 hours beginning 30 minutes before chemotherapy. Post-op (do not dilute): Infuse in not less than 30 seconds, preferably over 2–5 minutes: <1 month: see full labeling. 1month–12yrs (<40kg): 0.1mg/kg. $\geq 40\text{kg}$: 4mg. Give IV as single dose immediately before induction of anesthesia; or shortly post-op if nausea or vomiting occurs.

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Contraindications: Concomitant apomorphine.**Warnings/Precautions:** <4months of age (monitor closely). Congenital long QT syndrome: avoid. Electrolyte abnormalities, CHF, bradyarrhythmias, concomitant drugs that prolong QT: monitor ECG. May mask progressive ileus and/or gastric distention. Hepatic dysfunction. Pregnancy (Cat.B). Nursing mothers.**Interactions:** See Contraindications. Profound hypotension, loss of consciousness with apomorphine. May antagonize tramadol.

Adverse reactions: Diarrhea, headache, fever, constipation, abdominal pain, weakness, rash, transient blindness; rare: angina, bronchospasm, anaphylaxis, seizures, ECG changes (including QT prolongation).

How supplied: Tabs 4mg, 8mg-30; ODT 4mg-30; ODT 8mg-10, 30; Oral soln-50mL; Single-dose vial (2mg/mL)-5 (2mL/vial); Multidose vial (2mg/mL)-1 (20mL/vial)

PALONOSETRON

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ALOXI Eisai

Selective 5-HT₃ receptor antagonist. Palonosetron (as HCl) 0.075mg/1.5mL, 0.25mg/5mL; IV inj; contains mannitol.

Indications: Prevention of acute nausea and vomiting due to initial and repeat courses of moderately and highly emetogenic chemotherapy. Prevention of delayed nausea and vomiting due to initial and repeat courses of moderately emetogenic chemotherapy. Prevention of post-op nausea and vomiting for up to 24hrs after surgery.

Adults: ≥18yrs: give 30 minutes prior to chemotherapy. 0.25mg IV over 30 seconds; max 1 dose/week. Post-op: give immediately before anesthesia induction. 0.075mg IV over 10 seconds.

Children: <18yrs: not recommended.

Warnings/Precautions: Pregnancy (Cat.B). Labor & delivery. Nursing mothers: not recommended.

Adverse reactions: Headache, constipation, fatigue, GI disturbances, dizziness, tachycardia, bradycardia, hypotension, QT prolongation.

How supplied: Single-use vial (0.075mg/1.5mL)-5; (0.25mg/5mL)-1

PROCHLORPERAZINE

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PROCHLORPERAZINE (various)

Piperazine phenothiazine. Prochlorperazine (as maleate) 5mg, 10mg; tabs.

Also: Prochlorperazine

PROCHLORPERAZINE SUPPOSITORIES

Prochlorperazine 25mg.

Indications: Severe nausea and vomiting.

Adults: Oral: 5-10mg 3-4 times daily; usual max 40mg/day. Rectal: 25mg twice daily.

Children: <2yrs or <20lbs: not recommended.

Oral: 20-29lbs: 2½mg once or twice daily; max 7.5mg/day. 30-39lbs: 2½mg 2-3 times daily; max 10mg/day. 40-85lbs: 2½mg 3 times daily or 5mg twice daily; max 15mg/day.

Contraindications: Coma. CNS depression. Pediatric surgery. Children <2yrs or <20lbs.

Warnings/Precautions: Discontinue 48 hrs before to 24 hrs after myelography. Cardiovascular disease. Epilepsy. Bone marrow depression. Reye's syndrome. Glaucoma. History of breast cancer. Exposure to extreme heat. Monitor blood, liver, and ocular function. Write ℞ using fractions rather than

decimals. Children with acute illness or dehydration. Debilitated. Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Potentiates α-blockers. Levels of both drugs increased with propranolol. May potentiate phenytoin; monitor for toxicity. Adjust anticonvulsant doses. May antagonize oral anticoagulants. Hypotension potentiated with thiazide diuretics. Antagonized by anticholinergics. Decreases guanethidine effects. Monitor for neurologic toxicity with lithium; discontinue if occurs. May cause false (+) PKU test.

Adverse reactions: Drowsiness, dizziness, amenorrhea, blurred vision, other anticholinergic effects, skin reactions, hypotension, cholestatic jaundice, photosensitivity, leukopenia, agranulocytosis, neuroleptic malignant syndrome, agitation, insomnia, dystonias, extrapyramidal reactions, pseudoparkinsonism, tardive dyskinesia, may mask emetic signs of disease, lowered seizure threshold, EKG changes, aspiration, deep sleep, hyperprolactinemia, paradoxical excitement in children.

How supplied: Contact supplier.

PROMETHAZINE

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PROMETHAZINE HCl INJECTION (various)

Phenothiazine. Promethazine HCl 25mg/mL, 50mg/mL; sol for IM or IV inj; contains sulfites.

Indications: Motion sickness. Prevention and treatment of nausea & vomiting with anesthesia and surgery.

Adults: 12.5-25mg IM or IV every 4 hours.

Children: <2yrs: see Contraindications. ≥2yrs: should not exceed half that of suggested adult dose (see literature). Should not be used in vomiting of unknown etiology in children and adolescents.

Contraindications: Children <2 years. Coma. Intra-arterial or subcutaneous injection.

Warnings/Precautions: Sulfite sensitivity. CNS depression. Impaired respiratory function (eg, COPD, sleep apnea). Narrow-angle glaucoma. GI or GU obstruction. Cardiovascular or liver disease. Seizure disorders. Peptic ulcer. Bone marrow depression. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Caution with epinephrine, anticholinergics, MAOIs. May alter hCG pregnancy test results and glucose tolerance tests.

Adverse reactions: Inj site reactions, CNS depression/drowsiness, lowered seizure threshold, cholestatic jaundice, anticholinergic and extrapyramidal effects, neuroleptic malignant syndrome, photosensitivity, hypo- or hypertension, rash, blood dyscrasias, nausea, dry mouth, paradoxical reactions; children: respiratory depression (may be fatal).

How supplied: Contact supplier.

PROMETHAZINE**PROMETHAZINE HCl TABLETS** (various)

Phenothiazine. Promethazine HCl 12.5mg +, 25mg +, 50mg; tabs; + scored.

Also: Promethazine**PROMETHAZINE HCl RECTAL SUPPOSITORIES**

Promethazine HCl 12.5mg, 25mg, 50mg.

Indications: Motion sickness. Perioperative nausea & vomiting.**Adults:** Motion sickness: 25mg 30–60 minutes before travel; may repeat in 8–12 hours; maintenance 25mg twice daily. Perioperative nausea & vomiting: 25mg; may give additional doses of 12.5–25mg at 4–6 hour intervals.**Children:** <2 years: see Contraindications.

Motion sickness: ≥2 years: 12.5–25mg twice daily.

Perioperative nausea & vomiting: 0.5mg/lb or 25mg; may give additional doses of 12.5–25mg or 0.5mg/lb at 4–6 hour intervals.

Contraindications: Children <2 years.

Dehydrated or ill children (esp. Reye's syndrome).

History of sleep apnea. Asthma and lower respiratory disorders. Uncomplicated nausea in children.

Warnings/Precautions: Glaucoma. GI or urinary obstruction. Cardiovascular or liver disease. Seizure disorders. Peptic ulcer. Bone marrow depression. Elderly. Children ≥2 years. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** Potentiates CNS depression with alcohol, other CNS depressants. Caution with MAOIs. May alter hCG pregnancy test results.**Adverse reactions:** Drowsiness, lowered seizure threshold, cholestatic jaundice, anticholinergic and extrapyramidal effects, photosensitivity, hypotension, rash, blood dyscrasias, nausea, neonatal platelet abnormalities; children: respiratory depression (may be fatal).**How supplied:** Contact supplier.**SCOPOLAMINE****TRANSDERM SCOP** Novartis Consumer

Anticholinergic. Scopolamine 1.5mg (delivers approximately 1mg over 3 days); transdermal patch.

Indications: Prevention of motion sickness and post-op nausea and vomiting.**Adults:** Apply to dry skin behind ear; do not cut patch. Motion sickness: 1 patch at least 4 hours before travel; remove after 72 hours. Post-op: 1 patch evening before surgery; for cesarean section: 1 patch 1 hour before surgery. Remove 24 hours after surgery.**Children: Not recommended.****Contraindications:** Narrow angle glaucoma. Allergy to belladonna alkaloids.**Warnings/Precautions:** Wash hands and skin after use; avoid eyes. GI or urinary tract obstruction. Hepatic, renal, or metabolic dysfunction. Seizure.

Psychosis. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Alcohol, other CNS depressants potentiate CNS depression. Additive anticholinergic

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effects with other anticholinergics, antihistamines (eg, meclizine), antidepressants. May affect absorption of other drugs.

Adverse reactions: Dry mouth, drowsiness, blurred vision, disorientation, confusion, difficult urination; withdrawal symptoms may occur if used for >3 days.**How supplied:** Patches–4**SECTION 6:****HEMATOLOGICAL DISORDERS
6A Anemias****DARBEPOETIN ALFA**

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ARANESP Amgen

Erythropoiesis stimulating protein. Darbepoetin alfa 25mcg/mL, 40mcg/mL, 60mcg/mL, 100mcg/mL, 150mcg/0.75mL, 200mcg/mL, 300mcg/mL, 500mcg/mL; for IV or SC inj; preservative-free; contains albumin (human) or polysorbate 80.

Also: Darbepoetin alfa

R

ARANESP SINGLEJECT

Darbepoetin alfa 25mcg/0.42mL, 40mcg/0.4mL, 60mcg/0.3mL, 100mcg/0.5mL, 150mcg/0.3mL, 200mcg/0.4mL, 300mcg/0.6mL, 500mcg/mL; per prefilled syringe; for IV or SC inj; preservative-free; contains albumin (human) or polysorbate 80.

Also: Darbepoetin alfa

R

ARANESP SURECLICK

Darbepoetin alfa 25mcg/0.42mL, 40mcg/0.4mL, 60mcg/0.3mL, 100mcg/0.5mL, 150mcg/0.3mL, 200mcg/0.4mL, 300mcg/0.6mL, 500mcg/mL; per prefilled autoinjector; for SC inj; preservative-free; contains albumin (human) or polysorbate 80.

Indications: Anemia of chronic renal failure (CRF), including patients on and not on dialysis. Chemotherapy-induced anemia in patients with non-myeloid malignancies.**Adults:** CRF (not currently on epoetin alfa): initially 0.45mcg/kg SC or IV once weekly; alternatively for CRF (not on dialysis): 0.75mcg/kg SC once every 2 weeks. Cancer: initially 2.25mcg/kg SC once weekly or 500mcg SC once every 3 weeks. Discontinue after completion of chemotherapy course. Adjust dose to maintain hemoglobin level (target 10–12g/dL; max 12g/dL) sufficient to avoid red blood cell transfusion; see literature. Converting from epoetin alfa, and for dose adjustment: see literature.**Children: Not recommended.****Contraindications:** Uncontrolled hypertension. Do not use in patients with pure red cell aplasia due to erythropoietin antibodies.**Warnings/Precautions:** See literature. Evaluate serum iron, ferritin, transferrin saturation before and during therapy; most patients will need iron supplementation. Monitor hemoglobin weekly for 4 weeks after start and dose changes, until stabilized,

then periodically; reduce dose if hemoglobin increases $>1\text{g/dL}$ in any 2-week period; withhold dose if hemoglobin exceeds 12g/dL . Monitor BP (reduce or withhold dose if hypertension occurs), folate, Vit. B_{12} , renal function, electrolytes, fluid balance, and for premonitory neurological symptoms. Seizure, cardiovascular, or hematologic disorders. Infection, inflammation, malignancy, occult blood loss, severe albumin toxicity, bone marrow fibrosis may reduce effectiveness; consider other etiologies in treatment failures. Adjust dialysis R as needed. Latex allergy. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Infection, hyper- or hypotension, myalgia, headache, GI upset, dyspnea, edema, arthralgia, limb or back pain, arrhythmia/cardiac arrest, cough, fatigue, chest pain, dizziness, pruritus, clotted vascular access, CHF, flu-like symptoms, local reactions, asthenia, seizure, iron deficiency. Increased risk of death, cardiovascular or thrombotic events if hemoglobin $>12\text{g/dL}$. May stimulate tumor growth, shorten time to tumor progression or overall survival if hemoglobin $\geq 12\text{g/dL}$. Cancer patients also: pneumonia, dehydration.

How supplied: Single-dose vials (25, 40, 60, 100, 150, 200, 300mcg)–4; Single-dose vial (200, 300, 500mcg)–1; Single-dose prefilled syringes (25, 40, 60, 100, 150, 200, 300mcg)–4; Single-dose prefilled syringes (200, 300, 500mcg)–1; Single-dose prefilled SureClick autoinjector (25, 40, 60, 100, 150, 200, 300, 500mcg)–1

EPOETIN ALFA

EPOGEN Amgen

Erythropoietin (human, recombinant). Epoetin alfa 2000 Units, 3000 Units, 4000 Units, 10000 Units, 40000 Units; per mL; soln for IV or SC inj; contains albumin (human); preservative-free.

Also: Epoetin alfa
EPOGEN MULTIDOSE

Epoetin alfa 10000 Units, 20000 Units; per mL; soln for IV or SC inj; contains albumin (human) and benzyl alcohol.

Indications: Anemia in chronic renal failure (CRF). Anemia related to zidovudine in HIV-infected patients. Chemotherapy-induced anemia in patients with non-myeloid malignancies (serum erythropoietin $\leq 200\text{ mUnits/mL}$). To reduce need for allogeneic blood transfusions in anemic (hemoglobin >10 to $\leq 13\text{g/dL}$) patients scheduled for elective, noncardiac, nonvascular surgery.

Adults: Individualize (see literature for titration). CRF: initially 50–100 Units/kg 3 times per week IV (dialysis or non dialysis) or SC (non dialysis); usual max (non dialysis) 150 Units/kg 3 times per week; (dialysis) 200 Units/kg 3 times per week; target hemoglobin 10–12g/dL. Zidovudine-treated HIV patients: if serum erythropoietin $\leq 500\text{ mUnits/mL}$ and zidovudine dose $\leq 4.2\text{ g/wk}$: initially 100 Units/kg IV or SC 3 times per week for 8 weeks; usual max 300 Units/kg 3 times per week. Chemotherapy-induced: initially

150 Units/kg SC 3 times per week; may increase to 300 Units/kg 3 times per week after 8 weeks. Or, initially 40000 Units SC once weekly; may increase to 60000 Units once weekly after 4 weeks. Discontinue after completion of chemotherapy course. Surgery: If ≥ 21 days until surgery: 600 Units/kg once weekly SC at 21, 14 and 7 days before surgery, and a 4th dose on day of surgery. If <21 days until surgery: 300 Units/kg per day SC for 10 days before, on day of, and for 4 days after surgery. All: adjust dose to maintain the lowest hemoglobin level (target max 12g/dL) sufficient to avoid red blood cell transfusion; see literature.

Children: Individualize (see literature for monitoring).

CRF (dialysis): <1 month: not recommended.

≥ 1 month of age: initially 50 Units/kg three times per week IV or SC. Target hemoglobin: 10–12g/dL. Chemotherapy-induced: ≥ 5 ys: 600 Units/kg IV weekly (max 40,000 Units); may increase to 900 Units/kg IV weekly (max 60,000 Units) after 4 weeks. Discontinue after completion of chemotherapy course. Other uses: see literature.

Contraindications: Uncontrolled hypertension.

Warnings/Precautions: See literature. Evaluate serum iron, ferritin, transferrin saturation before therapy; all patients will need iron supplementation. Monitor hemoglobin (measure twice weekly for 2–6 weeks after any dosage adjustment; reduce dose if hemoglobin increases $>1\text{g/dL}$ in any 2-week period; withhold dose if hemoglobin exceeds 12g/dL), blood pressure, renal function, iron levels, clotting times, serum chemistry, CBC, and for premonitory neurological symptoms. Seizure disorders. Cardiovascular or hematologic disorders. Hypertension (esp. in renal failure). Porphyria. Concurrent infection, inflammation, increased zidovudine dose, or other factors may reduce effectiveness. Perisurgery: consider DVT prophylaxis. Consider other etiologies in treatment failures. Adjust anticoagulant dose in dialysis patients. Menses may resume. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Iron deficiency, hypertension, headache, arthralgia, GI disturbances, edema, local reaction, rash, paresthesia, dizziness, clotted vascular access (A-V shunt), pyrexia, respiratory congestion, seizures. Increased risk of death, cardiovascular or thrombotic events if hemoglobin $>12\text{g/dL}$. May stimulate tumor growth, shorten time to tumor progression or overall survival if hemoglobin $\geq 12\text{g/dL}$. Children: also abdominal pain, upper respiratory infection, cough, pharyngitis, constipation.

How supplied: Single-use 1mL vials (all)–10; Multidose 2mL vials (10000 Units/mL)–10; Multidose 1mL vials (20000 Units/mL)–10

EPOETIN ALFA

PROCRIIT Janssen Biotech

Erythropoietin (human, recombinant). Epoetin alfa 2000 Units, 3000 Units, 4000 Units, 10000 Units, 40000 Units; per mL; soln for IV or SC inj; contains albumin (human); preservative-free.

**Also: Epoetin alfa
PROCRT MULTIDOSE**

Epoetin alfa 10000 Units, 20000 Units; per mL; soln for IV or SC inj; contains albumin (human) and benzyl alcohol.

Indications: Anemia in chronic renal failure (CRF). Anemia related to zidovudine in HIV-infected patients. Chemotherapy-induced anemia in patients with non-myeloid malignancies (serum erythropoietin ≤ 200 mUnits/mL). To reduce need for allogeneic blood transfusions in anemic (hemoglobin > 10 to ≤ 13 g/dL) patients scheduled for elective, noncardiac, nonvascular surgery.

Adults: Individualize (see literature for titration). CRF: initially 50–100 Units/kg 3 times per week IV (dialysis or non dialysis) or SC (non dialysis); usual max (non dialysis) 150 Units/kg 3 times per week; (dialysis) 200 Units/kg 3 times per week; target hemoglobin: 10–12g/dL. Zidovudine-treated HIV patients: if serum erythropoietin ≤ 500 mUnits/mL and zidovudine dose ≤ 4.2 g/wk: initially 100 Units/kg IV or SC 3 times per week for 8 weeks; usual max 300 Units/kg 3 times per week. Chemotherapy-induced: initially 150 Units/kg SC 3 times per week; may increase to 300 Units/kg 3 times per week after 8 weeks. Or, initially 40000 Units SC once weekly; may increase to 60000 Units once weekly after 4 weeks. Discontinue after completion of chemotherapy course. Surgery: If ≥ 21 days until surgery: 600 Units/kg once weekly SC at 21, 14 and 7 days before surgery, and a 4th dose on day of surgery. If < 21 days until surgery: 300 Units/kg per day SC for 10 days before, on day of, and for 4 days after surgery. All: adjust dose to maintain the lowest hemoglobin level (target max 12g/dL) sufficient to avoid red blood cell transfusion; see literature.

Children: Individualize (see literature for monitoring). CRF (dialysis): < 1 month: not recommended. ≥ 1 month of age: initially 50 Units/kg three times per week IV or SC. Target hemoglobin: 10–12g/dL. Chemotherapy-induced: ≥ 5 yrs: 600 Units/kg IV weekly (max 40,000 Units); may increase to 900 Units/kg IV weekly (max 60,000 Units) after 4 weeks. Discontinue after completion of chemotherapy course. Other uses: see literature.

Contraindications: Uncontrolled hypertension.

Warnings/Precautions: See literature. Evaluate serum iron, ferritin, transferrin saturation before therapy; all patients will need iron supplementation. Monitor hemoglobin (measure twice weekly for 2–6 weeks after any dosage adjustment; reduce dose if hemoglobin increases > 1 g/dL in any 2-week period; withhold dose if hemoglobin exceeds 12g/dL, blood pressure, renal function, iron levels, clotting times, serum chemistry, CBC, and for premonitory neurological symptoms. Seizure disorders. Cardiovascular or hematologic disorders. Hypertension (esp. in renal failure). Porphyria. Concurrent infection, inflammation, increased zidovudine dose, or other factors may reduce

R

effectiveness. Perisurgery: consider DVT prophylaxis. Consider other etiologies in treatment failures. Adjust anticoagulant dose in dialysis patients. Menses may resume. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Iron deficiency, hypertension, headache, arthralgia, GI disturbances, edema, local reaction, rash, paresthesia, dizziness, clotted vascular access (A-V shunt), pyrexia, respiratory congestion, seizures. Increased risk of death, cardiovascular or thrombotic events if hemoglobin > 12 g/dL. May stimulate tumor growth, shorten time to tumor progression or overall survival if hemoglobin ≥ 12 g/dL. Children: also abdominal pain, upper respiratory infection, cough, pharyngitis, constipation.

How supplied: Single-use 1mL vials (2000 Units/mL, 3000 Units/mL, 4000 Units/mL, 10000 Units/mL)–6, 25; Single-use 1mL vials (40000 Units/mL)–4; Multidose 2mL vials (10000 Units/mL)–4, 6; Multidose 1mL vials (20000 Units/mL)–4, 6

FOLIC ACID

R

FOLIC ACID (various)
Hematinic. Folic acid 1mg; tabs.

Also: Folic acid

R

FOLIC ACID INJECTION

Folic acid 5mg/mL; soln for IV, IM or SC inj; contains benzyl alcohol and aluminum.

Indications: Megaloblastic anemias of folic acid deficiency. Anemias of nutritional origin, pregnancy, infancy or childhood.

Adults and Children: Usual dose: up to 1mg daily; may need higher dose if resistant disease. Maintenance: infants: 0.1mg/day; < 4 yrs: 0.3mg/day; ≥ 4 yrs: 0.4mg/day. Pregnant or lactating: 0.8mg/day. Alcoholism, hemolytic anemia, anticonvulsant therapy or chronic infection: may require higher dose.

Warnings/Precautions: Use injectable form if disease is severe or GI absorption impaired. Rule out or treat vitamin B₁₂ deficiency prior to treatment. May obscure diagnosis of pernicious anemia. Pregnancy (Cat.A).

Interactions: May antagonize phenytoin. False low serum and red cell folate levels may occur with antibiotics (eg, tetracycline).

Adverse reactions: Allergic sensitization.

How supplied: Contact supplier.

IRON (AS DEXTRAN COMPLEX)

R

DEXFERRUM American Regent

Hematinic. Iron (as dextran complex) 50mg/mL; soln for IV inj.

Indications: Iron deficiency where oral therapy is unsatisfactory or impossible.

Adults and Children: < 4 months: not recommended. Give by IV inj. Administer 0.5mL test dose first; if no signs/symptoms of anaphylactoid-type reactions, may give full therapeutic dose. ≥ 4 months: Iron deficiency anemia: determine total dose based

on hemoglobin and body weight (see literature). Iron replacement for blood loss: $\text{Replacement iron (in mg)} = \text{blood loss (in mL)} \times \text{hematocrit}$. Max daily doses: $<5\text{kg}$: 0.5mL (25mg), $<10\text{kg}$: 1mL (50mg), $\geq 10\text{kg}$: 2mL (100mg).

Contraindications: Anemia not associated with iron deficiency.

Warnings/Precautions: Monitor for signs/symptoms of anaphylactic-type reactions, esp. in patients with history of allergies, asthma; have epinephrine available. Hepatic impairment. Avoid during acute phase of infectious kidney disease. Cardiovascular disease. Avoid large IV doses: higher incidence of adverse events. Iron overload more likely with hemoglobinopathies or refractory anemias. Rheumatoid arthritis. Neonates. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant ACE inhibitors may increase the risk for anaphylactic-type reactions. May falsely elevate serum bilirubin and decrease serum calcium.

Adverse reactions: See literature. Anaphylactic reactions (may be fatal, even in patients who tolerated test dose), cardiovascular events, pruritus, GI upset, arthralgia, arthritis, inj site reactions, others.

How supplied: Single-dose vials (1mL, 2mL)–10

IRON (AS DEXTRAN COMPLEX) R

INFED Actavis

Hematinic. Iron (as dextran complex) 50mg/mL; soln for IV or IM inj.

Indications: Iron deficiency where oral therapy is unsatisfactory or impossible.

Adults and Children: Give by IV or by deep IM (into upper outer quadrant of buttock only) inj. Administer 0.5mL test dose first; if no signs/symptoms of anaphylactic-type reactions, may give full therapeutic dose. Iron deficiency anemia: determine total dose based on hemoglobin and body weight (see literature). Iron replacement for blood loss: $\text{Replacement iron (in mg)} = \text{blood loss (in mL)} \times \text{hematocrit}$. Max daily doses: $<5\text{kg}$: 0.5mL (25mg), $<10\text{kg}$: 1mL (50mg), $\geq 10\text{kg}$: 2mL (100mg).

Contraindications: Anemias not associated with iron deficiency.

Warnings/Precautions: Monitor for signs/symptoms of anaphylactic-type reactions, esp. in patients with history of drug allergies, asthma; have epinephrine available. Avoid large IV doses: higher incidence of adverse events. Severe hepatic impairment. Avoid during acute phase of infectious kidney disease. Dialysis. Cardiovascular disease. May reactivate quiescent rheumatoid arthritis. Neonates (avoid during first 4 months). Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant ACE inhibitors may increase the risk for anaphylactic-type reactions. May falsely elevate serum bilirubin or decrease serum calcium levels.

Adverse reactions: See literature. Anaphylactic reactions (may be fatal; even if test dose was tolerated), cardiovascular events, pruritus, GI upset, arthralgia, arthritis, inj site reactions, others; possible IM inj site tumors, sepsis in neonates.

How supplied: Vials (2mL)–10

IRON (AS SUCROSE) R

VENOFER American Regent

Hematinic. Iron (as sucrose) 20mg/mL; soln for IV inj or infusion; preservative-free.

Indications: Iron deficiency anemia in chronic kidney disease.

Adults: Give by slow IV inj (undiluted) or infusion (diluted). Usual total cumulative dose: 1000mg. Hemodialysis dependent: 100mg slow IV inj over 2–5 minutes or infuse 100mg over at least 15 minutes per consecutive session. Non-dialysis dependent: 200mg slow IV inj over 2–5 minutes on 5 different occasions within a 14-day period; limited experience with IV infusion (see literature). Peritoneal dialysis dependent: Two infusions of 300mg over 1.5 hours 14 days apart, then one 400mg infusion over 2.5 hours 14 days later.

Children: Not recommended.

Contraindications: Anemia not caused by iron deficiency. Iron overload.

Warnings/Precautions: Withhold therapy if tissue iron overload suspected. Monitor hemoglobin, hematocrit, serum ferritin, transferrin saturation; obtain serum iron values 48 hours after dosing. Pregnancy (Cat.B). Nursing mothers.

Interactions: May reduce absorption of concomitant oral iron preparations.

Adverse reactions: Hypotension (esp. by IV infusion), hypertension, muscle cramps, GI upset, headache, dizziness, chest pain, graft complications, dysgeusia, pruritus, edema, constipation; rare: hypersensitivity reactions (may be severe).

How supplied: Single-dose vials (100mg/5mL)–1, 10, 25
200mg/10mL–1, 5, 10

IRON GLUCONATE R

NULECIT Watson

Hematinic. Iron (as sodium ferric gluconate complex in sucrose) 12.5mg/mL; soln for IV inj or infusion; contains benzyl alcohol.

Indications: Iron deficiency anemia in patients on chronic hemodialysis receiving epoetin therapy.

Adults: Give by IV infusion (diluted) or slow IV inj (undiluted). 125mg infused over 1 hour or by slow IV inj (at a rate of up to 12.5mg/min). Minimum cumulative dose: 1g given over 8 sequential dialysis sessions; usual max: 125mg/dose.

Children: $<6\text{yrs}$: not recommended. Give by IV infusion (diluted) over 1 hour. $\geq 6\text{yrs}$: 1.5mg/kg per dose at 8 sequential dialysis sessions; max: 125mg/dose.

Contraindications: Anemias not caused by iron deficiency. Iron overload.

Warnings/Precautions: Hemoglobinopathies. Refractory anemias. Avoid in neonates. Pregnancy (Cat.B). Nursing mothers.

Interactions: May reduce absorption of concomitant oral iron preparations.

Adverse reactions: Hypotension, hypertension, GI upset, chest pain, back pain, abdominal pain, pruritus, inj site reaction, cramps, headache, dizziness, syncope, fatigue, fever, dyspnea, tachycardia; rare: hypersensitivity reactions.

How supplied: Vials (5mL)–10

LENALIDOMIDE

R

REVLIMID Celgene

Immunomodulator. Lenalidomide 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg; caps.

Indications: Transfusion-dependent anemia due to Low- or Intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality.

Adults: Do not break, chew, or open caps. Swallow whole with water. ≥ 18 yrs: initially 10mg per day; adjust dose based on response. Renal impairment: Moderate (CrCL 30–60mL/min): 5mg per day. Severe (CrCL < 30 mL/min without dialysis): 2.5mg per day. ESRD (CrCL < 30 mL/min with dialysis): 2.5mg once daily; administer after dialysis (on dialysis days). Dose adjustments if thrombocytopenia or neutropenia develops: see full labeling.

Children: < 18 yrs: **not established.**

Contraindications: Pregnancy (Cat.X). Women who may become pregnant.

Warnings/Precautions: Must register patient in RevAssist program; patient must understand toxicity with fetal exposure. Counsel patient on need for contraception; female: use 2 forms of contraception 1 month before, during, and 1 month after therapy; male: use condom during and 1 month after therapy; obtain 2 negative pregnancy tests (one within 10–14 days, and then another within 24 hours prior to starting therapy), repeat at least weekly for 1st month then every 4 weeks; get informed consent. Monitor for signs/symptoms of thromboembolic events. Obtain CBCs weekly for first 8 weeks, then monthly. Renal impairment (monitor). Monitor for tumor lysis syndrome in those with high tumor burden. Monitor liver enzymes; discontinue if elevation occurs. Maximum 1 month per R. Nursing mothers: not recommended.

Interactions: Monitor digoxin. Concomitant warfarin; monitor PT, INR. May increase risk of thrombosis with erythropoietic agents or estrogen containing therapies.

Adverse reactions: Birth defects, thrombocytopenia, neutropenia, GI upset, pruritus, rash, fatigue, arthralgia, pyrexia, back pain, cough, dizziness, headache, dyspnea, blurred vision, muscle cramp; thrombosis/embolism, allergic reactions (discontinue if occurs; do not resume), tumor flare reaction (monitor; esp. in treating MCL), hepatotoxicity.

Note: Available only through RevAssist program. Report any suspected fetal exposure to the FDA at (800) FDA-1088 and Celgene at (888) 423-5436.

How supplied: Caps 2.5mg, 5mg, 10mg–28, 100 15mg, 20mg, 25mg–21, 100

LEUCOVORIN

R

LEUCOVORIN Teva Health Systems

Folic acid derivative. Leucovorin calcium 100mg/vial, 350mg/vial; lyophilized pwd for IV or IM inj after reconstitution; preservative-free.

Indications: Megaloblastic anemia due to folic acid deficiency when oral therapy is not feasible.

Adults: Up to 1mg daily.

Children: See literature.

Contraindications: Pernicious anemia and other megaloblastic anemias due to Vit. B₁₂ deficiency.

Warnings/Precautions: Do not administer intrathecally. CNS metastases. Monitor CBCs with differential, platelets, electrolytes, liver function tests prior to each treatment, then periodically. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates toxicity of 5-fluorouracil; use lower 5-fluorouracil dose. May antagonize phenobarbital, phenytoin, and primidone. Caution with trimethoprim-sulfamethoxazole.

Adverse reactions: Leukopenia, thrombocytopenia, infection, GI upset, stomatitis, constipation, lethargy, malaise, fatigue, alopecia, dermatitis, anorexia; seizures, syncope.

How supplied: Single-use vials–1

LEUPROLIDE

R

LUPRON DEPOT 3.75MG AbbVie

GnRH analogue. Leuprolide acetate 3.75mg; depot susp for IM inj; preservative-free.

Indications: Presurgical treatment of patients with anemia due to uterine leiomyomata (fibroids), with iron therapy if iron therapy alone is inadequate.

Adults: ≥ 18 years: 3.75mg IM once per month for up to 3 months.

Children: < 18 years: **not applicable.**

Also: *Leuprolide*

R

LUPRON DEPOT-3 MONTH 11.25MG

Leuprolide acetate 11.25mg; depot susp for IM inj; preservative-free.

Adults: ≥ 18 years: 11.25mg IM once every 3 months (1 injection). Do not split doses.

Children: < 18 years: **not applicable.**

Contraindications: Undiagnosed abnormal vaginal bleeding. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Exclude pregnancy before starting; use nonhormonal contraception during therapy; discontinue if pregnancy occurs. Risk factors for decreased bone mineral density (eg, chronic alcohol, tobacco, anticonvulsants, corticosteroids). Missing successive doses may cause breakthrough bleeding or ovulation. Elderly.

Adverse reactions: Hot flashes, headache, vaginitis, depression, emotional lability, pain,

decreased libido, breast changes, amenorrhea, mastodynia, joint disorder, asthenia, GI upset, edema, bone density loss, local reactions, acne, memory disorders, others; rarely: anaphylaxis, asthma, increased serum transaminases or lipids.

How supplied: Kit-1 (single-dose syringe w. diluent, supplies)

PEGINESATIDE

OMONTYS Affymax and Takeda

Erythropoiesis-stimulating agent (ESA). Peginesatide 2mg, 3mg, 4mg, 5mg, 6mg per 0.5mL single-use vial (preservative-free); 1mg, 2mg, 3mg, 4mg, 5mg, 6mg per 0.5mL single-use prefilled syringe (preservative-free); 10mg/mL, 20mg/2mL multiple-use vial (w. preservatives); solution for IV or SC inj.

Indications: Anemia due to chronic kidney disease (CKD) in adult patients on dialysis.

Adults: Use lowest effective dose. Initiate when Hb <10g/dL. Not currently on ESA: Initially 0.04mg/kg as a single IV or SC inj once monthly. Converting from epoetin alfa: give first Omontys dose 1 week after last epoetin alfa dose. Converting from darbepoetin alfa: give first Omontys dose at next scheduled dose in place of darbepoetin alfa. See literature for estimated Omontys starting doses for patients based on previous weekly ESA dose. Do not increase dose > once every 4 weeks. If Hb rises rapidly (eg, >1g/dL in 2 weeks prior to dose or >2g/dL in 4 weeks), reduce dose by 25% or more to reduce rapid responses. If Hb approaches or exceeds 11g/dL, reduce or interrupt dose; when Hb decreases, resume at a dose approx. 25% below previous dose. If response is inadequate and Hb does not increase by >1g/dL after 4 weeks, increase dose by 25%. If response inadequate over 12-week escalation period, use lowest dose that will maintain Hb sufficient to reduce need for RBC transfusions. Discontinue if response does not improve.

Children: Not established.

Contraindications: Uncontrolled hypertension.

Warnings/Precautions: Risk of death, serious cardiovascular reactions, stroke when ESA given to target Hb >11g/dL. Not for patients with CKD not on dialysis or for anemia due to cancer chemotherapy. Not a substitute for RBC transfusions in patients who require immediate correction of anemia. Evaluate iron status before and during therapy; maintain iron repletion. Correct or exclude other causes of anemia. Monitor Hb at least every 2 weeks, then monthly. Control hypertension prior to initiating; reduce or withhold dose if BP difficult to control. Risk of tumor progression/recurrence in cancer patients receiving ESAs. Consider antibody formation in treatment failures. Adjust anticoagulant dose to prevent clotting of extracorporeal circuit during hemodialysis. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Dyspnea, diarrhea, nausea, cough, arteriovenous fistula site complication; serious allergic reactions (discontinue permanently if occurs).

How supplied: Single-use vial, single-use prefilled syringe, multi-use vial-1

6B Bleeding disorders

ANTI-INHIBITOR COAGULANT COMPLEX

FEIBA VH Baxter

Hemostatic. Anti-inhibitor Coagulant Complex (AICC) 500 units, 1000 units, 2500 units; per vial; for IV infusion after reconstitution; contains Factors II, IX, X (non-activated); Factor VII (activated); Factor VIII inhibitor bypassing activity; Prothrombin Complex Factors; heparin-free.

Indications: To control spontaneous bleeding or to cover surgical interventions in Hemophilia A and B with inhibitors (see literature).

Adults and Children: Infusion rate: ≤2units/kg per minute. Joint hemorrhage: 50units/kg every 12hrs; may increase to 100units/kg. Mucous membrane bleeding: 50units/kg every 6hrs; if bleeding continues, increase to 100units/kg every 6hrs; max: 2 doses. Soft tissue: 100units/kg every 12hrs. Other severe hemorrhages (eg, CNS bleeding): 100units/kg every 12hrs; may increase to 6hr intervals. All: Max 200units/kg per day (100units/kg per dose).

Contraindications: Normal coagulation mechanism.

Warnings/Precautions: Not for treating bleeding episodes due to coagulation factor deficiencies; must have circulating inhibitors to one or more coagulation factors. Disseminated intravascular coagulation (DIC); fibrinolysis: not recommended. Monitor for development of DIC and/or acute coronary ischemia; discontinue if occurs. Contains human plasma; monitor for possible infection transmission. Non-hemophilic. Latex allergy. Newborns. Pregnancy (Cat.C).

Interactions: Separate antifibrinolytics by 12 hours.

Adverse reactions: Allergic reactions, thromboembolic events, DIC; rare: myocardial infarction.

Note: Report all infections suspected to be transmitted by Feiba VH to (800) 423-2862.

How supplied: Single-dose vials-1 (w. diluent, transfer device)

ANTIHEMOPHILIC FACTOR VIII

HELIXATE FS CSL Behring

Clotting factor. Antihemophilic Factor VIII (recombinant) 250 IU, 500 IU, 1000 IU; per bottle; dried concentrate for IV infusion after reconstitution; contains sucrose; preservative-free.

Indications: Prevention and control of hemorrhagic episodes or in order to perform emergency or elective surgery in Hemophilia A patients.

Adults and Children: See prescribing information for dosing equation. Individualize. Infuse over 5-10minutes if tolerated. Minor hemorrhage: 10-20 IU/kg; may repeat dose if needed. Moderate/major

hemorrhage or minor surgery: 15–30 IU/kg; may repeat 1 dose at 12–24hrs if needed. Major/life-threatening hemorrhage, fractures or head trauma: initially 40–50 IU/kg, then 20–25 IU/kg every 8–12hrs. Major surgery: pre-op dose: 50 IU/kg (verify ~100% activity prior to surgery); may repeat after 6–12hrs initially, and for 10–14 days until completely healed.

Contraindications: Mouse or hamster protein sensitivity.

Warnings/Precautions: Not for treating von Willebrand's disease. Confirm Factor VIII deficiency prior to treatment. Monitor for development of Factor VIII inhibitors. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Inj site reactions, dizziness, rash, dysgeusia, increased BP, pruritus, depersonalization, GI upset, rhinitis; antibody formation, hypersensitivity reactions.

How supplied: Single-use bottle–1 (w. diluent)

ANTHEMOPHILIC FACTOR VIII R

KOGENATE FS Bayer

Clotting factor. Antihemophilic Factor VIII (recombinant) 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU; per vial; lyophilized pwd for IV infusion after reconstitution; contains sucrose; preservative-free.

Indications: Prevention and control of hemorrhagic episodes in Hemophilia A. Surgical prophylaxis in Hemophilia A. Routine prophylaxis to reduce frequency of hemorrhagic episodes and joint damage in children with Hemophilia A with no pre-existing joint damage.

Adults and Children: See prescribing information for dosing equation. Individualize. Infuse over 1–15mins if tolerated. Minor hemorrhage: 10–20 IU/kg; may repeat dose if needed. Moderate hemorrhage or minor surgery: 15–30 IU/kg; may repeat dose every 12–24hrs until resolved. Major hemorrhage, fractures or head trauma: initially 40–50 IU/kg, then 20–25 IU/kg every 8–12hrs until resolved. Major surgery: pre-op: 50 IU/kg (verify 100% activity prior to surgery); repeat if needed after 6–12hrs initially, and for 10–14 days until completely healed. Routine prophylaxis in children: 25 IU/kg every other day.

Contraindications: Mouse or hamster protein sensitivity.

Warnings/Precautions: Not for von Willebrand's disease. Confirm Factor VIII deficiency prior to treatment. Monitor for development of Factor VIII inhibitors. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Inj site reactions, dizziness, rash, BP increase, pruritus, hypersensitivity reactions, antibody formation, central venous line-associated infections.

How supplied: Kit–1 (vial w. diluent and BIO-SET system)

ANTHEMOPHILIC FACTOR VIII R

RECOMBINATE Baxter

Clotting factor. Antihemophilic Factor VIII (recombinant) 250 IU, 500 IU, 1000 IU; per bottle; lyophilized pwd for IV infusion after reconstitution; contains albumin; preservative-free.

Indications: Prevention and control of hemorrhagic episodes and perioperative management in Hemophilia A.

Adults and Children: See prescribing information for dosing equation. Infuse at rate of up to 10mL/min. Monitor pulse rate; if increased significantly, reduce infusion rate or hold.

Hemorrhage: Mild: obtain 20–40% FVIII increase; give every 12–24hrs for 1–3 days until resolved.

Moderate: obtain 30–60% FVIII increase; give every 12–24hrs for 3 days or until pain or disability resolved.

Life-threatening: obtain 60–100% FVIII increase; give every 8–24hrs until resolved.

Surgery: Minor: obtain 60–80% FVIII increase; give single infusion plus oral antifibrinolytic therapy within 1 hour; Major: pre- and post-op: obtain 80–100% FVIII increase; repeat every 8–24hrs based on healing.

Contraindications: Mouse, hamster, or bovine protein sensitivity.

Warnings/Precautions: Not for von Willebrand's disease. Confirm Factor VIII deficiency prior to treatment. Monitor for development of Factor VIII inhibitors. Latex allergy. Pregnancy (Cat.C).

Adverse reactions: Allergic reactions, nausea, fever, chills, urticaria, antibody formation.

How supplied: Single-dose bottle–1 (w. diluent)

ANTHEMOPHILIC FACTOR VIII R

XYNTHA Pfizer

Clotting factor. Antihemophilic Factor (recombinant): nominally 250 IU, 500 IU, 1000 IU, or 2000 IU per vial; pwd for IV infusion after reconstitution; plasma/albumin-free; preservative-free; contains polysorbate 80. Actual factor VIII activity noted on each vial.

Indications: In Hemophilia A: to control bleeding episodes, and for surgical prophylaxis.

Adults: Individualize and titrate. Give by IV infusion over several minutes. One IU of factor VIII per kg raises the plasma factor VIII activity by about 2 IU/dL.

Minor bleeds: factor VIII level required is 20–40 IU/dL or % of normal, repeat infusion every 12–24 hours as needed for at least 1 day, until resolution.

Moderate bleeds: 30–60 IU/dL or % of normal; repeat infusion every 12–24 hours for 3–4 days or until hemostasis.

Major bleeds: 60–100 IU/dL or % of normal, repeat infusion every 8–24 hours until resolution.

Minor surgical procedures: 30–60 IU/dL or % of normal, repeat infusion every 12–24 hours for 3–4 days or until hemostasis.

Major surgery: 60–100 IU/dL or % of normal; repeat infusion every 8–24 hours until hemostasis and wound healing occurs.

Children: Consult manufacturer (limited pharmacokinetic data available; studies are ongoing).

Warnings/Precautions: Monitor for development of Factor VIII inhibitors; may need dose adjustment. Pregnancy (Cat.C). Labor & delivery. Nursing mothers.

Adverse reactions: Hypersensitivity reactions/anaphylaxis, pyrexia, headache, GI upset, asthenia.

How supplied: Kit-1 (w. diluent, supplies)

ANTIHEMOPHILIC FACTOR VIII + VON WILLEBRAND FACTOR R

HUMATE-P CSL Behring

Clotting factors. Antihemophilic Factor VIII/Von Willebrand Factor Complex (human) 250 IU FVIII + 600 IU VWF, 500 IU FVIII + 1200 IU VWF, 1000 IU FVIII + 2400 IU VWF; per vial; lyophilized pwd for IV infusion after reconstitution; contains albumin.

Indications: Treatment and prevention of bleeding in adults with Hemophilia A. Treatment of spontaneous and trauma-induced bleeding, and prevention of excessive bleeding during and after surgery in adults and children with von Willebrand disease (VWD).

Adults: Max injection rate: 4mL/min. Hemophilia A: Minor bleed: 15 IU FVIII/kg (obtain 30% FVIII increase) once; if needed, may give ½ dose once or twice daily for 1–2 days. Moderate bleed: initially 25 IU FVIII/kg (obtain 50% FVIII increase), then 15 IU FVIII/kg (maintain 30% FVIII increase) every 8–12hrs for 1–2 days, then repeat dose for 1–2 times daily for a total of 7 days or until healed. Severe bleed: initially 40–50 IU FVIII/kg, then 20–25 IU FVIII/kg every 8hrs (maintain 80–100% FVIII increase) for 7 days, then repeat dose for 1–2 times daily for additional 7 days (maintain 30–50% FVIII increase). VWD: Type 1 (Mild): major bleed: initially 40–60 IU/kg, then 40–50 IU/kg every 8–12hrs for 3 days, then once daily for a total of 7 days. Type 1 (Moderate or severe): minor bleed: 40–50 IU/kg for 1–2 doses; major bleed: initially 50–75 IU/kg, then 40–60 IU/kg every 8–12hrs for 3 days, then once daily for a total of 7 days. Types 2 and 3: minor bleed: 40–50 IU/kg for 1–2 doses; major bleed: initially 60–80 IU/kg, then 40–60 IU/kg every 8–12hrs for 3 days, then once daily for a total of 7 days. For dosing in surgery: see literature.

Children: Max injection rate: 4mL/min. VWD: Type 1 (Mild): major bleed: initially 40–60 IU/kg, then 40–50 IU/kg every 8–12hrs for 3 days, then once daily for a total of 7 days. Type 1 (Moderate or severe): minor bleed: 40–50 IU/kg for 1–2 doses; major bleed: initially 50–75 IU/kg, then 40–60 IU/kg every 8–12hrs for 3 days, then once daily for a total of 7 days. Types 2 and 3: minor bleed: 40–50 IU/kg for 1–2 doses; major bleed: initially 60–80 IU/kg, then 40–60 IU/kg every 8–12hrs for 3 days, then once daily for a total of 7 days. For dosing in surgery: see literature.

Contraindications: Previous anaphylactic or severe systemic response to antihemophilic factor or von Willebrand factor preparations.

Warnings/Precautions: Confirm Factor VIII or von Willebrand factor deficiency prior to treatment.

Increased risk of thromboembolic events in VWD. Contains human plasma; monitor for possible infection transmission. Large or frequent doses: monitor hematocrit for signs of hemolytic anemia. Monitor for development of inhibitors. Pregnancy (Cat.C).

Adverse reactions: Allergic reaction, GI upset, inj site reactions, mild vasodilation, pruritus, paresthesia, peripheral edema, antibody formation; anaphylaxis, thrombosis.

Note: Report all infections suspected to be transmitted by Humate-P to (800) 504-5434.

How supplied: Single-use vials-1 (w. diluent, supplies)

COAGULATION FACTOR VIIA R

NOVOSEVEN RT Novo Nordisk

Clotting factors. Recombinant Coagulation Factor VIIa (rFVIIa) Room Temperature Stable 1mg, 2mg, 5mg, 8mg; per vial; lyophilized pwd for IV inj after reconstitution; preservative-free.

Indications: Treatment of bleeding and for surgical prophylaxis in Hemophilia A and B with inhibitors to Factors VIII and IX, in acquired hemophilia, and in congenital FVII deficiency.

Adults and Children: Give by IV bolus.

Individualize; base treatment schedule on hemostasis. Hemophilia A and B with inhibitors: Bleeding: 90micrograms/kg every 2hrs; post-hemostatic dosing: continue at 3–6hrs intervals for severe bleeds; caution with prolonged dosing. Surgery: initially 90micrograms/kg prior to surgery, repeat at 2hr intervals during surgery; minor (post-surgical dosing): every 2hrs for 1st 48hrs, then every 2–6hrs until healed; major (post-surgical dosing): every 2hrs for 5 days, then every 4hrs until healed. Congenital Factor VII deficiency: 15–30micrograms/kg every 4–6hrs until hemostasis achieved. Acquired hemophilia: 70–90micrograms/kg every 2–3hrs until hemostasis achieved.

Warnings/Precautions: Increased risk of arterial thromboembolic adverse events when administered outside the current approved indications. Disseminated intravascular coagulation, advanced atherosclerotic disease, crush injury, septicemia, history of cardiovascular disease, hepatic disease, post-op immobilization, elderly, neonates; increased risk of thrombotic events. Monitor for signs/symptoms of coagulation activation or thrombosis; discontinue or reduce dose if occur. Monitor prothrombin time and FVII coagulant activity before and after dosing in FVII deficiency. Monitor for antibody formation. Mouse, hamster, or bovine protein hypersensitivity. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid concomitant activated or non-activated prothrombin complex concentrates; may increase risk of thrombotic events. Do not mix with infusion solutions.

Adverse reactions: Pyrexia, hemorrhage, inj site reactions, arthralgia, headache, hypertension,

angina, hypotension, GI upset, pain, edema, rash; thrombosis, increased levels of fibrin degradation products, disseminated intravascular coagulation, elevated D-dimer and AT-III levels, thrombophlebitis.

How supplied: Single-dose vials-1 (with diluent)

COAGULATION FACTOR IX

R

BENEFIX Pfizer

Clotting factor. Coagulation Factor IX (recombinant) 250 IU, 500 IU, 1000 IU, 2000 IU; per vial; lyophilized pwd for IV infusion after reconstitution; preservative-free.

Indications: Prevention and control of bleeding in hemophilia B. Peri-operative management in patients with hemophilia B.

Adults: See prescribing information for dosing equation. Give by IV infusion over several minutes. If inhibitor present or low Factor IX recovery, may need higher doses. Minor hemorrhage: 20–30% increase every 12–24hrs for 1–2 days. Moderate: 25–50% increase every 12–24hrs for 2–7 days until resolved. Major: 50–100% increase every 12–24 hrs for 7–10 days.

Children: <15yrs: See literature. Dose (IU) = body weight (kg) × % FIX increase × 1.4 IU/kg.

Contraindications: Hamster protein hypersensitivity.

Warnings/Precautions: Not for Hemophilia A with FVIII inhibitors or other factor deficiencies, reversal of coumarin-induced anticoagulation or for low levels of liver-dependant coagulation factors. Fibrinolysis, disseminated intravascular coagulation (DIC), liver disease, neonates, or during post-op period; increased risk of thromboembolic events. Monitor for Factor IX inhibitors and deletion mutations of Factor IX gene; increased risk of anaphylaxis. Immune tolerance induction. Latex allergy. Pregnancy (Cat.C).

Adverse reactions: Headache, fever, chills, flushing, GI upset, lethargy, taste perversion, hypoxia, inj site reactions, dizziness, allergic rhinitis; hypersensitivity reactions, inhibitor development, thrombosis.

How supplied: Single-use vials-1 (w. diluent, supplies)

DESMOPRESSIN

R

DDAVP INJECTION Sanofi Aventis

Antidiuretic hormone. Desmopressin acetate 4mcg/mL; soln for inj or IV infusion after dilution.

Indications: To maintain hemostasis or to stop bleeding in Hemophilia A and mild-to-moderate Type 1 von Willebrand's disease (VWD), each with >5% Factor VIII activity.

Adults and Children: <3 months: not recommended. ≥3 months: 0.3mcg/kg IV over 15–30 minutes. Pre-op: give 30 minutes before scheduled procedure. May repeat dose based on clinical response. Repeated administration before 48hrs associated with tachyphylaxis.

Contraindications: Moderate to severe renal impairment (CrCl <50mL/min). Hyponatremia, or history of.

Warnings/Precautions: Not for treating Hemophilia A with Factor VIII coagulant activity levels ≤5%, Hemophilia B, in patients with FVIII antibodies, or for Type IIB VWD, or severe Type 1 VWD and evidence of abnormal molecular form of FVIII antigen. Monitor fluid intake, urine volume plasma osmolality. Fluid/electrolyte imbalance (eg, cystic fibrosis). Adjust fluid intake downward (esp in children and elderly) to decrease risk of water intoxication, hyponatremia. Habitual or psychogenic polydipsia. Coronary artery insufficiency. Hypertension. Predisposition to thrombosis. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with other pressor agents, drugs that may increase the risk of water intoxication with hyponatremia (eg, tricyclic antidepressants, SSRIs, chlorpromazine, opiates, NSAIDs, lamotrigine, carbamazepine). Possible convulsions with oxybutynin, imipramine.

Adverse reactions: Headache, nausea, flushing, abdominal cramps, vulval pain, inj site reaction, water intoxication, hyponatremia, rare: changes in BP, severe allergic reactions, thrombotic events (inj).

How supplied: Amp (1mL)-10; Multi-dose vial (10mL)-1

ELTROMBOPAG

R

PROMACTA GlaxoSmithKline

Thrombopoietin receptor agonist. Eltrombopag (as olamine) 25mg, 50mg; tabs.

Indications: Thrombocytopenia due to chronic immune (idiopathic) thrombocytopenic purpura (ITP) in adults who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Adults: Take on empty stomach. Initially 50mg once daily. Moderate to severe hepatic impairment or East Asian ancestry: initially 25mg once daily. Titrate to maintain platelet count ≥50×10⁹/L; max 75mg once daily. Adjust dose based on platelet count: see literature.

Children: Not recommended.

Warnings/Precautions: Monitor CBC, platelet count, and peripheral blood smears for cytopenias and abnormal morphologies; discontinue if no increase in platelet count occurs after 4 weeks at max dose, or if excessive increase in platelet count occurs (eg, >400×10⁹/L), or if evidence of bone marrow fibrosis occurs (eg, cytopenias, nucleated RBCs). Monitor liver function closely before, during, and after treatment (see literature); discontinue if ALT >3×ULN and is progressive or persistent for ≥4 weeks, or if it occurs with evidence of hepatic injury; reinitiation of therapy: not recommended; if restarted, use lower dose and monitor carefully. Do baseline eye exam; monitor for cataracts. Thromboembolism risk factors. Myelodysplastic syndromes. Renal impairment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Do not take within 4 hours of food/drugs containing polyvalent cations (eg, Fe^{+2} , Ca^{+2} , Al^{+3} , Mg^{+2} , Se^{+2} , Zn^{+2}). May potentiate substrates of organic anion transporter polypeptide 1B1 (eg, benzylpenicillin, most statins, methotrexate, nateglinide, repaglinide, rifampin); monitor and consider reducing their doses. May be potentiated by strong inhibitors of CYP1A2 (eg, ciprofloxacin, fluvoxamine) or CYP2C8 (eg, gemfibrozil, trimethoprim), and with moderate or strong inhibitors of UGT1A1 or UGT1A3.

Adverse reactions: Nausea, vomiting, menorrhagia, myalgia, paresthesia, cataract, ecchymosis, thrombocytopenia, increased ALT/AST, conjunctival hemorrhage, increased risk of hematologic malignancies; thrombotic events with excessive increases in platelet counts; worsened thrombocytopenia after discontinuation.

Note: Physicians, pharmacies, and patients must enroll in Promacta Cares program. Register pregnant patients taking eltrombopag by calling (888) 825-5249.

How supplied: Tabs-30

IMMUNE GLOBULIN

R

GAMUNEX-C Grifols Biologicals

IVIG. Immune Globulin (human) 1g/10mL, 2.5g/25mL, 5g/50mL, 10g/100mL, 20g/200mL; soln for IV or SC infusion; preservative- and sucrose-free.

Indications: Idiopathic thrombocytopenic purpura (ITP).

Adults and Children: Give by IV infusion at a rate of 1mg/kg/min for first 30 minutes, if tolerated may increase to max 8mg/kg/min. 1g/kg once daily given on 2 consecutive days or 0.4g/kg once daily given on 5 consecutive days. If adequate response after first 1g/kg dose, may withhold second dose. Risk of renal dysfunction or thrombotic event: infuse at a rate <8mg/kg/min. Expanded fluid volumes: high dose regimen not recommended.

Contraindications: Severe selective IgA deficiency (serum IgA <0.05g/L) with known antibody against IgA.

Warnings/Precautions: Renal insufficiency, diabetes, >65yrs, volume depletion, sepsis, paraproteinemia: increased risk of renal dysfunction, acute renal failure, osmotic nephrosis and death; monitor urine output, BUN/serum creatinine before and during treatment; consider discontinuing if renal dysfunction develops. Correct hypovolemia before starting treatment. Contains human plasma; monitor for possible infection transmission. Monitor for hemolysis. Hyperviscosity (perform baseline assessment of blood viscosity). High dose (2g/kg) and/or rapid infusion may increase risk of aseptic meningitis syndrome. Monitor for pulmonary dysfunction; perform test for anti-neutrophil antibodies if transfusion-related acute lung injury

(TRALI) suspected. Pregnancy (Cat.C). Nursing mothers: not evaluated.

Interactions: Avoid live viral vaccines for ≥ 6 months. Concomitant nephrotoxic drugs: increased risk of acute renal failure. May contain low levels of anti-Blood Group A and B antibodies of IgG4; direct antiglobulin tests may be false-positive.

Adverse reactions: Headache, vomiting, fever, nausea, back pain, rash; renal dysfunction (may be fatal), hypersensitivity reactions; rare: hemolytic anemia, aseptic meningitis syndrome, TRALI, thrombosis.

Note: Report all infections suspected to be transmitted by Gamunex-C to (800) 520-2807.

How supplied: Vials-1

OPRELVEKIN

R

NEUMEGA Pfizer

Thrombopoietic growth factor (Interleukin-11).

Oprelvekin 5mg/vial; lyophilized pwd for SC inj after reconstitution; preservative-free.

Indications: Prevention of severe thrombocytopenia. To reduce platelet transfusions following myelosuppressive chemotherapy in adults with non-myeloid malignancies who are at high risk of severe thrombocytopenia.

Adults: Initiate 6-24hrs after chemotherapy completion. Give by SC inj into abdomen, thigh, or hip; also upper arm if not self-injecting. 50micrograms/kg once daily until post-nadir platelet count is $\geq 50,000/\text{microliter}$; max 21 days. Discontinue ≥ 2 days prior to next chemotherapy cycle. Severe renal impairment: $\text{CrCl} < 30\text{mL/min}$: 25micrograms/kg. May give for ≤ 6 cycles following chemotherapy.

Children: Not recommended.

Warnings/Precautions: Not for use after myeloablative chemotherapy. Monitor fluid balance and electrolytes; increased risk of serious fluid retention with CHF, renal impairment, chronic diuretic or aggressive hydration therapy. Consider draining pre-existing fluid collections (eg, pericardial effusion, ascites). Obtain CBCs before and during therapy; monitor platelet counts. Pre-existing papilledema or tumors involving the CNS. History of stroke, transient ischemic attack, or atrial arrhythmias. Effectiveness unknown with chemotherapy regimens >5 days duration or with regimens associated with delayed myelosuppression (eg, nitrosoureas, mitomycin-C). Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Edema, dyspnea, tachycardia, conjunctival injection, palpitations, atrial arrhythmias, pleural effusions, neutropenic fever, syncope, atrial fibrillation, fever, pneumonia, CHF, pulmonary edema, dilutional anemia, blurred vision, paresthesia, dehydration, skin discoloration, exfoliative dermatitis, eye hemorrhage, stroke, papilledema, hypersensitivity reactions (permanently discontinue if occur).

How supplied: Single-use vials-7 (w. diluent)

RHO(D) IMMUNE GLOBULIN

R

RHOPHYLAC CSL Behring

Rh₀ (D) immune globulin human 1500 IU (300mcg)/2mL; syringe; for IV or IM inj; preservative- and latex-free; contains albumin (human); solvent/detergent treated.

Indications: Raising platelet counts in Rh₀ (D) positive non-splenectomized patients with chronic immune thrombocytopenic purpura (ITP).

Adults: See literature. 250 IU (50mcg) per kg by IV only at rate of 2mL per 15–60 seconds.

Children: Not recommended.

Contraindications: Rh₀ (D) positive patients. IgA deficiency.

Warnings/Precautions: Monitor patients 20 minutes after administration. Pregnancy (Cat.C).

Interactions: Do not give live vaccines within 3 months.

Adverse reactions: Local or infusion reactions, fever, chills, headache; see literature.

How supplied: Single-dose prefilled syringes–1, 10

RHO(D) IMMUNE GLOBULIN

R

WINRHO SDF Baxter

Rh₀(D) immune globulin intravenous human 600IU (120mcg), 1500IU (300mcg), 2500IU (500mcg), 5000IU (1000mcg), 15000IU (3000mcg); per vial; lyophilized pwd or soln; for IV or IM inj after reconstitution; preservative-free.

Indications: Treatment of non-splenectomized, Rh₀(D) positive children with acute immune thrombocytopenic purpura (ITP); adults and children with chronic ITP and ITP secondary to HIV infection; in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage.

Adults and Children: Give by IV inj only. Confirm Rh₀(D) positive prior to treatment. Initially: 250 IU/kg as single dose or 2 divided doses on separate days; if Hgb <10g/dL, reduce to 125–200 IU/kg. Maintenance: 125–300 IU/kg; Hgb >10g/dL: 250–300 IU/kg; Hgb 8–10g/dL: 125–200 IU/kg; Hgb <8g/dL: use with caution. Base frequency and dose on clinical response.

Contraindications: IgA deficiency. Allergy to blood products. Treatment of immune globulin deficiency syndromes.

Warnings/Precautions: Not for use in Rh₀(D) negative or splenectomized patients; monitor for intravascular hemolysis, anemia, renal insufficiency; hemoglobin <10g/dL decrease dose, if <8g/dL use extreme caution. Pregnancy (Cat.C).

Interactions: Do not give live vaccines within 3 months.

Adverse reactions: Headache, chills, fever, local or infusion reactions; see literature.

Note: Report all infections suspected to be transmitted by WinRho SDF to (800) 423-2090.

How supplied: Single-dose vials (pwd) 600IU, 1500IU, 5000IU–1 (w. diluent)
Single-dose vials (soln) 600IU, 1500IU, 2500IU, 5000IU, 15000IU–1

ROMIPLOSTIM

R

NPLATE Amgen

Thrombopoietin receptor agonist. Romiplostim (recombinant) 250mcg, 500mcg; per vial; lyophilized pwd for SC inj after reconstitution; contains sucrose and mannitol; preservative-free.

Indications: Thrombocytopenia in patients with chronic immune (idiopathic) thrombocytopenic purpura (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.

Adults: Give by SC inj. To reduce risk of bleeding: use lowest effective dose to achieve and maintain platelets $\geq 50 \times 10^9/L$. ≥ 18 yrs: initially: 1mcg/kg weekly; may increase by 1mcg/kg if platelets $< 50 \times 10^9/L$; max: 10mcg/kg weekly. May reduce by 1mcg/kg if platelets $> 200 \times 10^9/L$ for 2 consecutive weeks. Do not dose if platelets $> 400 \times 10^9/L$; resume Nplate at a dose reduced by 1mcg/kg when platelets fall to $< 200 \times 10^9/L$. Discontinue if platelets have not increased after 4 weeks at max dose.

Children: <18 yrs: not recommended.

Warnings/Precautions: Not for normalization of platelet counts or to treat thrombocytopenia due to MDS or any cause of thrombocytopenia other than chronic ITP. Risk of bone marrow fibrosis with cytopenias. Worsened thrombocytopenia after discontinuation. Monitor CBCs, platelets, and peripheral blood smears before and weekly during dose adjustments then monthly after achieving stable dose; and weekly for 2 weeks after discontinuation of therapy. Monitor after initial response for formation of neutralizing antibodies. Risk of hematologic malignancies (esp. myelodysplastic syndrome). Renal or hepatic impairment. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May increase bleeding risk with anticoagulants or antiplatelet agents.

Adverse reactions: Arthralgia, dizziness, insomnia, myalgia, pain in extremity, abdominal pain, shoulder pain, dyspepsia, paresthesia, headaches; bone marrow reticulinn deposition, worsening thrombocytopenia, risk of bleeding, thrombotic/thromboembolic complications, antibody formation.

How supplied: Single-use vial–1

THROMBIN

R

RECOTHROM ZymoGenetics

Topical hemostatic. Thrombin [recombinant] 5000 IU, 20000 IU; per vial; pwd for topical use after reconstitution; preservative-free.

Indications: Aid to hemostasis for minor bleeding/oozing from capillaries and venules when standard surgical techniques are inadequate or ineffective. May use with absorbable gelatin sponge.

Adults: Apply directly to bleeding area, or soak into absorbable gelatin sponge and apply in a single layer.

Children: Not recommended.

Contraindications: Not for direct injection into circulatory system. Not for treatment of massive or brisk arterial bleeding. Hypersensitivity to hamster proteins.

Warnings/Precautions: Avoid systemic absorption (thrombosis may occur). Hypersensitivity to snake proteins. Pregnancy (Cat.C).

Adverse reactions: Incision site complication, infection, pain, bleeding, nausea/vomiting, cardiac events, thromboembolic events.

How supplied: Single-use vial (5000 IU, 20000 IU)-1 (w. diluent, supplies)
20000 IU Recothrom kit (co-packaged with ZymoGenetics Spray Applicator Kit)-1

THROMBIN

THROMBIN-JMI King

Topical hemostatic. Thrombin [bovine origin] 5000 IU, 20000 IU; per vial; pwd for topical use after reconstitution; preservative-free.

Indications: Aid to hemostasis for oozing blood and minor bleeding from accessible capillaries and small venules. Adjunct for surgical hemostasis with absorbable gelatin sponge.

Adults: For topical use only. See literature. Profuse bleeding (eg, abraded surfaces of liver or spleen): 1000IU/mL. General use (eg, plastic surgery, dental extractions, skin grafting): 100IU/mL. May dilute to prepare intermediate strengths, if needed. Oozing surfaces: may use dry form.

Children: Not recommended.

Warnings/Precautions: Not for injection or use in large blood vessels. Antibody formation: do not re-expose, abnormalities in hemostasis (eg, severe bleeding or thrombosis) more likely with repeated use. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Hypersensitivity reactions, antibody formation.

How supplied: Vials-1 (w. diluent)
Pump Spray Kit (20000 IU)-1 (w. diluent)
Syringe Spray Kit (20000 IU)-1 (w. diluent)
Epistaxis Kit (5000 IU)-1 (w. diluent)

TRANEXAMIC ACID

CYKLOKAPRON Pfizer

Plasminogen activation inhibitor. Tranexamic acid 100mg/mL; soln for IV inj.

Indications: Short-term use in hemophilia to reduce or prevent hemorrhage, and reduce the need for replacement therapy during and following tooth extraction.

Adults and Children: Give by IV inj. Max injection rate: 1mL/min. Pre-extraction: 10mg/kg; post-op: 10mg/kg 3-4 times daily for 2-8 days. Renal impairment: serum creatinine 1.36-2.83mg/dL: 10mg/kg twice daily; 2.83-5.66mg/dL: 10mg/kg once daily; >5.66mg/dL: 10mg/kg every 48hrs or 5mg/kg every 24 hours.

Contraindications: Acquired defective color vision. Subarachnoid hemorrhage. Active intravascular clotting.

Warnings/Precautions: Therapy longer than several days: do ophthalmologic exam (before and during); discontinue if visual changes occur. Renal insufficiency; reduce dose. History of thromboembolic disease. Disseminated intravascular coagulation. Upper urinary tract bleeding. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid concomitant Factor IX complex concentrates or Anti-inhibitor Coagulant concentrates; increased risk of thrombosis. Do not mix with solutions containing penicillin.

Adverse reactions: GI upset, giddiness, hypotension, visual abnormalities; rare: thromboembolic events.

How supplied: Amps (10mL)-10

VON WILLEBRAND FACTOR + FACTOR VIII COMPLEX

WILATE Octapharma

Coagulation factor complex. Von Willebrand Factor/Factor VIII Complex (human); 450 IU VWF:RCO and 450 IU FVIII activities per 5mL; 900 IU VWF:RCO and 900 IU FVIII activities per 10mL; pwd; for IV injection after reconstitution; preservative-free; solvent-detergent treated.

Indications: Bleeding episodes (spontaneous and trauma induced) in patients with severe von Willebrand disease, and patients with mild to moderate von Willebrand disease for whom desmopressin is ineffective or contraindicated.

Adults and Children: <5yrs: contact manufacturer. Give by IV injection at 2-4mL/min. ≥5yrs: Minor bleed: 20-40 IU/kg once, then 20-30 IU/kg every 12-24 hours. Major bleed: 40-60 IU/kg once, then 20-40 IU/kg every 12-24 hours. Monitor and adjust according to VWF:RCO and FVIII activity, and location of bleed; usual treatment duration is 3 days (minor hemorrhage) and 5-7 days (major hemorrhage). See literature for activity level goals.

Warnings/Precautions: Not for prophylaxis of spontaneous bleeding, prevention of surgical bleeding, or hemophilia A. Treatment should be supervised by physician trained in coagulopathies. Risk of thrombotic events with sustained excessive FVIII levels; monitor. Ineffectiveness may indicate antibody formation; discontinue if confirmed. Risk of transmission of blood-borne diseases; consider vaccination against hepatitis A and B. Monitor pulse during injection; slow or stop infusion if marked increase in heart rate occurs. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Urticaria, dizziness, hypersensitivity reactions, antibody formation.

How supplied: Kit-1 (w. diluent, supplies)

6C Hyperuricemia

ALLOPURINOL

ALOPRIM Bioniche

Xanthine oxidase inhibitor. Allopurinol (as sodium) 500mg/vial; pld for IV infusion after reconstitution and dilution; preservative-free.

Indications: Chemotherapy-induced hyperuricemia and hyperuricosuria when oral therapy not feasible.

Adults: Give by IV infusion in single or divided doses. Start 1–2 days before chemotherapy. Adjust based on serum uric acid levels. Initially 200–400mg/m² per day; max 600mg/day. Renal impairment: CrCl 10–20mL/min: 200mg/day; 3–10mL/min: 100mg/dose. <3mL/min: 100mg/day and extend dosing interval (see literature).

Children: Give by IV infusion in single or divided doses. Start 1–2 days before chemotherapy. Adjust based on serum uric acid levels. Initially 200mg/m² per day. Renal impairment: CrCl 10–20mL/min: 200mg/day; CrCl 3–10mL/min: 100mg/day; CrCl <3mL/min: 100mg/day and extend dosing interval; see literature.

Contraindications: Asymptomatic hyperuricemia.

Warnings/Precautions: Maintain adequate hydration (urine output at least 2L/day in adults) and urine alkalization. Discontinue if rash occurs. Monitor blood counts, renal, and hepatic function for first few months of therapy. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates oral anticoagulants, hypoglycemics, cyclosporine, theophylline. Antagonized by uricosurics. Monitor renal function with thiazides. Reduce concomitant azathioprine, mercaptopurine doses.

Adverse reactions: Rash, GI disorders, acute gout, ecchymosis, fever, headache, hepatic necrosis, drowsiness, neuritis, arthralgia, blood dyscrasias, toxic skin reactions, renal failure.

How supplied: Vial–1

RASBURICASE

ELITK Sanofi Aventis

Urate oxidase. Rasburicase (recombinant) 1.5mg, 7.5mg; per vial; lyophilized pld for IV infusion after reconstitution and dilution; contains mannitol.

Indications: Single course treatment for initial management of plasma uric acid levels in patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anti-cancer therapy expected to result in tumor lysis and subsequent elevation of plasma uric acid.

Adults and Children: Give by IV infusion over 30 mins. 0.2mg/kg daily for 5 days. Dosing >5 days or more than one course of treatment: not recommended.

Contraindications: History of anaphylaxis, or development of hemolytic reactions or methemoglobinemia to rasburicase. G6PD deficiency.

Warnings/Precautions: Discontinue permanently if serious hypersensitivity reaction, hemolysis, or methemoglobinemia develops. Screen high risk patients (eg, African or Mediterranean ancestry) for G6PD deficiency before starting therapy. Pregnancy (Cat.C); avoid. Nursing mothers: not recommended.

Interactions: Interferes with uric acid measurements in blood samples left at room temperature.

Adverse reactions: GI upset, pyrexia, peripheral edema, anxiety, headache, abdominal pain, constipation, mucositis, sepsis; anaphylaxis, hemolysis, methemoglobinemia.

How supplied: Single-use vials 1.5mg–3 (w. diluent) 7.5mg–1 (w. diluent)

6D Immune-mediated blood disorders

RHO(D) IMMUNE GLOBULIN

RHOGAM Ortho Diagnostics

Rh₀(D) immune globulin human 300mcg; for IM inj.

Indications: Preventing Rh₀(D) sensitization in nonsensitized Rh₀(D) negative or Du negative patients to the Rh₀(D) factor, following pregnancy or accidental transfusion.

Adults: Each vial or syringe (approx. 300mcg) prevents sensitization to a volume of up to 15mL of Rh positive red blood cells. Administer IM at 28 weeks of gestation, within 72 hours of an Rh incompatible delivery, miscarriage, abortion, or transfusion accident.

Children: See literature.

Also: Rh₀(D) immune globulin

MICRHOGAM

Rh₀(D) immune globulin human 50mcg; for IM inj.

Indications: Prevention of Rh₀(D) sensitization following termination of pregnancies up to 12 weeks gestation.

Adults: Each syringe (approx. 50mcg) prevents sensitization to 2.5mL of Rh positive red blood cells.

Children: See literature.

Contraindications: Rh₀(D) positive patients.

Warnings/Precautions: Pregnancy (Cat.C).

Adverse reactions: Local reactions.

How supplied: Single-dose syringes–5, 25

RHO(D) IMMUNE GLOBULIN

RHOPHYLAC CSL Behring

Rh₀(D) immune globulin human 1500 IU (300mcg)/2mL; syringe; for IV or IM inj; preservative- and latex-free; contains albumin (human); solvent/detergent treated.

Indications: Suppression of Rh isoimmunization in non-sensitized Rh₀(D) negative women during pregnancy and in appropriate obstetrical conditions, unless the fetus or father is known to be Rh₀(D) negative. Suppression of Rh isoimmunization in

Rh₀ (D) negative individuals transfused with Rh₀ (D) positive blood products.

Adults: See literature. Pregnancy (28–30 weeks gestation), postpartum prevention (within 72 hours), obstetric complications, invasive procedures during pregnancy: 1500 IU (300mcg). Incompatible transfusions (within 72 hours): 100 IU (20mcg) per 2mL transfused blood or per 1mL erythrocyte concentrate.

Children: Not recommended.

Contraindications: Rh₀ (D) positive patients. IgA deficiency.

Warnings/Precautions: Monitor patients 20 minutes after administration. Pregnancy (Cat.C).

Interactions: Do not give live vaccines within 3 months.

Adverse reactions: Local or infusion reactions, fever, chills, headache; see literature.

How supplied: Single-dose prefilled syringes–1, 10

RHO(D) IMMUNE GLOBULIN

WINRHO SDF Baxter

Rh₀(D) immune globulin intravenous human 600IU (120mcg), 1500IU (300mcg), 2500IU (500mcg), 5000IU (1000mcg), 15000IU (3000mcg); per vial; lyophilized pld or soln; for IV or IM inj after reconstitution; preservative-free.

Indications: Suppression of Rh isoimmunization in nonsensitized Rh₀(D) negative women in appropriate obstetrical conditions, unless the fetus or father is known to be Rh₀(D) negative. Suppression of Rh isoimmunization in Rh₀(D) negative females after accidental transfusion of Rh₀(D) positive blood products.

Adults: Pregnancy: 1500IU at 28 weeks gestation; if given early in pregnancy, repeat every 12 weeks. Post-delivery: 600IU as soon as possible (preferably within 72 hrs, up to 28 days) of an Rh incompatible delivery. Amniocentesis or other manipulation late in pregnancy (after 34 weeks gestation), abortion: 600IU as soon as possible (within 72 hrs). Chorionic villus sampling, amniocentesis (before 34 weeks gestation), threatened abortion: 1500IU as soon as possible, repeat every 12 weeks during pregnancy. Transfusion: IV route: 3000IU (600micrograms) every 8 hours; or IM route: 6000IU (1200micrograms) every 12 hours; for both: total dose based on exposure (see literature); give within 72 hours.

Children: See literature. Do not give to infant for maternal Rh incompatibility.

Contraindications: Rh₀(D) positive patients. IgA deficiency. Allergy to blood products. Treatment of immune globulin deficiency syndromes.

Warnings/Precautions: Rh₀(D) negative patients who are Rh immunized. Thrombocytopenia. Pregnancy (Cat.C).

Interactions: Do not give live vaccines within 3 months.

Adverse reactions: Local or infusion reactions, fever; see literature.

Note: Report all infections suspected to be transmitted by WinRho SDF to (800) 423-2090.

How supplied: Single-dose vials (pld) 600IU, 1500IU, 5000IU–1 (w. diluent)

Single-dose vials (soln) 600IU, 1500IU, 2500IU, 5000IU, 15000IU–1

6E Intermittent claudication

CILOSTAZOL

PLETAL Otsuka

Antiplatelet/vasodilator (PDE III inhibitor). Cilostazol 50mg, 100mg; tabs.

Indications: Intermittent claudication.

Adults: 100mg twice daily, ½ hr before or 2 hrs after breakfast and dinner. May reduce to 50mg twice daily if used with CYP3A4 or CYP2C19 inhibitors.

Children: Not recommended.

Contraindications: CHF of any severity.

Warnings/Precautions: Severe underlying heart disease. Moderate to severe hepatic dysfunction. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by drugs that inhibit CYP3A4 (eg, azole antifungals, macrolides, diltiazem, fluvoxamine, fluoxetine, nefazodone, sertraline) or CYP2C19 (eg, omeprazole). Avoid grapefruit juice. Cilostazol has been used with aspirin; caution with other antiplatelets, anticoagulants.

Adverse reactions: Headache, diarrhea, abnormal stools, palpitations, peripheral edema, dizziness, tachycardia.

How supplied: Tabs–60

PENTOXIFYLLINE

TRENTAL Sanofi Aventis

Hemorrhologic agent (xanthine). Pentoxifylline 400mg; sust-rel tabs.

Indications: Intermittent claudication.

Adults: 400mg three times daily with meals. Continue for at least 8 wks. Digestive or CNS effects: lower dosage to 400mg twice daily; discontinue if side effects persist.

Children: Not established.

Contraindications: Recent cerebral or retinal hemorrhage. Methylxanthines intolerance (eg, caffeine, theophylline, theobromine).

Warnings/Precautions: Discontinue if anaphylactic/anaphylactoid reaction occurs. Monitor for bleeding including hematocrit, hemoglobin in patients with hemorrhagic risk factors (eg, recent surgery, peptic ulcer, cerebral and/or retinal bleeding). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. May potentiate antihypertensives; monitor BP. Concomitant theophylline-containing drugs; monitor closely and

adjust dose. Concomitant warfarin; monitor PT frequently.

Adverse reactions: GI upset, nausea, dyspepsia, headache, dizziness, insomnia, blurred vision.

How supplied: Tabs-100

6F Thromboembolic disorders

ABCIXIMAB

R

REOPRO Janssen Biotech

Antiplatelet (GP IIb/IIIa blocker). Abciximab 2mg/mL; soln for IV inj; preservative-free.

Indications: Adjunct to percutaneous coronary intervention (PCI) for prevention of cardiac ischemic complications: in patients undergoing PCI and; in patients with unstable angina not responding to conventional medical therapy when PCI is planned within 24hrs. For use with heparin and aspirin.

Adults: 0.25mg/kg IV bolus administered 10–60 minutes before start of PCI, followed by a continuous IV infusion of 0.125micrograms/kg/min (max 10micrograms/min) for 12 hrs. Unstable angina not responding to conventional therapy: 0.25mg/kg IV bolus followed by an 18–24hr IV infusion of 10micrograms/min, concluding 1hr after PCI.

Children: Not recommended.

Contraindications: Active internal bleeding. GI or GU bleeding within 6 wks. Cerebrovascular accident within 2yrs or with residual neurologic deficit. Bleeding diathesis. Oral anticoagulants within 7 days, unless prothrombin time ≤ 1.2 times control. Thrombocytopenia. Major surgery or trauma within 6 wks. Intracranial neoplasm, arteriovenous malformation, or aneurysm. Severe uncontrolled hypertension. Vasculitis. IV dextran before or during PCI.

Warnings/Precautions: See literature. Increased risk of bleeding when PCI within 12hrs of MI symptom onset, PCI lasting >70min, failed PCI. Discontinue infusion if uncontrolled bleeding occurs. Properly care for femoral artery access site to minimize bleeding. Minimize other arterial and venous punctures, IM inj, catheter use, intubation, NG tube, automatic BP cuffs, to lower bleeding risk; avoid use of non-compressible IV access sites. Discontinue heparin 2hrs prior to arterial sheath removal. Monitor prothrombin time, ACT, APTT, and platelet count before and during treatment. Discontinue if confirmed thrombocytopenia occurs. Pregnancy (Cat.C). Nursing mothers.

Interactions: Risk of bleeding increased with concomitant heparin, thrombolytics, anticoagulants, NSAIDs, dipyridamole, and ticlopidine.

Adverse reactions: Bleeding, intracranial hemorrhage, stroke, thrombocytopenia, hypersensitivity reactions, hypotension, bradycardia, GI upset, abdominal, back, chest, and puncture site pain, peripheral edema, arrhythmias.

How supplied: Vial (5mL)-1

ALTEPLASE

R

ACTIVASE Genentech

Tissue plasminogen activator (tPA). Alteplase 50mg, 100mg; per vial; lyophilized pwd for IV infusion after reconstitution and dilution.

Indications: Management of acute myocardial infarction (AMI) to improve ventricular function and reduce the incidence of CHF and mortality. Management of acute ischemic stroke to improve neurologic recovery and reduce disability. Management of acute massive pulmonary embolism (PE).

Adults: AMI: Max total dose: 100mg. Accelerated infusion: ≤ 67 kg: 15mg IV bolus followed by 0.75mg/kg (max 50mg) infused over 30min, then 0.5mg/kg (max 35mg) over 60min. > 67 kg: 15mg IV bolus followed by 50mg infused over 30min, then 35mg infused over 60min; 3-hour infusion: > 65 kg: 60mg infused in the first hour (of which 6–10mg is given as bolus), then 20mg/hr for 2hrs; smaller patients (< 65 kg): 1.25mg/kg over 3hrs (as described above). Stroke: start treatment within 3hrs of symptom onset. 0.9mg/kg (max 90mg total dose) infused over 60min with 10% of the total dose given as an initial IV bolus over 1 minute. PE: 100mg infused over 2hrs. Heparin may be used concomitantly in MI or after infusion in PE.

Children: Not recommended.

Contraindications: AMI and PE: History of cerebrovascular accident. Intracranial or intraspinal surgery or trauma. Stroke: Intracranial or subarachnoid hemorrhage. Intracranial or intraspinal surgery, serious head trauma or previous stroke. Seizure at onset of stroke. All: Active internal bleeding. Intracranial neoplasm, arteriovenous malformation or aneurysm. Severe uncontrolled hypertension. Bleeding diathesis.

Warnings/Precautions: Stroke: treatment > 3 hrs after symptom onset not recommended. Minor neurological deficit or rapidly improving symptoms: not recommended. Avoid IM inj and nonessential handling of patient during treatment. Increased bleeding risk at puncture sites (eg, arterial, internal jugular, subclavian venous); avoid. Discontinue if serious bleeding occurs or if INR > 1.7 or prothrombin time > 15 seconds, or an elevated activated partial thromboplastin time identified. Increased risk of complications with recent major surgery, GI or GU bleeding, recent trauma, cerebrovascular disease, hypertension (systolic BP > 175 mm Hg and/or diastolic BP > 110 mm Hg), left heart thrombus, acute pericarditis, endocarditis, hemostatic defects, hepatic dysfunction, pregnancy, hemorrhagic ophthalmic conditions, septic thrombophlebitis, major early infarct signs on CT scan, elderly, severe neurologic deficit. Avoid extravasation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Increased risk of bleeding with heparin, warfarin, vitamin K antagonists, drugs that alter platelet function (eg, aspirin, dipyridamole, abciximab). Angioedema risk with ACEI (monitor). May interfere with coagulation tests.

Adverse reactions: Bleeding, hypersensitivity reactions. AML: arrhythmias, AV block, cardiogenic shock, heart failure, recurrent ischemia, myocardial rupture, pericardial effusion, pericarditis, cardiac tamponade, pulmonary edema, nausea, vomiting, hypotension, fever. PE: pulmonary reemboilization or edema, pleural effusion, thromboembolism. Stroke: cerebral edema or herniation, seizure, new ischemic stroke. Also: cholesterol embolism.

How supplied: Vials—1 (w. diluent)

ANAGRELIDE

AGRYLIN Shire

Platelet-reducing agent. Anagrelide (as HCl) 0.5mg; caps

Indications: Treatment of thrombocythemia, secondary to myeloproliferative disorders, to reduce elevated platelet count and the risk of thrombosis and to improve symptoms.

Adults: Initially 0.5mg four times daily or 1mg twice daily for ≥ 1 week. May increase dose by 0.5mg/day weekly to maintain normal platelet count; max 10mg/day or 2.5mg/dose. Moderate hepatic impairment: initially 0.5mg/daily.

Children: Initially 0.5mg daily. May increase dose by 0.5mg/day weekly to maintain normal platelet count; max 10mg/day or 2.5mg/dose.

Contraindications: Severe hepatic impairment.

Warnings/Precautions: Heart disease; do baseline cardiovascular exam and monitor during treatment. Moderate hepatic impairment. Monitor blood counts, liver and renal function before and during treatment. Obtain platelet counts every 2 days during 1st week of treatment, then weekly until maintenance dose reached. Cessation may cause platelet count to rise within 4 days. Pregnancy (Cat.C; use adequate contraception); nursing mothers: not recommended.

Interactions: Potentiated by fluvoxamine or other CYP1A2 inhibitors. May potentiate aspirin, theophylline, other CYP1A2 substrates, milrinone, amrinone, cilostazol. Sucralfate may decrease absorption.

Adverse reactions: Headache, palpitations, GI upset, asthenia, edema, dizziness, dyspnea, fever, rash, tachycardia; cardiovascular disease, pulmonary disorders, pancreatitis, GI ulceration, seizure.

How supplied: Caps—100

ANTITHROMBIN III

THROMBATE III Grifols Biologicals

Thrombin inhibitor (α_2 -glycoprotein). Antithrombin III (human) 500 IU, 1000 IU; per vial; lyophilized pwd for IV infusion after reconstitution; preservative-free.

Indications: Treatment of patients with hereditary antithrombin III deficiency (AT-III) in surgical or obstetrical procedures and thromboembolism.

Adults: Give by IV infusion over 10–20 minutes. Individualized. Dose (units required) = [desired (% of normal)—baseline (% of normal) AT-III level] $\times$ weight

(kg)/1.4. Loading dose: increase AT-III to 120% of normal. Subsequent dose should be based on AT-III levels obtained 20 minutes post-infusion, every 12hrs, and before the next dose. Maintain AT-III levels at 80–120% of normal for 2–8 days.

Children: Not recommended.

Warnings/Precautions: Surgery. Hemorrhage.

Acute thrombosis. Monitor AT-III levels during treatment. Contains human plasma; monitor for possible infection transmission. Pregnancy (Cat.B).

Interactions: Potentiates anticoagulant effect of heparin; reduce heparin dose.

Adverse reactions: Dizziness, chest tightness, nausea, taste disturbances, chills, cramps, shortness of breath, chest pain, light-headedness, bowel fullness, hives, fever, hematoma formation.

Note: Report all infections suspected to be transmitted by Thrombate III to (800) 520-2807.

How supplied: Single-use vial—1 (w. diluent, needles)

APIXABAN

ELIQUIS Bristol-Myers Squibb

Factor Xa inhibitor. Apixaban 2.5mg, 5mg; tablets.

Indications: To reduce risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF).

Adults: 5mg twice daily. If any two of the following: age ≥ 80 years; body weight ≤ 60 kg, serum creatinine ≥ 1.5 mg/dL: 2.5mg twice daily. Concomitant strong dual inhibitors of CYP3A4 and P-gp (eg, ketoconazole, itraconazole, ritonavir, clarithromycin): 2.5mg twice daily; if already on 2.5mg twice daily, coadministration should be avoided. Switching from warfarin: discontinue warfarin, start Eliquis when INR is < 2 . Switching from Eliquis to warfarin: discontinue Eliquis and begin both parenteral anticoagulant and warfarin at the time the next dose of Eliquis would have been taken, discontinue parenteral anticoagulant when INR reaches acceptable range. Switching between Eliquis and anticoagulants other than warfarin: discontinue one being taken and begin the other at next scheduled dose. Discontinue at least 48 hours prior to surgery with moderate-to-high risk of bleeding or 24 hours for procedures with low risk of bleeding. Moderate hepatic impairment: dosing recommendation cannot be provided. Severe hepatic impairment: not recommended.

Children: Not established.

Contraindications: Active pathological bleeding.

Warnings/Precautions: Increased risk of stroke if discontinued without adequate continuous anticoagulation. Prosthetic heart valve: not recommended. Labor & delivery. Pregnancy (Category B). Nursing mothers: not recommended.

Interactions: See Adult dose. Potentiated by dual inhibitors of CYP3A4 and P-gp. Antagonized by concomitant strong dual inducers of CYP3A4 and P-gp (eg, rifampin, carbamazepine, phenytoin, St. John's

wort); avoid. Increased risk of bleeding with concomitant aspirin, antiplatelet agents, fibrinolytics, other anticoagulants, heparin, thrombolytic agents, SSRIs, SNRIs, NSAIDs.

Adverse reactions: Bleeding.

How supplied: Tabs-60, 180

ARGATROBAN

ARGATROBAN GlaxoSmithKline

Anticoagulant (thrombin inhibitor). Argatroban 100mg/mL; soln for IV infusion after dilution.

Indications: Prophylaxis and treatment of thrombosis in heparin-induced thrombocytopenia (HIT) or in those with or at risk of HIT undergoing percutaneous coronary intervention (PCI).

Adults: ≥ 18 yrs: HIT: Discontinue heparin and obtain baseline aPTT. Initially 2mcg/kg per minute by continuous IV infusion; check aPTT 2 hrs after starting; titrate to 1.5-3x baseline aPTT (max 100seconds); max 10mcg/kg per minute. PCI: initially 25mcg/kg per minute by IV infusion, and 350mcg/kg bolus by large bore IV line over 3-5 minutes; titrate based on activated clotting time (ACT) to therapeutic ACT of 300-450seconds. For both: hepatic impairment: reduce dose (see literature).

Children: < 18 yrs: not recommended.

Contraindications: Overt major bleeding.

Concomitant other parenteral anticoagulants.

Warnings/Precautions: Increased bleeding risk (eg, unexpected decreases in hematocrit or BP, severe hypertension, recent lumbar puncture, spinal anesthesia, major surgery, bleeding disorders, GI lesions). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Increased risk of bleeding with thrombolytics (eg, t-PA, streptokinase). Vit. K antagonists (eg, warfarin), heparin, antiplatelets, GPlIb/IIIa blockers (eg, eptifibatide).

Adverse reactions: Hemorrhagic events, chest pain, dyspnea, cough, hypotension, rash, fever, GI upset, cardiac arrest, ventricular tachycardia, others.

How supplied: Single-use vial (2.5mL)-1

ASPIRIN

BAYER, ASPIRIN REGIMEN Bayer Consumer
Antiplatelet. Aspirin 81mg tabs, 325mg caplets; e.c.

Also: Aspirin

BAYER CHEWABLE

Aspirin 81mg; chew tabs; orange or cherry flavor.

Also: Aspirin

BAYER

Aspirin 325mg; tabs; caplets; gelscaps.

Indications: To reduce combined risk of death and nonfatal stroke after ischemic stroke or TIA. To reduce risk of vascular mortality in suspected acute MI. To reduce combined risk of death and nonfatal MI after MI or unstable angina pectoris. To reduce

combined risk of MI and sudden death in chronic stable angina. Revascularization procedures.

Adults: Ischemic stroke and TIA: 50-325mg once daily. Suspected acute MI: 160-162.5mg once daily (start as soon as MI suspected) then for at least 30 days post-MI. Prevention of recurrent MI, unstable angina pectoris, chronic stable angina: 75-325mg once daily. Coronary artery bypass graft: 325mg once daily (start 6 hours after procedure) for 1 year. Percutaneous transluminal coronary angioplasty: 325mg 2 hours before surgery, then 160-325mg once daily. Carotid endarterectomy: 80mg once daily to 650mg twice daily (start before surgery).

Children: Not recommended.

Contraindications: NSAID allergy. Viral infection in children and teenagers. 3rd trimester pregnancy.

Warnings/Precautions: History of asthma or peptic ulcer. Severe hepatic or renal dysfunction. Bleeding disorders. Diabetes. Gout. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates anticoagulants, hypoglycemics, methotrexate, acetazolamide, valproic acid, highly protein-bound drugs. Urinary alkalizers, antacids, corticosteroids may increase excretion. May antagonize ACE inhibitors, β -blockers, diuretics, uricosurics. Increased bleeding risk with NSAIDs or chronic, heavy alcohol use. NSAIDs increase risk of renal dysfunction.

Adverse reactions: GI upset/bleed, prolonged bleeding time, anaphylaxis, salicylism.

How supplied: Aspirin Regimen 81mg-32, 120, 180; Aspirin Regimen 325mg-100; Children's-36; Bayer Tabs-12, 24, 50, 100, 200, 300, 365; Caplets-50, 100, 200; Gelscaps-40, 80

BIVALIRUDIN

ANGIOMAX The Medicines Company
Anticoagulant (thrombin inhibitor). Bivalirudin 250mg/vial; pwd for IV inj after reconstitution and dilution.

Indications: With aspirin: anticoagulation in unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA). Patients with, or at risk of, heparin-induced thrombocytopenia (HIT) and thrombosis syndrome (HITS) undergoing percutaneous coronary intervention (PCI), and in patients undergoing PCI with provisional use of glycoprotein IIb/IIIa (GPI).

Adults: Give with aspirin 300-325mg daily; initiate 0.75 mg/kg IV bolus (may give additional bolus of 0.3 mg/kg after 5 min if needed), followed by 1.75 mg/kg/hr for duration of PCI procedure. May continue infusion up to 4hrs post-procedure; after 4hrs, may give additional infusion of 0.2 mg/kg/hr up to 20 hrs, if needed. Renal impairment: CrCl < 30 mL/min: reduce infusion rate to 1 mg/kg/hr; hemodialysis: 0.25 mg/kg/hr.

Children: < 18 yrs: not recommended.

Contraindications: Active major bleeding.

Warnings/Precautions: Consider stopping if symptoms of bleeding occur. Increased risk of thrombus formation with brachytherapy. Diseases associated with an increased bleeding risk. Pregnancy (Cat.B). Nursing mothers.

Interactions: Increased bleeding risk with warfarin, heparin, thrombolytics.

Adverse reactions: Bleeding, back pain, pain, headache, GI upset, hypo- or hypertension, inj site pain, urinary retention.

How supplied: Single-use vial-1

CLOPIDOGREL

R

PLAVIX Bristol-Myers Squibb and

Sanofi Aventis

Platelet aggregation inhibitor. Clopidogrel (as bisulfate) 75mg, 300mg; tabs.

Indications: Reduction of atherosclerotic events in: recent MI or stroke, established peripheral arterial disease; non-ST-segment elevation acute coronary syndrome (unstable angina/non-ST-elevation MI) or ST-elevation MI; see literature.

Adults: 75mg once daily. Non-ST-segment acute coronary syndrome (give with aspirin 75–325mg once daily): give one 300mg loading dose first. ST-segment elevation MI (give with aspirin, with or without thrombolytics): may start with or without a loading dose. CYP2C19 poor metabolizers: may need higher doses. If concomitant PPI required: consider acid-reducing agent with minimal or no CYP2C19 inhibitory effect.

Children: Not recommended.

Contraindications: Active pathological bleeding (eg, peptic ulcer, intracranial hemorrhage).

Warnings/Precautions: CYP2C19 poor metabolizers: diminished effectiveness and higher cardiovascular event rates. Consider testing for CYP2C19 genotype before starting therapy; consider alternative treatment if identified as poor metabolizer. Risk of bleeding (eg, surgery, ulcers, trauma, concomitant NSAIDs). Consider discontinuing 5 days before elective surgery. Avoid lapses in therapy; if temporarily discontinued, restart as soon as possible. Increased risk of cardiovascular events if discontinued prematurely. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid concomitant CYP2C19 inhibitors (eg, omeprazole, esomeprazole, cimetidine, fluconazole, ketoconazole, voriconazole, etravirine, felbamate, fluoxetine, fluvoxamine, ticlopidine). Caution with drugs that increase risk of bleeding (eg, NSAIDs, warfarin), and with drugs metabolized by CYP2C9 (eg, phenytoin, tolbutamide, tamoxifen, warfarin, torsemide, fluvastatin, many NSAIDs).

Adverse reactions: Bleeding (may be fatal), GI upset/ulcers, bruising, rash, pruritus, headache; rare: thrombotic thrombocytopenic purpura, agranulocytosis.

How supplied: Tabs 75mg-30, 90, 100, 500; 300mg-30, 100

DABIGATRAN ETEXILATE

R

PRADAXA Boehringer Ingelheim

Direct thrombin inhibitor. Dabigatran etexilate mesylate 75mg, 150mg; capsules.

Indications: To reduce risk of stroke and systemic embolism in non-valvular atrial fibrillation.

Adults: Swallow whole. CrCl>30mL/min:

150mg twice daily. Severe renal impairment (CrCl 15–30mL/min): 75mg twice daily; CrCl<15mL/min or on dialysis: not recommended. Moderate renal impairment (CrCl 30–50mL/min) with concomitant dronedarone or systemic ketoconazole: consider reducing dose to 75mg twice daily. Severe renal impairment (CrCl 15–30mL/min) with concomitant P-gp inhibitors: avoid. Converting from warfarin, other anticoagulants: see full labeling. Take missed dose as soon as possible on same day; skip dose if it cannot be taken at least 6 hours before the next scheduled dose; do not double doses.

Children: Not established.

Contraindications: Active pathological bleeding. Mechanical prosthetic heart valve.

Warnings/Precautions: Increased risk of stroke with discontinuation; if necessary, consider coverage with other anticoagulant. Increased risk of serious bleeding. Promptly evaluate signs/symptoms of blood loss (eg, a drop in hemoglobin and/or hematocrit or hypotension). Suspend treatment before invasive therapy or surgery, including dental procedures (see full labeling); restart promptly. Bioprosthetic heart valve: not recommended. Avoid lapses in therapy. Monitor renal function before starting treatment then periodically; discontinue if acute renal failure develops and consider alternate therapy. Bleeding risk can be assessed by ecarin clotting time (ECT), or if not available, aPTT. Severe renal impairment. Elderly (>75 years). Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Antagonized by P-gp inducers (eg, rifampin); avoid. Increased dabigatran levels with P-gp inhibitors (eg, dronedarone, ketoconazole, verapamil, amiodarone, quinidine, clarithromycin). Concomitant NSAIDs, platelet inhibitors, heparin, fibrinolytic therapy: increased risk of bleeding. Switching to or from warfarin: monitor closely.

Adverse reactions: Gastritis-like symptoms (eg, GERD, esophagitis, erosive gastritis, gastric hemorrhage), bleeding (may be fatal).

How supplied: Caps-60

DALTEPARIN

R

FRAGMIN Eisai

Low molecular weight heparin. Dalteparin sodium 2500 IU/0.2 mL syringe, 5000 IU/0.2 mL syringe, 7500 IU/0.3 mL syringe, 10000 IU/0.4 mL syringe, 10000 IU/1 mL graduated syringe, 12500 IU/0.5 mL syringe, 15000 IU/0.6 mL syringe, 18000 IU/0.72 mL syringe for SC inj (preservative-free); 10000 IU/1 mL, 25000 IU/1 mL multidose vial, for SC inj (contains benzyl alcohol).

Indications: Prevention of ischemic complications in unstable angina and non-Q-wave MI with aspirin. Prevention of DVT in patients undergoing hip replacement or abdominal surgery or those with severely restricted mobility during acute illness at risk for thromboembolic complications. Extended treatment of symptomatic venous thromboembolism (VTE) (proximal DVT and/or pulmonary embolism), to reduce the recurrence of VTE in cancer patients.

Adults: Give deep SC; rotate inj sites. Angina, MI: 120 IU/kg (max 10000 IU) every 12 hrs until stabilized (usually 5–8 days), with aspirin 75–165 mg once daily. Hip replacement, post-op start: 2500 IU 4–8 hrs after surgery, then 5000 IU once daily (at least 6 hrs after 1st dose); hip replacement, pre-op start day of surgery: 2500 IU within 2 hrs before surgery, then 2500 IU 4–8 hrs after surgery, then 5000 IU once daily (at least 6 hrs after previous dose); hip replacement pre-op evening before surgery: 5000 IU 10–14 hrs before surgery, then 5000 IU 4–8 hrs after surgery, then 5000 IU once daily (allow 24 hrs between doses); for all hip replacement regimens: usually treat for 5–10 days; max up to 14 days post-op. Abdominal surgery: 2500 IU once daily (usually for 5–10 days) starting 1–2 hrs pre-op; for high risk of thromboembolism (eg, malignancy): see literature. Severely restricted mobility: 5000 IU once daily (usually for 12–14 days). Extended treatment of symptomatic VTE in patients with cancer: 200 IU/kg once daily for the first 30 days, then 150 IU/kg once daily for months 2–6; max daily dose 18000 IU; dose reductions for thrombocytopenia or renal insufficiency: see literature.

Children: Not recommended.

Contraindications: Active major bleeding. Not for use in unstable angina, non-Q-wave MI, or cancer patients undergoing regional anesthesia. Thrombocytopenia associated with (+) *in vitro* tests for anti-platelet antibody in presence of dalteparin. Heparin or pork allergy.

Warnings/Precautions: Not interchangeable (unit-for-unit) with heparin or other low molecular weight heparin products. Neuraxial anesthesia or spinal puncture (esp. with indwelling epidural catheters, drugs that affect hemostasis, traumatic or repeated epidural or spinal puncture) increase risk of epidural or spinal hematoma; monitor for neurological impairment. Hemorrhage risk. Bleeding diathesis. Thrombocytopenia (esp. heparin-induced). Platelet dysfunction or defects. Severe renal or hepatic insufficiency. Retinopathy. Recent GI bleeding. Pregnancy (Cat.B; do not use multidose vial). Nursing mothers.

Interactions: Caution with oral anticoagulants, platelet inhibitors, thrombolytics.

Adverse reactions: Inj site pain, hematoma, hemorrhage; rare: anaphylaxis, rash, fever, thrombocytopenia.

How supplied: Prefilled syringes (w. needle)–10; 10000 IU/mL (9.5mL multidose vial)–1 (95000 IU/vial); 25000 IU/mL (3.8mL multidose vial)–1 (95000 IU/vial)

DESIRUDIN

R

IPRIVASK Canyon

Direct thrombin inhibitor (recombinant hirudin).

Desirudin 15mg/vial; pwd for SC inj after reconstitution; preservative-free; diluent contains mannitol.

Indications: DVT prophylaxis in patients undergoing hip replacement surgery.

Adults: Not interchangeable with other hirudins. Give by SC inj, preferably in abdomen or thigh. 15mg every 12hrs starting up to 5–15min before surgery (after induction of regional block anesthesia, if used); may continue for 9–12 days post-op. Renal impairment (CrCl<60mL/min): reduce dose (see literature).

Children: Not recommended.

Warnings/Precautions: Renal impairment: monitor aPTT and serum creatinine closely. Hemorrhagic stroke. Diabetic retinopathy. Severe uncontrolled hypertension. Recent GI or pulmonary bleeding. Recent surgery or biopsy. Neuraxial puncture. Post-op indwelling epidural catheter (place catheter before starting therapy and remove when desirudin effect is low). Bacterial endocarditis. Hepatic impairment. Monitor for neurological impairment (may indicate spinal/epidural hematoma). Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant heparins (fractionated or unfractionated): not recommended. Concomitant NSAIDs, platelet inhibitors, other anticoagulants: increased risk of bleeding, neuraxial hematoma with epidural catheters; discontinue these and others that increase bleeding risk (eg, glucocorticoids, Dextran 40) before starting desirudin. Caution with drugs that affect platelets (eg, salicylates, ticlopidine, clopidogrel, abciximab, gp IIb/IIIa antagonists). Switching to or from coumadin: monitor closely.

Adverse reactions: Bleeding, inj site reaction/mass, nausea, anaphylaxis, antibody formation.

How supplied: Single-use vials–10 (w. diluent, supplies)

DIPYRIDAMOLE

R

PERSANTINE Boehringer Ingelheim

Antiplatelet. Dipyridamole 25mg, 50mg, 75mg; tabs.

Indications: Adjunct to oral anticoagulants after cardiac valve replacement to prevent thromboembolism.

Adults: 75mg–100mg four times a day.

Children: Not recommended.

Warnings/Precautions: Hypotension. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Dizziness, GI upset, headache, rash.

How supplied: Tabs 25mg, 50mg–100, 1000; 75mg–100, 500

ENOXAPARIN

R

LOVENOX Sanofi Aventis

Low molecular weight heparin. Enoxaparin sodium 100mg/mL, 150mg/mL; syringes (preservative-free); 300mg/3mL multidose vials (contain benzyl alcohol).

Indications: Prevention of DVT in hip or knee replacement surgery, or in abdominal surgery or acutely ill patients with severely restricted mobility at risk for thromboembolism. With warfarin: for inpatient treatment of acute DVT with or without pulmonary embolism (PE), or outpatient treatment of acute DVT without PE. With aspirin: to prevent ischemic complications of unstable angina and non-Q-wave MI. Treatment of acute ST-segment elevation MI (STEMI) managed medically or with subsequent percutaneous coronary intervention (PCI).

Adults: For post-op dosing, assure hemostasis before starting. Knee: 30mg SC every 12 hrs for 7–10 days; max 14 days (1st dose 12–24 hrs post-op). Hip: 30mg SC every 12 hours (1st dose 12–24 hrs post-op), or 40mg SC once daily (1st dose 9–15 hrs pre-op), for 7–10 days, then 40mg SC once daily for 3 weeks. Abdominal: 40mg SC once daily (1st dose 2 hrs pre-op) for 7–10 days; max 12 days. Severely restricted mobility due to acute illness: 40mg SC once daily for 6–11 days, max 14 days. DVT (without PE) outpatient: 1mg/kg every 12 hrs SC; inpatient (with or without PE): 1mg/kg every 12 hrs SC or 1.5mg/kg once daily SC; for both, start warfarin usually within 72 hrs, continue enoxaparin at least 5 days and until INR is between 2–3 (usually 7 days; usual max 17 days). Unstable angina and non-Q-wave MI: 1mg/kg SC every 12 hrs for at least 2 days, with aspirin 100–325mg once daily, until stable (usually 2–8 days; usual max 12.5 days). STEMI: 30mg IV bolus plus 1mg/kg SC dose, then 1mg/kg SC every 12 hrs (max 100mg for 1st 2 doses only, then 1mg/kg dosing for remaining doses), with aspirin 75–325mg once daily; usually for 8 days or until hospital discharge. Concomitant thrombolytics: give between 15 minutes before or 30 minutes after start of fibrinolytic therapy. PCI: if last enoxaparin dose given <8 hrs before balloon inflation, no additional dose needed; >8 hrs before balloon inflation, give 0.3mg/kg IV bolus. Elderly with STEMI: ≥75yrs: Do not give IV bolus; initially 0.75mg/kg SC every 12 hrs (max 75mg for 1st 2 doses only, then 0.75mg/kg dose for remaining doses). Severe renal impairment (CrCl <30mL/min) or low body weight: adjust dose (see literature).

Children: Not recommended.

Contraindications: Active major bleeding. Thrombocytopenia associated with a (+) *in vitro* test for antiplatelet antibody associated with enoxaparin sodium. Hypersensitivity to heparin or pork products.

Warnings/Precautions: Prosthetic heart valves: not recommended (esp. if pregnant). Neuraxial anesthesia and post-op indwelling epidural catheter or spinal puncture (risk of epidural or spinal hematoma). Heparin-induced thrombocytopenia. Bacterial endocarditis. Bleeding disorders. Bleeding diathesis. Active ulceration and angiodysplastic GI disease. Recent history of GI ulcer. Hemorrhagic stroke. Uncontrolled hypertension. Diabetic retinopathy. Recent brain, spinal or eye surgery. Renal impairment

or low body weight (monitor bleeding). PCI: obtain hemostasis before sheath removal; monitor site for bleeding or hematoma (see literature). Monitor CBC and for occult blood in stool. Not interchangeable (unit-for-unit) with heparin or other low molecular weight heparins. Elderly. Pregnancy (Cat.B): monitor carefully (congenital anomalies, bleeding); avoid using multidose vials. Nursing mothers.

Interactions: Avoid concomitant drugs that affect hemostasis (eg, oral anticoagulants, platelet inhibitors including aspirin, NSAIDs, dipyridamole, flupyrizone).

Adverse reactions: Hemorrhage, thrombocytopenia, inj site reactions, fever, nausea, ecchymosis, hypochromic anemia, edema, skin necrosis, thrombocytopenia, systemic allergic reaction, inflammatory nodules, elevated serum transaminases; angina/MI patients: also atrial fibrillation, heart failure, lung edema, pneumonia.

How supplied: Prefilled syringes 100mg/mL (30mg, 40mg)–10; Prefilled syringes 100mg/mL (60mg, 80mg, 100mg)–10; Prefilled syringes 150mg/mL (120mg, 150mg)–10; Multidose vial (300mg/3mL)–1

EPTIFIBATIDE

R

INTEGRILIN Merck

Antiplatelet (GP IIb/IIIa blocker). Eptifibatide 0.75mg/mL, 2mg/mL; soln for IV inj.

Indications: For acute coronary syndrome, including patients who are to be managed medically and those undergoing percutaneous coronary intervention (PCI), including those undergoing intracoronary stenting.

Adults: See literature. Use in combination with aspirin and heparin. ACS: 180micrograms/kg IV bolus, followed by a continuous IV infusion of 2micrograms/kg/min until discharge or CABG surgery, up to 72 hours. If PCI planned, continue infusion until discharge, or for up to 18–24hrs after procedure, whichever comes first, allowing up to 96hrs of therapy. PCI: 180micrograms/kg IV bolus followed by 2micrograms/kg/min infusion; repeat 180micrograms/kg IV bolus 10minutes after the 1st bolus; continue infusion until discharge, or for up to 18–24hrs, whichever comes first, minimum 12hr-infusion recommended. CrCl <50mL/min: reduce infusion rate to 1microgram/kg/min.

Children: Not recommended.

Contraindications: Bleeding diathesis or active abnormal bleeding within previous 30 days. Severe uncontrolled hypertension. Major surgery within previous 6 weeks. History of stroke within 30 days or any history of hemorrhagic stroke. Concomitant parenteral GP IIb/IIIa inhibitors. Renal dialysis.

Warnings/Precautions: See literature. Discontinue if uncontrolled bleeding occurs. Platelet count <100,000/mm³. Properly care for femoral artery access site to minimize bleeding. Minimize other arterial and venous punctures, IM inj, catheter use, intubation, NG tubes, to lower bleeding risk;

avoid use of non-compressible IV access sites. Do baseline platelet counts, hemoglobin, hematocrit, others and monitor during therapy (see literature). Discontinue if confirmed thrombocytopenia occurs. Renal insufficiency. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Antiplatelet effects may be potentiated by thrombolytics, oral anticoagulants, NSAIDs, and dipyridamole.

Adverse reactions: Bleeding, intracranial hemorrhage, stroke, thrombocytopenia, hypersensitivity reactions, hypotension.

How supplied: Vial 0.75mg/mL (100mL)–12mg/mL (10mL, 100mL)–1

FONDAPARINUX

R

ARIXTRA GlaxoSmithKline

Anticoagulant (Factor Xa inhibitor). Fondaparinux sodium 2.5mg/0.5mL, 5mg/0.4mL, 7.5mg/0.6mL, 10mg/0.8mL; soln for SC inj; preservative free.

Indications: Prophylaxis of DVT in patients undergoing hip fracture surgery, or hip or knee replacement, or abdominal surgery with risk of thromboembolic complications. With warfarin: Treatment of acute pulmonary embolism (PE) (initiate in hospital), or treatment of acute DVT.

Adults: Give by SC inj. Prophylaxis: Once hemostasis is achieved, give 1st dose no earlier than 6–8 hours post-op. 2.5mg once daily for 5–9 days. Hip or knee replacement: max 11 days. Hip fracture: give for up to 24 more days (max 32 days). Abdominal: max 10 days. Treatment: (<50kg): 5mg; (50–100kg): 7.5mg; (>100kg): 10mg; for all: give once daily for at least 5 days and until INR = 2–3; usually 5–9 days; max 26 days; start warfarin usually within 72 hours.

Children: Not recommended.

Contraindications: Severe renal impairment (CrCl <30mL/min). Active major bleeding. Bacterial endocarditis. Thrombocytopenia associated with (+) *in vitro* test for antiplatelet antibody in presence of fondaparinux. Also for prophylaxis: body weight <50kg.

Warnings/Precautions: Neuraxial anesthesia and post-op indwelling epidural catheter or spinal puncture (risk of epidural or spinal hematoma); monitor for signs and symptoms of neurologic impairment. Hepatic or moderate renal impairment (CrCl 30–50mL/min). Monitor hepatic and renal function; discontinue if severe renal impairment develops. Bleeding disorders. Acute ulcerative or angiodysplastic GI disease. Hemorrhagic stroke. Uncontrolled hypertension. Diabetic retinopathy. Recent brain, spinal, or eye surgery. History of heparin-induced thrombocytopenia. Obtain CBCs, platelets, serum creatinine level, stool occult blood tests during therapy; discontinue if platelets <100,000 per mm³. Not interchangeable (unit-for-unit) with heparin, low molecular weight heparins, or heparinoids. PE and DVT treatment: low body weight (<50kg). Latex allergy. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with drugs that affect hemostasis (eg, warfarin, ticlopidine, platelet inhibitors, NSAIDs).

Adverse reactions: Bleeding, thrombocytopenia, local reactions (rash, pruritus, hematoma, pain), elevated ALT/AST, anemia, fever, edema, insomnia, GI upset, hypokalemia, hypotension, dizziness, purpura, confusion, headache.

How supplied: Prefilled syringes–2, 10

HEPARIN

R

HEPARIN SODIUM (various)

Anticoagulant. Heparin sodium 1000, 5000, 10000, 20000units; per mL; IV or SC inj.

Indications: Anticoagulation therapy.

Adults and Children: See literature. Individualize based on lab results and disease.

Contraindications: Severe thrombocytopenia. Uncontrollable active bleeding, except if due to DIC. When monitoring is not feasible.

Warnings/Precautions: IM use not recommended. Monitor for heparin-induced thrombocytopenia and thrombosis (HITT): discontinue if platelet count falls <100000/mm³ or if recurrent thrombosis develops. Bleeding or conditions with increased risk of bleeding. Monitor blood coagulation tests, platelet, hematocrit and occult blood in stool. Surgery. Bacterial endocarditis. Severe hypertension. White-clot syndrome. Heparin resistance. Women >60yrs of age. Not interchangeable (unit-for-unit) with low molecular weight heparins. Elderly. Some formulations may contain benzyl alcohol; avoid in neonates, infants, nursing mothers. Pregnancy (Cat.C).

Interactions: Potentiated by anticoagulants (eg, dicumerol, warfarin), antiplatelets (eg, acetylsalicylic acid, dextran, phenylbutazone, ibuprofen, indomethacin, dipyridamole, hydroxychloroquine). Antagonized by digitalis, tetracyclines, nicotine, antihistamines. IV nitroglycerin may decrease PTT with rebound effect upon discontinuation; monitor.

Adverse reactions: Bleeding, thrombocytopenia, local reactions, hypersensitivity reactions, increased aminotransferase levels.

How supplied: Contact supplier.

NIMODIPINE

R

NIMODIPINE CAPSULES (various)

Calcium channel blocker. Nimodipine 30mg; soft-gel caps.

Indications: To improve neurological outcome of subarachnoid hemorrhage from ruptured intracranial berry aneurysms, regardless of post-ictus neurological condition.

Adults: Take on empty stomach. 60mg every 4 hours for 21 consecutive days. Start within 96 hours of subarachnoid hemorrhage. If oral therapy is not feasible, may extract capsule contents into a syringe and give via *in situ* NG tube, then flush tube with

normal saline. Hepatic impairment: 30mg every 4 hours; monitor.

Children: Not recommended.

Warnings/Precautions: Not for IV or other parenteral administration (may be fatal). Hepatic impairment. Monitor BP, heart rate. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May potentiate other calcium channel blockers. Potentiated by cimetidine.

Adverse reactions: Decreased blood pressure, GI upset, headache, bradycardia, flushing, edema, rash; rare: intestinal pseudo-obstruction and ileus.

How supplied: Contact supplier.

PRASUGREL

EFFIENT Daiichi Sankyo and Lilly
P2Y₁₂ platelet inhibitor (thienopyridine). Prasugrel 5mg, 10mg; tabs.

Indications: To reduce risk of thrombotic cardiovascular events in patients with acute coronary syndrome who are to be managed with percutaneous coronary intervention (patients with unstable angina (UA) or non-ST-elevation myocardial infarction (NSTEMI); patients with ST-elevation MI (STEMI) when managed with either primary or delayed PCI).

Adults: Loading dose: 60mg once. Maintenance: 10mg once daily. <60kg: consider 5mg once daily. Take with aspirin (75mg–325mg daily).

Children: Not recommended.

Contraindications: Active pathological bleeding (eg, peptic ulcer, intracranial hemorrhage). Prior TIA or stroke. Do not start if patient likely to undergo urgent CABG.

Warnings/Precautions: ≥75yrs: usually not recommended. Weight <60kg, or CABG or other surgery or trauma, recent or recurrent GI bleeding, severe hepatic dysfunction, moderate to severe renal impairment: increased risk of bleeding. Discontinue 7 days before surgery, and if TIA or stroke occurs. Premature discontinuation increases risk for cardiac events (eg, stent thrombosis, MI, death). Pregnancy (Cat.B). Nursing mothers.

Interactions: Increased bleeding risk with heparin, warfarin, fibrinolytics, chronic NSAID use.

Adverse reactions: Bleeding (may be fatal), hyper- or hypotension, hyperlipidemia, headache, back pain, GI upset, dizziness, cough, chest pain, atrial fibrillation, leukopenia; rare: thrombotic thrombocytopenic purpura, thrombocytopenia, anemia, abnormal hepatic function, allergic reactions, angioedema.

How supplied: Tabs 5mg–7, 30; 10mg–30

RETEPLASE

RETAVASE EKR Therapeutics
Tissue plasminogen activator (tPA). Reteplase 10.4Units (18.1mg); per vial; lyophilized pwd for IV inj after reconstitution; preservative-free.

Indications: Management of acute myocardial infarction (AMI) to improve ventricular function and

to reduce the incidence of congestive heart failure and mortality.

Adults: Start as soon as possible after onset of AMI symptoms. 10Units as IV bolus over 2 minutes; repeat dose 30 minutes after initiation of 1st bolus.

Children: Not recommended.

Contraindications: Active internal bleeding.

History of cerebrovascular accident. Recent intracranial or intraspinal surgery or trauma.

Intracranial neoplasm, arteriovenous malformation, or aneurysm. Bleeding diathesis. Severe uncontrolled hypertension.

Warnings/Precautions: Avoid noncompressible arterial puncture, internal jugular and subclavian venous punctures, IM inj, nonessential handling of patient to minimize risk of bleeding. Discontinue concomitant anticoagulant therapy if severe bleeding occurs. Recent major surgery. Cerebrovascular disease. GI or GU bleeding. Hypertension. Left heart thrombus. Acute pericarditis. Subacute bacterial endocarditis. Hemostatic defects. Severe hepatic or renal dysfunction. Hemorrhagic ophthalmic conditions. Septic thrombophlebitis. Occluded AV cannula. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Bleeding risks increased with heparin, vitamin K antagonists, aspirin, dipyridamole, abciximab. Coagulation tests may be unreliable during therapy.

Adverse reactions: Bleeding, hypersensitivity reactions, GI upset, hypotension, fever; cardiogenic shock, arrhythmias, AV block, pulmonary edema, heart failure, cardiac arrest, ischemia, reinfarction, myocardial rupture, mitral regurgitation, pericardial effusion, pericarditis, cardiac tamponade, venous thrombosis, cholesterol embolism, electromechanical dissociation.

How supplied: Kit-1 (2 vials w. diluents, supplies) Half-Kit-1 (1 vial w. diluent)

RIVAROXABAN

XARELTO Janssen
Factor Xa inhibitor. Rivaroxaban 10mg, 15mg, 20mg; tablets.

Indications: To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. Treatment of deep vein thrombosis (DVT), pulmonary embolism (PE). To reduce the risk of recurrence of DVT, PE following 6 months treatment for DVT, PE. Prophylaxis of DVT, which may lead to pulmonary embolism in patients undergoing knee or hip replacement surgery.

Adults: 15mg and 20mg tablets: take with food. Nonvalvular atrial fibrillation: CrCl ≥50mL/min: 20mg once daily with the evening meal; CrCl 15–50mL/min: 15mg once daily with the evening meal; CrCl <15mL/min: avoid. Treatment of DVT, PE: 15mg twice daily for first 21 days, then 20mg once daily for remaining treatment. Reduction in risk of recurrence of DVT, PE: 20mg once daily. DVT, PE treatment, risk reduction: avoid use if CrCl <30mL/min. Prophylaxis

of DVT: take 6–10 hours after surgery once hemostasis established. 10mg once daily; severe renal impairment (CrCl <30mL/min): avoid; moderate renal impairment (CrCl 30–50mL/min): monitor closely for blood loss; discontinue if acute renal failure develops. Hip: treat for 35 days. Knee: treat for 12 days. Switching from or to warfarin, or other anticoagulants: see literature.

Children: Not recommended.

Contraindications: Active pathological bleeding.

Warnings/Precautions: Discontinuation in nonvalvular atrial fibrillation may increase risk of thrombotic events (eg, stroke); consider alternative anticoagulants. Increased risk of bleeding; monitor for signs/symptoms of blood loss; discontinue if active pathological hemorrhage occurs. Increased risk of spinal/epidural hematoma in anticoagulated patients receiving neuraxial anesthesia or undergoing spinal puncture; monitor for signs/symptoms of neurological impairment. Moderate or severe hepatic impairment, hepatic disease associated with coagulopathy: avoid. Discontinue 24hrs before surgery. Elderly. Labor & delivery. Pregnancy (Cat.C); use with caution, risk of pregnancy-related hemorrhage. Nursing mothers: not recommended.

Interactions: Increased risk of bleeding with concomitant aspirin, P2Y₁₂ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, NSAIDs, clopidogrel; avoid. Avoid with concomitant combined P-gp and strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, lopinavir/ritonavir, ritonavir, indinavir/ritonavir, conivaptan). Avoid with concomitant combined P-gp and strong CYP3A4 inducers (eg, carbamazepine, phenytoin, rifampin, St. John's wort). May be potentiated with concomitant renal impairment and combined P-gp and weak or moderate CYP3A4 inhibitors (eg, erythromycin, azithromycin, diltiazem, verapamil, quinidine, ranolazine, dronedarone, amiodarone, felodipine).

Adverse reactions: Bleeding events (may be serious or fatal), wound secretion, pain in extremity, muscle spasm, syncope, pruritus, blister; hypersensitivity reactions.

How supplied: Tabs 10mg–30, 100 (10 × 10 blister cards); 15mg, 20mg–30, 90, 100 (10 × 10 blister cards)

TENECTEPLASE

R

TNKASE Genentech

Tissue plasminogen activator (tPA). Tenecteplase 50mg/vial; lyophilized pwd for IV inj after reconstitution.

Indications: To reduce mortality associated with acute myocardial infarction (AMI).

Adults: Start treatment soon after onset of AMI symptoms. Give as single IV bolus over 5 seconds. <60kg: 30mg; ≥60kg–<70kg: 35mg; ≥70kg–<80kg: 40mg; ≥80kg–<90kg: 45mg; ≥90kg: 50kg. Max: 50mg.

Children: Not recommended.

Contraindications: Active internal bleeding. History of cerebrovascular accident. Intracranial or intraspinal surgery or trauma within 2 months. Intracranial neoplasm, arteriovenous malformation, or aneurysm. Bleeding diathesis. Severe uncontrolled hypertension.

Warnings/Precautions: Avoid noncompressible arterial puncture, internal jugular and subclavian venous puncture, IM injections and nonessential handling of patient during treatment. Increased bleeding risk at puncture sites; minimize arterial and venous punctures. Increased risk of complications with recent major surgery, cerebrovascular disease, GI or GU bleeding, recent trauma, hypertension (systolic BP ≥180mm Hg and/or diastolic BP ≥110mm Hg), left heart thrombus, acute pericarditis, endocarditis, hemostatic defects, hepatic dysfunction, pregnancy, hemorrhagic ophthalmic conditions, septic thrombophlebitis, elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Increased bleeding risk with heparin, vitamin K antagonists, aspirin, dipyridamole, GP IIb/IIIa inhibitors. May interfere with coagulation tests.

Adverse reactions: Bleeding, hypersensitivity reactions, cardiogenic shock, arrhythmias, AV block, pulmonary edema, heart failure, cardiac arrest, recurrent MI, myocardial rupture, cardiac tamponade, pericarditis, pericardial effusion, mitral regurgitation, thromboembolism, electromechanical dissociation, nausea, vomiting, hypotension, fever; cholesterol embolism.

How supplied: Vial–1 (w. diluent, supplies)

TICAGRELOR

R

BRILINTA AstraZeneca

P2Y₁₂ platelet inhibitor (cyclopentyltriazolopyrimidine). Ticagrelor 90mg; tabs.

Indications: To reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina or non-ST-elevation myocardial infarction [MI] or ST-elevation MI).

Adults: Initiate loading dose: 180mg once, then continue with 90mg twice daily. After the initial loading dose of aspirin (usually 325mg), take ticagrelor with maintenance dose of aspirin 75–100mg daily. ACS patients: may start ticagrelor after receiving a loading dose of clopidogrel.

Children: Not established.

Contraindications: History of intracranial hemorrhage. Active pathological bleeding (eg, peptic ulcer, intracranial hemorrhage). Severe hepatic impairment.

Warnings/Precautions: Do not start in patients planned to undergo urgent CABG. When possible, discontinue at least 5 days before any surgery. Suspect bleeding in hypotensive patients who have recently undergone coronary angiography, PCI, CABG, or other surgery. Older age, history of bleeding disorders, undergoing percutaneous invasive procedures, concomitant anticoagulants, fibrinolytics,

higher doses of aspirin, and chronic NSAID use: increased risk of bleeding. Avoid interruption of treatment; if temporarily discontinued, restart as soon as possible. Premature discontinuation increases risk for CV events (eg, MI, stent thrombosis, death). Effectiveness reduced with aspirin maintenance dose >100mg; avoid. Moderate hepatic impairment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant strong CYP3A inhibitors (eg, ketoconazole, itraconazole, voriconazole, clarithromycin, nefazodone, ritonavir, saquinavir, nelfinavir, indinavir, atazanavir, telithromycin,) or potent CYP3A inducers (eg, rifampin, dexamethasone, phenytoin, carbamazepine, phenobarbital): not recommended. Potentiates simvastatin, lovastatin; avoid >40mg/day doses. Monitor digoxin during ticagrelor initiation and dose adjustments.

Adverse reactions: Bleeding (may be fatal), dyspnea, headache, cough, dizziness, nausea, diarrhea, atrial fibrillation, hyper- or hypotension, back pain, fatigue, chest pain.

How supplied: Tabs-60, 180

TICLOPIDINE

R

TICLOPIDINE HCl TABLETS (various)
Platelet aggregation inhibitor. Ticlopidine HCl 250mg; tabs.

Indications: To reduce the risk of thrombotic stroke in selected patients intolerant of aspirin.

Adults: 250mg twice daily with food.

Children: Not recommended.

Contraindications: Hematopoietic disorders including neutropenia, thrombocytopenia, or history of thrombotic thrombocytopenic purpura (TTP). Hemostatic or active bleeding disorders. Severe hepatic impairment.

Warnings/Precautions: Monitor for hematologic toxicity at baseline, every 2 weeks for the first 3 months, and for 2 weeks after discontinuation; test more frequently if signs of hematologic changes occur. Discontinue if neutropenia or TTP occur. Renal or hepatic impairment. Bleeding risk (eg, ulcers). Discontinue 10–14 days before surgery. Hyperlipidemia. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Discontinue anticoagulants, fibrinolytics before use. Avoid aspirin. Potentiates aspirin, NSAIDs, anticoagulants, antipyrene, theophylline. Antacids reduce absorption. May be potentiated by cimetidine. Monitor phenytoin. May antagonize digoxin. Caution with propranolol, drugs that increase risk of bleeding, and drugs metabolized by CYP450.

Adverse reactions: Diarrhea, GI upset, rash, neutropenia, pruritus, dizziness, anorexia, abnormal liver function tests, bleeding complications, hyperlipidemia, TTP, aplastic anemia, agranulocytosis, other blood dyscrasias, jaundice.

How supplied: Contact supplier.

WARFARIN

R

COUMADIN Bristol-Myers Squibb
Coumarin anticoagulant. Warfarin sodium 1mg, 2mg, 2½mg, 3mg, 4mg, 5mg, 6mg, 7½mg, 10mg (dye-free); scored tabs.

Also: Warfarin

R

COUMADIN FOR INJECTION

Warfarin sodium 2mg/mL; lyophilized pwd for IV inj after reconstitution.

Indications: Venous thrombosis. Pulmonary embolism. Thromboembolic complications from atrial fibrillation and/or cardiac valve replacement. Reduce risk of death, recurrent MIs, and thromboembolic events (eg, stroke, systemic embolization) post-MI.

Adults: Individualize. IV: give as slow bolus dose over 1–2 minutes into a peripheral vein. ≥18yrs: Initially 2–5mg orally or IV daily. Usual maintenance: 2–10mg daily. Variations in CYP2C9 or VKORC1 enzymes, elderly, debilitated, Asians: use lower initial dose. Closely monitor INR; adjust dose based on response and clinical condition. Converting from heparin: see literature.

Children: <18yrs: see literature.

Contraindications: Hemorrhagic tendencies.

Blood dyscrasias. Recent CNS, ophthalmic, or traumatic surgery. Bleeding tendencies associated with certain conditions. Threatened abortion, eclampsia, and preeclampsia. Unsupervised patients with potential high levels of non-compliance. Major regional or lumbar block anesthesia. Spinal puncture and other procedures with potential uncontrollable bleeding. Malignant hypertension. Pregnancy (Cat.X) in women without mechanical heart valves.

Warnings/Precautions: Risk of major or fatal bleeding. Monitor INR frequently. History of GI bleed. Hypertension. Cerebrovascular disease. Anemia. Malignancy. Trauma. Risk of tissue necrosis and/or gangrene. Discontinue if tissue necrosis, systemic atheroemboli or cholesterol microemboli occurs. Heparin-induced thrombocytopenia. Hepatic or renal impairment. Infection. Disturbances of intestinal flora. Indwelling catheter. Protein C deficiency. Polycythemia vera. Vasculitis. Diabetes. Diarrhea. Poor nutritional status. Steatorrhea. Vitamin K deficiency or intake. Hereditary warfarin resistance. Eye surgery. Dental procedures. Elderly. Asian. Debilitated. Anticoagulation may persist 2–5 days after discontinuation. Write R using fractions rather than decimals. Pregnancy (Cat.D) in women with mechanical heart valves. Nursing mothers.

Interactions: See literature. Potentiated by CYP2C9, 1A2 and/or 3A4 inhibitors. Antagonized by CYP2C9, 1A2 and/or 3A4 inducers. Caution with drugs that can increase risk of bleeding (eg, anticoagulants, antiplatelets, NSAIDs, SSRIs) or herbal products (eg, garlic, ginkgo biloba, co-enzyme Q₁₀, St. John's wort, ginseng, echinacea, grapefruit juice, goldenseal). Closely monitor INR when starting

or stopping any antibiotic or antifungal agent.

Cholestatic hepatitis with concomitant ticlopidine.

Adverse reactions: Tissue or organ hemorrhage, skin or tissue necrosis, systemic atheroemboli and cholesterol microemboli, hypersensitivity reactions, vasculitis, hepatic disorders, GI upset, abdominal pain, taste perversion, rash, dermatitis, pruritus, alopecia, tracheal or tracheobronchial calcification, chills; purple toes syndrome.

How supplied: Tabs 1mg, 2mg, 2½mg, 3mg, 4mg, 5mg, 6mg-100, 1000; 7½mg, 10mg-100; Inj (5mg vial)-6

6G White blood cell disorders

FILGRASTIM

NEUPOGEN Amgen

Granulocyte colony stimulating factor. Filgrastim 600mcg/mL prefilled syringe; for SC or IV infusion; preservative-free.

Also: Filgrastim NEUPOGEN VIALS

Filgrastim 300mcg/mL; for SC or IV infusion; preservative-free.

Indications: See literature. To decrease incidence of infection in patients with nonmyeloid malignancies receiving certain myelosuppressive anti-cancer drugs. To reduce time to neutrophil recovery and fever duration after induction and consolidation chemotherapy treatment of adults with AML. To reduce duration of neutropenia and related sequelae in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone-marrow transplantation (BMT). To mobilize hematopoietic progenitor cells (PBPC) into peripheral blood for collection by leukapheresis. To reduce the incidence and duration of neutropenia sequelae in severe chronic neutropenia (SCN).

Adults: See literature. Do not give for at least 24 hrs before or after cytotoxic chemotherapy dose. BMT: Give 1st dose at least 24 hrs after bone marrow infusion. SCN: Give on a daily basis.

Children: See literature.

Contraindications: Hypersensitivity to *E. coli*-derived products.

Warnings/Precautions: Monitor blood, including CBC and differential and platelets, before and during therapy (myelosuppressive chemotherapy: monitor twice weekly; BMT: at least 3 times weekly; SCN: twice per week during initial 4 weeks of therapy and during 2 weeks after dose adjustment). Discontinue if post nadir absolute neutrophil count (ANC) reaches 10,000/mm³ for patients receiving myelosuppressive chemotherapy; other indications: see literature. Monitor for splenomegaly/splenic rupture and for adult respiratory distress syndrome (ARDS); suspend until ARDS resolves if fever or lung infiltrates occur. Confirm diagnosis and do appropriate pretreatment

hematological workup in SCN. Preexisting cardiac or hyperplastic skin conditions. Sickle cell disease (may cause sickle cell crisis). Avoid simultaneous chemo- and radiation therapy. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with mitomycin C, and with concomitant (same day) drugs that decrease platelets, or increase release of neutrophils (eg, lithium), or cause delayed myelosuppression, or with myelosuppressive doses of antimetabolites (eg, nitrosoureas, 5-FU).

Adverse reactions: Bone pain, cutaneous vasculitis, splenomegaly, others (see literature).

How supplied: Prefilled syringes (0.5mL, 0.8mL)-10 Vials (1mL, 1.6mL)-10

PEGFILGRASTIM

R

NEULASTA Amgen

Granulocyte colony stimulating factor. Pegfilgrastim (polyethylene glycol/filgrastim conjugate) 6mg/0.6mL soln; SC inj; preservative-free.

Indications: To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with clinically significant incidence of febrile neutropenia.

Adults: Do not give between 14 days before and 24 hours after chemotherapy. Adolescents <45 kg: not recommended. ≥45 kg: 6mg SC once per chemotherapy cycle.

Children: Not recommended.

Contraindications: Do not use for peripheral blood progenitor cell (PBPC) mobilization. Hypersensitivity to *E. coli*-derived products.

Warnings/Precautions: Monitor CBC and platelets before and during therapy. Monitor for splenomegaly/splenic rupture and for adult respiratory distress syndrome (ARDS); suspend until ARDS resolves if fever or lung infiltrates occur. Sickle cell disease (may cause sickle cell crisis). Myeloid malignancies. Myelodysplasia. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with drugs that cause delayed myelosuppression (eg, nitrosoureas, mitomycin C), or increase release of neutrophils (eg, lithium), antimetabolites (eg, 5-FU), and radiation therapy.

Adverse reactions: Bone pain, anaphylaxis, ARDS; splenic rupture (rare).

How supplied: Prefilled syringe-1

SARGRAMOSTIM

R

LEUKINE Genzyme

Granulocyte-macrophage colony stimulating factor (recombinant). Sargramostim (recombinant human granulocyte-macrophage colony stimulating factor, or rhu GM-CSF) 250mcg; per vial; pld for SC inj or IV infusion after reconstitution; preservative-free.

Indications: To speed neutrophil recovery and reduce infections after induction chemotherapy in treatment of acute myelogenous leukemia (AML) in patients >55 years of age. To mobilize

hematopoietic progenitor cells into peripheral blood for collection by leukapheresis. To speed myeloid recovery in non-Hodgkin's lymphoma, acute myeloblastic leukemia (ALL), and Hodgkin's disease in autologous bone marrow transplantation (BMT). To speed myeloid recovery in allogeneic BMT. Patients with BMT failure or engraftment delay.

Adults: See literature for timing and duration of dosing, and for repeat courses of therapy. Individualize. Neutrophil recovery: 250mcg/m² per day IV over 4 hrs. Mobilization or post peripheral blood progenitor cell transplantation: 250mcg/m² per day IV over 24 hrs or SC once daily. Myeloid recovery after BMT: 250mcg/m² per day IV over 2 hrs. BMT failure or engraftment delay: 250mcg/m² per day IV over 2 hrs for 14 days.

Children: See literature.

Contraindications: Excessive leukemic myeloid blasts in bone marrow or peripheral blood ($\geq 10\%$). Allergy to GM-CMF or yeast-derived products. Concomitant (within 24 hrs) chemotherapy or radiotherapy.

Warnings/Precautions: Fluid retention, pleural or pericardial effusions. Pulmonary infiltrates. Respiratory disease or symptoms. Hypoxia. Reduce infusion rate by $\frac{1}{2}$ if dyspnea occurs; discontinue if dyspnea worsens. Cardiac disease. CHF. Renal or hepatic dysfunction (monitor before and every other week during therapy). Monitor CBC and differential twice weekly. Reduce dose by $\frac{1}{2}$ or discontinue if absolute neutrophil count exceeds 20,000cells/mm³ or if platelet count exceeds 500,000cells/mm³. Myeloid malignancies. Monitor body weight and hydration. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with lithium, corticosteroids, others that may enhance myeloproliferative effects. May be antagonized by radiotherapy, myelotoxic drugs.

Adverse reactions: Flu-like symptoms, GI disturbances, edema, dyspnea, pharyngitis, rash, joint or bone or chest pain, eye hemorrhage, hypomagnesemia, anxiety, headache, pleural +/- pericardial effusion, arthralgia, myalgia, others.

How supplied: Vials-5

6H Miscellaneous hematological agents

DEFERASIROX

EXJADE Novartis

Iron chelating agent. Deferasirox 125mg, 250mg, 500mg; tabs for oral susp.

Indications: Chronic iron overload due to blood transfusions in patients ≥ 2 yrs of age. Chronic iron overload in patients ≥ 10 yrs of age with non-transfusion dependent thalassemia syndromes and with a liver iron concentration (LIC) of at least 5mg Fe per gram of dry weight and a serum ferritin > 300 mcg/L.

Adults and Children: Calculate dose to nearest whole tablet. Take on empty stomach at least 30mins

before food. Do not chew or swallow tabs; disperse completely in water, orange juice or apple juice; drink immediately; resuspend remainder and drink. Transfusional iron overload: < 2 yrs: not recommended. ≥ 2 yrs: initially 20mg/kg once daily; may adjust dose by 5 or 10mg/kg every 3 to 6 months based on serum ferritin levels or response. If inadequate control at 30mg/kg, may consider increasing up to max 40mg/kg. Adjust dose if severe skin rashes occur; consider suspending therapy if serum ferritin < 500 mcg/L. Non-transfusion dependent thalassemia syndromes: < 10 yrs: not recommended. ≥ 10 yrs: 10mg/kg once daily; if baseline LIC > 15 mg Fe/g dw, consider increasing dose to 20mg/kg after 4 weeks. Suspend therapy if serum ferritin < 300 mcg/L and obtain LIC to determine whether it has fallen to < 3 mg Fe/g dw. After 6 months, if LIC remains > 7 mg Fe/g dw, increase dose to max 20mg/kg/day. If after 6 months, LIC is 3–7mg Fe/g dw, continue with max 10mg/kg/day. When LIC is < 3 mg Fe/g dw, interrupt treatment and continue to monitor LIC. Restart when LIC rises again to > 5 mg Fe/g dw. Adjustments based on serum creatinine: see full labeling. Hepatic impairment: moderate: reduce dose by 50%; severe: avoid.

Contraindications: CrCl < 40 mL/min or serum creatinine > 2 x age-appropriate ULN. Poor performance status and high risk myelodysplastic syndromes or advanced malignancies. Platelets $< 50 \times 10^9$ /L.

Warnings/Precautions: May cause renal or hepatic failure, GI hemorrhage; may be fatal. Hepatic or renal impairment. Advanced disease or co-morbid conditions. Obtain baseline serum ferritin level, monitor monthly and adjust dose accordingly. Measure serum creatinine and CrCl in duplicate before starting therapy; monitor weekly during 1st month then at least monthly thereafter; more frequently if creatinine levels increase. Measure serum transaminases, bilirubin before initiating therapy then every 2 weeks during 1st month, then monthly. Monitor blood counts; interrupt therapy if cytopenias develop. For non-transfusion dependent thalassemia syndromes: obtain LIC by liver biopsy prior to starting therapy, monitor LIC every 6 months. Do baseline auditory and ocular exams, then every 12 months; if disturbances occur, adjust dose or suspend therapy. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid aluminum-containing antacids, bile acid sequestrants (eg, cholestyramine, colestesvelam, colestipol), or UGT inducers (eg, rifampicin, phenytoin, phenobarbital, ritonavir); if concomitant administration necessary consider increasing initial Exjade dose by 50% and monitor serum ferritin levels and clinical responses. Caution with drugs that have ulcerogenic or hemorrhagic potential (eg, NSAIDs, corticosteroids, oral bisphosphonates, anticoagulants) or drugs metabolized by CYP3A4 (eg, cyclosporine,

simvastatin, hormonal contraceptives). Potentiates repaglinide (consider reducing repaglinide dose); monitor blood glucose levels. Caution with other CYP2C8 substrates (eg, paclitaxel). Avoid concomitant theophylline or other CYP1A2 substrates with narrow therapeutic index. Other concomitant iron chelation therapy: not recommended.

Adverse reactions: GI upset, abdominal pain, elevated serum creatinine, rash; renal or hepatic impairment/failure (may be fatal), GI hemorrhage, cytopenias (eg, agranulocytosis, neutropenia, thrombocytopenia), hypersensitivity reactions (discontinue if occurs), erythema multiforme (discontinue if occurs).

How supplied: Tabs-30

DEFERIPRONE

FERRIPROX ApoPharma
Iron chelating agent. Deferiprone 500mg; scored tablets.

Indications: Treatment of transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Adults: Individualize. Initially 25mg/kg three times daily (total dose 75mg/kg/day). Max: 33mg/kg three times daily (total dose 99mg/kg/day). Round dose to the nearest 250mg (half-tablet). Adjust dose to individual response and therapeutic goals. Consider temporary dose interruption if serum ferritin falls consistently <500mcg/L.

Children: Not recommended.

Warnings/Precautions: Not established for use in treating other chronic anemias. Risk of neutropenia or fatal agranulocytosis. Measure ANC before starting therapy and monitor weekly during. Interrupt therapy if infection or neutropenia develops (ANC <1.5×10⁹/L). If neutropenia occurs, obtain CBCs, WBCs, ANC, and platelets daily until recovery (ANC ≥1.5×10⁹/L). History of QT prolongation (eg, those with CHF, bradycardia, diuretic use, cardiac hypertrophy, hypokalemia, hypomagnesemia). Monitor serum ALT monthly; consider interruption if persistent increase in transaminase levels. Monitor serum ferritin every 2–3 months. Monitor plasma zinc, supplement if deficient. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid concomitant use with other drugs associated with neutropenia or agranulocytosis. Allow at least 4-hour interval with antacids or mineral supplements containing polyvalent cations (eg, iron, aluminum, zinc). Concomitant UGT 1A6 inhibitors: closely monitor and may need dose adjustments or interruptions.

Adverse reactions: Chromaturia, GI upset, abdominal pain, increased ALT, arthralgia, neutropenia; agranulocytosis, possible Torsades de Pointes.

Note: This product is available from Centric Health Resources (CHR). CHR is a specialty pharmacy specializing in orphan drugs and is the sole distributor of Ferriprox in the U.S.

For more information, contact Ferriprox Total Care at (866) 758-7071.

How supplied: Tabs-100

PLERIXAFOR

MOZOBIL Genzyme

Hematopoietic stem cell mobilizer. Plerixafor 20mg/mL; soln for SC inj; preservative-free.

Indications: In combination with granulocyte colony stimulating factor (G-CSF): To mobilize hematopoietic stem cells to the peripheral blood for collection and autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma.

Adults: Start after 4 days' treatment with G-CSF. Give approximately 11 hours before starting apheresis. Repeat up to 4 consecutive days. Base dose on actual body weight. 0.24mg/kg SC; max 40mg/day. Renal impairment (CrCl ≤50mL/min): 0.16mg/kg; max 27mg/day.

Children: Not recommended.

Warnings/Precautions: Not for use in leukemia. May cause mobilization of tumor cells. Monitor blood and platelet counts (esp. neutrophils). Monitor for splenic rupture (eg, left upper quadrant/scapular or shoulder pain). Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: May be potentiated by drugs that reduce renal function or compete for active tubular secretion.

Adverse reactions: GI upset, fatigue, injection site reactions, headache, arthralgia, dizziness; tumor cell mobilization, increased circulating neutrophils, decreased platelet counts, enlarged spleen, vasovagal reaction may occur.

How supplied: Single-use vials (1.2mL)-1

SECTION 7:

IMMUNE DISORDERS

7A Immunomodulators

BELIMUMAB

BENLYSTA Human Genome Sciences and GlaxoSmithKline

Human IgG1gamma monoclonal antibody. Belimumab 120mg/vial, 400mg/vial; pld for IV infusion after reconstitution and dilution.

Indications: Systemic lupus erythematosus, in adults with active, autoantibody-positive SLE on standard therapy.

Adults: Give by IV infusion over 1 hour; slower if infusion reaction occurs. 10mg/kg every 2 weeks for 3 doses, then 10mg/kg every 4 weeks. May premedicate for infusion/hypersensitivity reactions (eg, APAP, diphenhydramine).

Children: Not recommended.

Warnings/Precautions: Severe active lupus nephritis or CNS lupus: not recommended. More

deaths reported with Benlysta than placebo in clinical trials. Supervise infusion; have resuscitative equipment and trained personnel available in case of infusion/hypersensitivity reactions. Chronic infections: do not start therapy; if initiated, consider suspending if new infections develop and monitor closely. Monitor for malignancies, depression or other mood changes. Elderly. Black/African American. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Immunizations (may get suboptimal response); avoid live vaccines for 30 days prior to and during treatment. Concomitant other biologicals or IV cyclophosphamide: not recommended.

Adverse reactions: Infections (eg, URI, UTI, nasopharyngitis, sinusitis, bronchitis, influenza; may be serious/fatal), psychological effects (eg, depression, insomnia, anxiety, suicide), GI upset, fever, migraine, extremity pain, infusion and/or hypersensitivity reactions.

How supplied: Single-use vials (120mg in 5mL, 400mg in 20mL)—1

CYCLOSPORINE

NEORAL Novartis

Immunosuppressant. Cyclosporine (modified) 25mg, 100mg; caps; contains alcohol.

Also: Cyclosporine

NEORAL ORAL SOLUTION

Cyclosporine (modified) 100mg/mL; contains alcohol.

Indications: Organ rejection prophylaxis in allogeneic kidney, liver, and heart transplant patients, in combination with azathioprine and corticosteroids.

Adults: See full labeling. Give consistently with regard to meals and time of day. ≥ 18 yrs: Give daily dose in two divided doses. Individualize. Give initial dose 4–12 hours prior to transplantation or post-op with corticosteroids. Adjust Neoral dose to achieve a pre-defined cyclosporine blood concentration. Dilute soln in glass of room temp orange or apple juice. Conversion from Sandimmune: initially 1:1 dose conversion, then adjust to attain pre-conversion cyclosporine blood trough concentration; monitor every 4–7 days until pre-conversion value attained. Monitor serum creatinine and BP every 2 weeks during first two months after conversion. If initial dose >10 mg/kg/day, monitor concentration daily until stabilized in desired range. Renal or severe hepatic impairment: consider reducing dose.

Children: Not studied.

Warnings/Precautions: Be fully familiar with immunosuppressive therapy before prescribing. Not bioequivalent to all other forms of cyclosporine; do not interchange without physician supervision. Increased risk of infections, lymphomas and other malignancies (eg, skin). Avoid sun or UV light exposure. Monitor renal and hepatic function, BP, CBC, serum magnesium, potassium, uric acid, lipids (see full labeling for monitoring frequency). Reduce dose if hypertension occurs; do not attempt to

manage medically. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid other nephrotoxic drugs (eg, ciprofloxacin, gentamicin, tobramycin, vancomycin, SMX/TMP, melphalan, amphotericin B, ketoconazole, cimetidine, ranitidine, tacrolimus, NSAIDs, colchicine), fibric acid derivatives. Cyclosporine levels increased by CYP3A inhibitors (eg, calcium channel blockers, amiodarone, azithromycin, azole antifungals, erythromycin, clarithromycin, quinupristin/dalfopristin, boceprevir, telaprevir, methylprednisolone, allopurinol, colchicine, bromocriptine, danazol, metoclopramide; probably indinavir, saquinavir, nelfinavir, ritonavir, imatinib, nefazodone, oral contraceptives). Avoid alcohol, grapefruit juice. Cyclosporine levels decreased by CYP3A inducers (eg, nafcillin, rifampin, carbamazepine, oxcarbazepine, bosentan, phenobarbital, phenytoin, octreotide, ticlopidine, St. John's wort), orlistat. Avoid potassium-sparing diuretics. Concomitant repaglinide: monitor blood glucose. Concomitant aliskiren: not recommended. Concomitant sirolimus: separate by 4 hours. May decrease effectiveness of vaccines; avoid live attenuated vaccines. May increase levels of digoxin (monitor), colchicine, prednisolone, statins (reduce dose), ambrisentan, and anthracycline antibiotics. Gingival hyperplasia with nifedipine (avoid). Convulsions with high-dose methylprednisolone.

Adverse reactions: Renal dysfunction, hypertension, headache, GI disturbances, hirsutism, hypertrichosis, leg cramps, pain, tremor, paresthesia, edema, dizziness, gum hyperplasia, liver dysfunction; increased risk of infections or malignancies, progressive multifocal leukoencephalopathy, hyperkalemia, thrombotic microangiopathy, possible encephalopathy.

How supplied: Caps—30; Soln—50mL

MYCOPHENOLATE MOFETIL

CELLCEPT CAPSULES Genentech

Immunosuppressant. Mycophenolate mofetil 250mg.

Also: Mycophenolate mofetil

CELLCEPT TABLETS

Mycophenolate mofetil 500mg.

Also: Mycophenolate mofetil

CELLCEPT ORAL SUSPENSION

Mycophenolate mofetil 200mg/mL; pwd for oral susp after reconstitution; mixed fruit flavor; contains phenylalanine.

Indications: Organ rejection prophylaxis in allogeneic renal, cardiac or hepatic transplant patients, in combination with cyclosporine and corticosteroids.

Adults: Give as soon as possible after transplantation on empty stomach. Renal: 1g twice daily (2g/day). Cardiac or hepatic: 1.5g twice daily (3g/day). Severe renal impairment: see literature.

Children: <3 months: not recommended. Give as soon as possible after transplantation on empty

stomach. Renal: 3months–18years: Oral susp: 600mg/m² twice daily (max 2g/10mL per day); also, may give via NG tube. BSA: 1.25m² to 1.5m²: 750mg twice daily (1.5g/day), may give in caps; if >1.5m²: 1g twice daily (2g/day), may give in caps or tabs.

Also: Mycophenolate mofetil

CELLCEPT INTRAVENOUS

Mycophenolate mofetil (as hydrochloride) 500mg/vial; lyophilized pld for IV infusion after reconstitution and dilution; preservative-free; contains polysorbate 80.

Adults: Administer within 24 hours after transplantation. Give by slow IV infusion over ≥2 hours. Renal or hepatic: 1g twice daily (2g/day). Cardiac: 1.5g twice daily (3g/day). May treat up to 14 days. Switch to oral forms when tolerated. Severe renal impairment: see literature.

Children: Not recommended.

Contraindications: Hypersensitivity to other forms of mycophenolate. IV: polysorbate 80 allergy.

Warnings/Precautions: Embryofetal toxicity; rule out pregnancy with serum or urine pregnancy test immediately before starting therapy, then another test 8–10 days later. Repeat pregnancy tests during routine follow-up visits. Increased risk of infections, lymphomas and other malignancies (eg, skin). Avoid sun, UV light. Monitor CBCs weekly for 1 month, twice monthly for 2 months, then monthly during first year. If ANC <1300/μL, discontinue or reduce dose. Active GI disease or renal impairment (monitor). Hypoxanthine-guanine phosphoribosyl transferase deficiency; avoid. Pregnancy (Cat.D); avoid; counsel patients to use 2 forms of contraception (or 1 form if using IUDs, tubal sterilization, or if partner has had vasectomy) during therapy, and for 6 weeks after discontinuation unless patient chooses abstinence). Nursing mothers: not recommended.

Interactions: Concomitant azathioprine, live vaccines, rifampin, cholestyramine, or the combination of norfloxacin and metronidazole: not recommended. Antagonized by antacids (separate dosing), PPIs (use with caution), drugs that alter GI flora. Antagonizes oral contraceptives; use additional birth control methods. May potentiate or be potentiated by acyclovir, ganciclovir, probenecid. Antagonized by sevelamer and other calcium-free phosphate binders; may give 2 hours after mycophenolate mofetil.

Adverse reactions: Blood dyscrasias, constipation, GI upset, peripheral edema, hypertension, infections (eg, UTI, cytomegalovirus, sepsis, herpes), progressive multifocal leukoencephalopathy, pure red cell aplasia (w. concomitant immunosuppressants), malignancies (eg, lymphomas, skin), insomnia; rare: GI bleeding, ulceration, perforation. IV: phlebitis, thrombosis.

How supplied: Caps, Tabs–100, 500; Susp–225mL (w. bottle adapter and 2 oral dispensers); Vials (20mL)–4

MYCOPHENOLIC ACID

R

MYFORTIC Novartis

Immunosuppressant. Mycophenolic acid 180mg, 360mg; delayed-release tabs.

Indications: Organ rejection prophylaxis in allogeneic renal transplant patients, in combination with cyclosporine and corticosteroids.

Adults: Swallow whole. Take on empty stomach. 720mg twice daily.

Children: <5yrs or BSA <1.19m²: not recommended. Swallow whole. Take on empty stomach. ≥5yrs: BSA: 1.19–1.58m²: 540mg twice daily; >1.58m²: 720mg twice daily.

Warnings/Precautions: Embryofetal toxicity; rule out pregnancy with serum or urine pregnancy test immediately before starting therapy, then another test 8–10 days later. Repeat pregnancy tests during routine follow-up visits. Increased risk of infections (eg, Polymavirus), lymphomas and other malignancies (eg, skin). Not interchangeable with other forms of mycophenolate. Avoid sun, UV light. Monitor CBCs weekly for first month, then twice monthly for the 2nd and 3rd months, then monthly during first year. If neutropenia or anemia occur, interrupt or reduce dose. Active GI disease or renal impairment (monitor). Hypoxanthine-guanine phosphoribosyl transferase deficiency; avoid. Pregnancy (Cat.D); avoid; counsel patients to use 2 forms of contraception (or 1 form if using IUDs, tubal sterilization, or if partner has had vasectomy) during therapy, and for 6 weeks after discontinuation unless patient chooses abstinence. Nursing mothers: not recommended; avoid breastfeeding within 6 weeks after discontinuation.

Interactions: Avoid concomitant live vaccines, azathioprine, cholestyramine, drugs that interfere with enterohepatic recirculation, drugs that may bind bile acids (eg, bile acid sequestrates, activated charcoal) or other forms of mycophenolate. Antagonized by antacids, drugs that alter GI flora. Antagonizes oral contraceptives; use additional birth control methods. May potentiate or be potentiated by acyclovir, ganciclovir.

Adverse reactions: Blood dyscrasias, constipation, GI upset, nasopharyngitis, infections (eg, UTI, cytomegalovirus, sepsis, herpes), progressive multifocal leukoencephalopathy, BK virus-associated nephropathy, pure red cell aplasia (w. concomitant immunosuppressants), malignancies (eg, lymphomas, skin), insomnia; rare: GI bleeding, ulceration, perforation.

How supplied: Tabs–120

RITUXIMAB

R

RITUXAN Genentech

B-lymphocyte-restricted differentiation antigen [CD20] inhibitor. Rituximab 10mg/mL; soln for IV infusion; preservative-free.

Indications: For the treatment of Wegener's granulomatosis and microscopic polyangiitis, in combination with glucocorticoids.

Adults: Give by IV infusion. Premedicate with an antihistamine and acetaminophen prior to each infusion. First infusion: initially at a rate of 50mg/hr; may increase infusion rate in 50mg/hr increments every 30 minutes. Subsequent infusions: initially at a rate of 100mg/hr; may increase infusion rate in 100mg/hr increments every 30 minutes. Both: max 400mg/hr if infusion reactions do not occur. 375mg/m² once weekly for 4 weeks. Begin glucocorticoids within 14 days prior to or with initiation of Rituxan and continue during and after the 4 week course (see full labeling). PCP prophylaxis recommended during and for at least 6 months following last infusion. Retreatment: safety and efficacy not established.

Children: Not recommended.

Warnings/Precautions: Severe, active infections: not recommended. Discontinue if severe infusion or mucocutaneous reactions occur (eg, hypoxia, pulmonary infiltrates, acute respiratory distress syndrome, MI, ventricular fibrillation, cardiogenic shock, Stevens-Johnson syndrome, toxic epidermal necrolysis). Tumor lysis syndrome (esp. with high tumor burden); monitor for renal toxicity, fluid balance, electrolyte abnormalities (correct if occurs). Monitor for new-onset neurologic manifestations; discontinue if progressive multifocal leukoencephalopathy (PML) develops. Pre-existing cardiovascular disease; monitor during and after treatment. Hepatitis B reactivation with fulminant hepatitis may occur; monitor for signs of active HBV infection, discontinue if occurs. Monitor CBCs, platelet counts at 2-4 month intervals during treatment, then periodically. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Live virus vaccines: not recommended. Renal toxicity with cisplatin. Concomitant immunosuppressants other than corticosteroids have not been studied.

Adverse reactions: Infections, GI upset, headache, muscle spasms, anemia, peripheral edema; myelosuppression (eg, lymphopenia, neutropenia, leukopenia, anemia, thrombocytopenia), infusion reactions (may be fatal), mucocutaneous reactions (may be fatal), progressive multifocal leukoencephalopathy, viral infections (discontinue if serious), tumor lysis syndrome, renal toxicity, bowel obstruction/perforation, hepatitis B reactivation with fulminant hepatitis, cardiac arrhythmias (discontinue if serious).

How supplied: Single-use vial (10mL, 50mL)-1

TACROLIMUS

PROGRAF Astellas

Immunosuppressant. Tacrolimus 0.5mg, 1mg, 5mg; caps.

Indications: Organ rejection prophylaxis in allogeneic hepatic transplant patients, in combination with corticosteroids; or in cardiac and renal transplant patients in combination with corticosteroids, azathioprine, or mycophenolate mofetil (MMF).

Adults: Give at least 6hrs after transplantation. If previously on IV infusion, initial oral dose may be given 8-12hrs post infusion. Hepatic: initially 0.1-0.15mg/kg/day in two divided doses every 12hrs. Cardiac: initially 0.075mg/kg/day in two divided doses every 12hrs. Concomitant corticosteroid is recommended early post-transplantation. Renal: may be given within 24hrs of transplantation but should be delayed until renal function has recovered. Initially 0.2mg/kg/day in two divided doses every 12hrs in combination with azathioprine; or 0.1mg/kg/day in two divided doses every 12hrs in combination with MMF and IL-2 receptor antagonist; black patients may require higher doses. Renal or hepatic impairment: use lowest effective dose (see full labeling). Post-op oliguria: may delay therapy until renal function recovers.

Children: Give at least 6hrs after transplantation. If previously on IV infusion, initial oral dose may be given 8-12hrs post infusion. Hepatic: initially 0.15-0.2mg/kg/day in two divided doses every 12hrs. Concomitant corticosteroid is recommended early post-transplantation.

Also: Tacrolimus PROGRAF INJECTION

Tacrolimus 5mg/mL; soln for IV infusion after dilution; contains polyoxyl 60 hydrogenated castor oil.

Adults: Give at least 6hrs after transplantation if unable to tolerate oral capsules. Cardiac: initially 0.01mg/kg/day. Hepatic or renal: initially 0.03-0.05mg/kg/day. All: give by continuous IV infusion until capsules can be tolerated (usually 2-3 days). Monitor patient for first 30 minutes of infusion and at frequent intervals thereafter. Concomitant corticosteroid is recommended early post-transplantation. Renal or hepatic impairment: use lowest effective dose (see full labeling). Post-op oliguria: may delay therapy until renal function recovers.

Children: Give at least 6hrs after transplantation if unable to tolerate oral capsules. Hepatic: initially 0.03-0.05mg/kg/day by continuous IV infusion until capsules can be tolerated (usually 2-3 days). Monitor patient for first 30 minutes of infusion and at frequent intervals thereafter.

Warnings/Precautions: Increased risk of infections (eg, bacterial, viral, fungal, protozoal, cytomegalovirus), opportunistic infections including polyoma virus. Increased risk of lymphomas and other malignancies (eg, skin). Avoid sun, UV light. Diabetes: monitor for hyperglycemia. Hepatic or renal impairment; monitor and consider dose reduction. Obtain tacrolimus blood concentrations, serum creatinine, potassium, and fasting glucose periodically. Discontinue or reduce dose if myocardial hypertrophy occurs. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Concomitant sirolimus, live vaccines: not recommended. Concomitant strong CYP3A4 inhibitors/inducers or substrates: must adjust dosing regimen, closely monitor tacrolimus

blood concentrations and for QT prolongation. Avoid potassium-sparing diuretics, grapefruit juice, nelfinavir. Additive nephrotoxicity with cyclosporine (discontinue at least 24hrs prior to initiating the other drug), aminoglycosides, ganciclovir, amphotericin B, cisplatin. May be potentiated by calcium channel blockers (eg, diltiazem, nifedipine), antifungals (eg, fluconazole, ketoconazole), macrolides (eg, troleandomycin, clarithromycin, erythromycin), metoclopramide, lansoprazole, omeprazole, bromocriptine, chloramphenicol, cimetidine, cyclosporine, danazol, ethinyl estradiol, amiodarone, methylprednisolone, protease inhibitors (eg, telaprevir, boceprevir, ritonavir), nefazodone, magnesium-aluminum-hydroxide. May be antagonized by carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, caspofungin, St. Johns Wort, sirolimus. Caution with mycophenolic acid.

Adverse reactions: Tremor, headache, GI upset, insomnia, hypertension, renal dysfunction, infections (eg, viral, cytomegalovirus, polyoma virus), hypophosphatemia, hyperkalemia, hypomagnesemia, hyperglycemia, nephrotoxicity or neurotoxicity (esp. in high doses), JC virus-associated progressive multifocal leukoencephalopathy, post-transplant diabetes mellitus, posterior reversible encephalopathy syndrome (consider reduced dose or discontinue), malignancies (eg, lymphomas, skin), post-transplant lymphoproliferative disorder, myocardial hypertrophy, pure red cell aplasia; IV: anaphylactic reactions.

How supplied: Caps-100

Ampules-10

SECTION 8: IMMUNIZATION 8A Vaccines

DIPHTHERIA TOXOID + TETANUS TOXOID + PERTUSSIS VACCINE + HEPATITIS B VACCINE + POLIOVIRUS VACCINE, INACTIVATED

PEDIARIX GlaxoSmithKline

DTaP + HB + IPV. Diphtheria and tetanus toxoids, acellular pertussis vaccine, aluminum hydroxide adsorbed; hepatitis B vaccine (recombinant), aluminum phosphate adsorbed; inactivated polio vaccine; susp for IM inj; preservative-free; contains traces of formaldehyde, yeast protein, neomycin, polymyxin B, polysorbate 80.

Indications: Immunization against diphtheria, tetanus, pertussis, hepatitis B, and poliovirus (types 1, 2, and 3) in infants age 6 weeks up to 7 years (before 7th birthday) born of HBsAg-negative mothers.

Adults: Not recommended.

Children: Each dose is 0.5mL IM in deltoid or anterolateral thigh. Give 1st dose preferably at

2 months of age (may give as early as 6 weeks of age); then give 2nd dose 6-8 weeks later; then give 3rd dose 6-8 weeks later (preferably 8 weeks between doses). Previously vaccinated with one or more doses of individual components: see literature. Not for use as booster dose.

Contraindications: Anaphylaxis associated with previous dose. Encephalopathy within 7 days after previous pertussis-containing vaccine. Progressive neurological disorders (eg, infantile spasms, uncontrolled epilepsy, progressive encephalopathy).

Warnings/Precautions: Guillain-Barre syndrome within 6 weeks of previous tetanus toxoid-containing vaccine. Fever ($\geq 105^{\circ}\text{F}$ within 48 hours), persistent inconsolable crying (≥ 3 hours within 48 hours), shock (within 48 hours), or seizures (within 3 days) after previous DTaP or DTwP vaccine: see literature. Seizure risk (may give antipyretic). Bleeding disorders. Have epinephrine available. Latex allergy (syringes). Immunodeficiency. Pregnancy (Cat.C).

Interactions: Concomitant vaccines: see literature. Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may get suboptimal response.

Adverse reactions: Local reactions (pain, redness, swelling), irritability/fussiness, fever, crying, drowsiness, loss of appetite; rare: seizure, anaphylaxis.

How supplied: Single-dose vials-10

Single-dose prefilled syringes-5

HEPATITIS A VACCINE

R

HAVERIX GlaxoSmithKline

Hepatitis A vaccine, inactivated 720 ELISA Units (EL.U.) per 0.5mL (pediatric), or 1440 EL.U. per 1mL (adult); susp for IM inj; aluminum adsorbed; contains neomycin (trace); preservative-free.

Indications: Hepatitis A immunization.

Adults: Inject into deltoid, preferably at least 2 weeks before expected exposure. >18 yrs: 1440 EL.U. once IM; give booster dose 6-12 months after initial course.

Children: Inject IM preferably at least 2 weeks before expected exposure. <12 months: not recommended. 12 months-18 yrs: 720 EL.U. once IM; give booster dose 6-12 months after initial course.

Contraindications: Neomycin allergy. Previous hypersensitivity reaction to hepatitis A-containing vaccine.

Warnings/Precautions: Have epinephrine (1:1000) inj available. Fever. Bleeding disorders. Immunodeficiency (may have suboptimal response). If given with immune globulin, use separate syringe and different site. Latex allergy. Pregnancy (Cat.C). Nursing mothers.

Interactions: Immunosuppressives may reduce efficacy. Concomitant vaccines: see literature.

Adverse reactions: Inj site reactions, headache, fatigue, fever, malaise, anorexia, GI upset.

How supplied: Single-dose vials-10; Single-dose prefilled Tip-Lok syringes-5 (without needles)

HEPATITIS A VACCINE

R

VAQTA Merck

Hepatitis A vaccine, inactivated 25Units per 0.5mL (pediatric/adolescent), or 50Units per 1mL (adult); susp for IM inj; aluminum adsorbed; preservative-free.

Indications: Hepatitis A immunization.

Adults: ≥ 19 yrs: 1mL IM at elected date and booster dose (1mL IM) 6–18 months later.

Children: < 12 months: not recommended.

1–18 yrs: 0.5mL IM at elected date and booster dose (0.5mL IM) 6–18 months later.

Warnings/Precautions: Have epinephrine (1:1000) available. Latex allergy. Inject into deltoid muscle, preferably at least 2 weeks before expected exposure. If given with immune globulin, use separate syringe and different site. Fever. Malignancies. Immunocompromised (may have suboptimal response). Bleeding disorders. Pregnancy (Cat.C). Nursing mothers.

Interactions: Immunosuppressives may reduce efficacy. Concomitant vaccines, immune globulins: see literature.

Adverse reactions: Injection site reactions (esp. pain, tenderness), headache, fever, GI upset, myalgia, abdominal pain, rash, pharyngitis and other upper respiratory tract effects.

How supplied: Prefilled syringes (0.5mL, 1mL)–1, 5
Single-dose vials (0.5mL)–1, 10
Single-dose vials (1mL)–1, 5, 10

**HEPATITIS A VACCINE +
HEPATITIS B VACCINE**

R

TWINRIX GlaxoSmithKline

Hepatitis A inactivated 720 ELISA Units (EL.U.), hepatitis B surface antigen (recombinant) 20 micrograms; per mL; susp for IM inj; aluminum adsorbed; contains trace amounts of thimerosal, formalin, neomycin, yeast protein.

Indications: Hepatitis A and hepatitis B immunization.

Adults: ≥ 18 years: 1 inj IM in deltoid area at 0-, 1-, and 6 months. Alternate 4-dose schedule: 1 inj IM in deltoid area at 0-, 7-, and 21 to 30-days followed by booster dose at month 12.

Children: < 18 yrs: not recommended.

Warnings/Precautions: May defer in acute febrile illness or active infection. Bleeding disorders. Thrombocytopenia. Immunodeficiency: may get suboptimal response. Have epinephrine (1:1000) inj available. If given with immune globulin, use separate syringe and different site. Pregnancy (Cat.C). Nursing mothers.

Interactions: Immunosuppressives may reduce efficacy.

Adverse reactions: Inj site reactions, headache, fatigue, GI upset, fever.

Note: Register pregnant patients exposed to Twinrix by calling (888) 452-9622. Report adverse events to VAERS by calling (800) 822-7967.

How supplied: Single-dose vials–1, 10; Single-dose prefilled syringes–5

HEPATITIS B VACCINE

R

ENGRIX-B PEDIATRIC/ADOLESCENT

GlaxoSmithKline

HB. Hepatitis B vaccine (recombinant) 10mcg/0.5mL; aluminum hydroxide adsorbed; IM inj; preservative-free; contains thimerosal (trace).

Also: Hepatitis B vaccine

R

ENGRIX-B ADULT

Hepatitis B vaccine (recombinant) 20mcg/mL; aluminum hydroxide adsorbed; IM inj; preservative-free; contains thimerosal (trace).

Indications: Hepatitis B immunization.

Adults: Give IM in deltoid muscle. 11–19yrs: 10mcg at elected date and repeat 1 and 6 months later, or 20mcg at elected date and repeat 1, 2, and 12 months later, or 20mcg at elected date and repeat 1 and 6 months later. > 19 yrs: 20mcg at elected date and repeat 1 and 6 months later, or 20mcg at elected date and repeat 1, 2, and 12 months later. Hemodialysis: 40mcg at elected date and repeat 1, 2, and 6 months later. High-risk: consider hepatitis B immune globulin also. Booster dose: when appropriate, may use 20mcg for persons 11yrs of age and older; hemodialysis patients booster dose is 40mcg.

Children: Give IM in anterolateral thigh or deltoid; see literature. Infants (mothers are HBsAg negative): 10mcg at birth and repeat 1 and 6 months later; infants (mothers are HBsAg positive) and children through age 10yrs: 10mcg at elected date and repeat 1 and 6 months later, or 10mcg at elected date and repeat 1, 2, and 12 months later. High risk: consider hepatitis B immune globulin also. Booster doses: when appropriate, may use 10mcg for children age 10yrs or younger, or 20mcg for ages 11yrs and older.

Contraindications: Yeast hypersensitivity.

Warnings/Precautions: May defer in acute febrile illness or active infection. May be given SC only if risk of hemorrhage. Have epinephrine inj available. Multiple sclerosis. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Local reactions, malaise, nausea, diarrhea, rash. Anaphylaxis.

How supplied: Pediatric/Adolescent (single-dose prefilled Tip-Lok syringe)–5 (without needles)
Pediatric/Adolescent (single-dose vials)–1, 10
Adult (single-dose prefilled Tip-Lok syringe)–5 (without needles)
Adult (single-dose vials)–1, 10, 25

HEPATITIS B VACCINE

R

RECOMBIVAX HB PEDIATRIC/ADOLESCENT

Merck

HB. Hepatitis B surface antigen vaccine (recombinant) 5mcg/0.5mL; susp for IM inj; aluminum hydroxide adsorbed; preservative-free.

Also: Hepatitis B vaccine

R

RECOMBIVAX HB ADULT

Hepatitis B surface antigen vaccine (recombinant) 10mcg/mL; susp for IM inj; aluminum hydroxide adsorbed; preservative-free.

Also: Hepatitis B vaccine
RECOMBIVAX HB DIALYSIS

Hepatitis B surface antigen vaccine (recombinant) 40mcg/mL; susp for IM inj; aluminum hydroxide adsorbed; preservative-free.

Indications: Hepatitis B immunization.

Adults and Children: Use correct formulation; see literature. Give IM into anterolateral thigh for children; deltoid for adults. May give SC if risk of hemorrhage. Patients 0–19yrs of age (three-dose regimen): give 1st dose of 5mcg at elected date and repeat after 1 month (2nd dose) and 6 months after first dose (3rd dose). Or, for patients 11–15yrs of age, may use alternate two-dose regimen: give 1st dose of 10mcg at elected date and repeat after 4–6 months (2nd dose). Patients ≥20yrs of age: give 1st dose of 10mcg at elected date and repeat after 1 month (2nd dose) and 6 months after first dose (3rd dose). Dialysis and pre-dialysis patients: give 1st dose of 40mcg at elected date and repeat after 1 month (2nd dose) and 6 months after first dose (3rd dose); consider booster dose if antibody levels fall to <10mIU/mL. High-risk infants (mother is HBsAg positive or unknown) or if exposed to HBsAg: give hepatitis B immune globulin also (see literature).

Contraindications: Yeast hypersensitivity.

Warnings/Precautions: Have epinephrine inj (1:1000) available. Serious active infection. Severely compromised cardiopulmonary status. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Local reactions, irritability, fatigue, headache, fever, malaise, nausea, diarrhea, anorexia, pharyngitis, upper respiratory infection, anaphylaxis.

How supplied: Single-dose vials: Ped/Adolescent 5mcg/0.5mL (yellow cap)–1, 10; Adult 10mcg/1mL (green cap)–1, 10; Dialysis 40mcg/1mL (blue cap)–1

HPV VACCINE

GARDASIL Merck

HPV. Quadrivalent human papillomavirus (HPV) types 6, 11, 16, and 18 vaccine; recombinant; aluminum adsorbed, susp for IM inj; preservative-free.

Indications: In females 9–26 years old, to prevent cervical, vulvar, vaginal and anal cancer caused by HPV types 16 and 18; genital warts caused by HPV types 6 and 11; cervical adenocarcinoma *in situ* (AIS) and cervical intraepithelial neoplasia (CIN) grades 2 and 3, vulvar intraepithelial neoplasia (VIN) grades 2 and 3, vaginal intraepithelial neoplasia (VAIN) grades 2 and 3, cervical intraepithelial neoplasia (CIN) grade 1, and anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types 6, 11, 16, and 18. In males 9–26 years old, to prevent anal cancer caused by HPV types 16 and 18; genital warts caused by HPV types 6 and 11; and anal intraepithelial neoplasia (AIN) grades 1, 2, and 3 caused by HPV types 6, 11, 16, and 18.

Adults and Children: Give by IM inj in deltoid or upper thigh. Each dose is 0.5mL. <9yrs: not

recommended. 9–26yrs: Give 1st dose at elected date, 2nd dose 2 months after the 1st dose, and 3rd dose 6 months after the 1st dose. Monitor patients for 15 minutes after administration.

Contraindications: Yeast allergies.

Warnings/Precautions: Not a substitute for routine cervical or anal cancer screening. Not for treating active external genital lesions; cervical, vulvar, vaginal and anal cancers; CIN; VIN; VAIN; or AIN. May not protect all vaccine recipients. Immunosuppressed. Bleeding disorders. Pregnancy (Cat.B): not recommended. Nursing mothers.

Interactions: Immunosuppressants: may get suboptimal response.

Adverse reactions: Headache, fever, nausea, dizziness, inj-site reactions; post-administration syncope (may be associated with tonic-clonic movements and other seizure-like activity).

Note: Register pregnant patients exposed to Gardasil by calling (800) 986-8999.

How supplied: Single-dose vials–1, 10; Prefilled syringes (w. needles or tip caps)–6

INFLUENZA VACCINE

FLUARIX GlaxoSmithKline

Trivalent inactivated “split virus” influenza vaccine (virus types A and B); formulation changes annually; susp for IM inj; may contain trace amounts of hydrocortisone, gentamicin, others; preservative-free.

Also: Influenza vaccine

FLUARIX QUADRIVALENT

Quadrivalent inactivated “split virus” influenza vaccine (virus types A and B); contains a total of 60mcg hemagglutinin per 0.5mL dose; formulation changes annually; susp for IM inj; may contain trace amounts of hydrocortisone, gentamicin, others; preservative-free.

Indications: Influenza immunization.

Adults and Children: <3yrs: not established. Each dose is 0.5mL by IM inj once in the deltoid. 3–8yrs (previously unvaccinated): 2 doses/season, give at least 4 weeks apart. 3–8yrs (vaccinated in a previous season): 1 or 2 doses/season (depending on vaccination history as per annual ACIP recommendation); if 2 doses/season; give at least 4 weeks apart. ≥9yrs: 1 dose/season.

Contraindications: Allergy to egg protein. Life-threatening reaction to any previous flu vaccine.

Warnings/Precautions: Use current formulation only. Guillain-Barre syndrome within 6 weeks of previous flu vaccine. Bleeding disorders. Immunosuppressed. Risk of syncope with injectable vaccines. Have epinephrine inj (1:1000) available. Latex allergy. Pregnancy (Cat.B). Nursing mothers.

Interactions: Concomitant vaccines: insufficient data (see full labeling). Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may result in suboptimal response.

Adverse reactions: Local reactions (eg, redness, swelling, pain), muscle aches, fatigue, headache,

arthralgias, GI symptoms, shivering, fever; children: irritability, loss of appetite, drowsiness.

How supplied: Single-dose prefilled Tip-Lok syringe (0.5mL)–5

INFLUENZA VACCINE

FLUCELVAX Novartis

Trivalent, inactivated, "subunit" influenza vaccine (virus types A and B); contains a total of 45mcg of hemagglutinin per 0.5mL dose; formulation changes annually; susp for IM inj; antibiotic- or preservative-free.

Indications: Influenza immunization.

Adults: ≥18yrs: 0.5mL by IM inj once in the deltoid.

Children: <18yrs: not established.

Warnings/Precautions: Use current formulation only. Guillain-Barre syndrome within 6 weeks of previous flu vaccine. Immunosuppressed. Latex allergy. Have epinephrine inj (1:1000) available. Pregnancy (Cat.B). Nursing mothers.

Interactions: Concomitant vaccines: insufficient data (see full labeling). Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may get suboptimal response.

Adverse reactions: Local reactions (eg, pain, erythema), headache, fatigue, myalgia, fever, malaise.

How supplied: Single-dose prefilled Luer Lock syringe (0.5mL)–10 (without needles)

INFLUENZA VACCINE

FLUMIST QUADRIVALENT MedImmune

Quadrivalent, live attenuated influenza vaccine (virus types A and B); formulation changes annually; susp in intranasal sprayer; contains gelatin, arginine, gentamicin (trace); preservative-free.

Indications: Influenza immunization.

Adults and Children: <2yrs or ≥50yrs: not recommended. Give before start of flu season; each dose is 0.2mL intranasally (as 0.1mL/nosrtill). 2–8yrs: 1 or 2 doses/season (depends on vaccination history as per annual ACIP recommendation); if 2 doses, give at least 1 month apart. 9–49yrs: 1 dose/season.

Contraindications: Allergy to egg protein, gentamicin, gelatin, or arginine. Life-threatening reaction to previous flu vaccine. Concomitant aspirin in patients 2–17yrs of age (Reye's syndrome).

Warnings/Precautions: Use current formulation only. Asthmatics or children <5yrs old with recurrent wheezing: may be at increased risk of wheezing following administration. Guillain-Barre syndrome within 6 weeks of previous flu vaccine. Underlying medical conditions predisposing to flu complications. Immunocompromised. Have epinephrine inj (1:1000) available. Pregnancy (Cat.B). Nursing mothers.

Interactions: Concomitant vaccines: see full labeling. Do not administer until 48hrs after antiviral therapy cessation. Do not give antivirals within 2 weeks of administration.

Adverse reactions: Rhinorrhea/nasal congestion, fever, sore throat, decreased appetite, irritability; wheezing.

How supplied: Single-dose pre-filled nasal spray (0.2mL)–10

INFLUENZA VACCINE

FLUZONE Sanofi Pasteur

Trivalent inactivated "split virus" influenza vaccine (Types A and B); 0.25mL dose contains a total of 22.5micrograms of influenza virus hemagglutinin; 0.5mL dose contains a total of 45micrograms of influenza virus hemagglutinin; formulation changes annually; susp for IM inj; antibiotic-free.

Also: Influenza vaccine

FLUZONE QUADRIVALENT

Quadrivalent inactivated "split virus" influenza vaccine (Types A and B); 0.25mL dose contains a total of 30micrograms of influenza virus hemagglutinin; 0.5mL dose contains a total of 60micrograms of influenza virus hemagglutinin; formulation changes annually; susp for IM inj; preservative-, antibiotic-free.

Indications: Influenza immunization.

Adults and Children: <6 months: not recommended. 6 months–8 years: 1 or 2 doses/season (depending on vaccination history as per annual ACIP recommendation); if 2 doses/season; give at least 4 weeks apart. 6–35 months: 0.25mL IM. ≥3 years: 0.5mL IM. Infants: give in anterolateral thigh; toddlers, young children and adults: give in deltoid muscle.

Also: Influenza vaccine

FLUZONE INTRADERMAL

Trivalent inactivated "split virus" influenza vaccine (Types A and B); 0.1mL dose contains a total of 27micrograms of influenza virus hemagglutinin; formulation changes annually; susp for intradermal inj.

Adults: 18–64yrs: One dose per year. 0.1mL intradermally in the region of the deltoid.

Children: <18yrs: not recommended. Use **Fluzone IM**.

Also: Influenza vaccine

FLUZONE HIGH-DOSE

Trivalent inactivated "split virus" influenza vaccine (Types A and B); 0.5mL dose contains a total of 180micrograms of influenza virus hemagglutinin; formulation changes annually; susp for IM inj.

Indications: Influenza immunization for patients ≥65 years of age.

Adults: <65yrs: use Fluzone or Fluzone Intradermal. ≥65yrs: One dose per year. 0.5mL IM in deltoid muscle.

Children: Use Fluzone.

Contraindications: Allergy to egg proteins. Life-threatening reaction to any previous flu vaccine.

Warnings/Precautions: Use current formulation only. Guillain-Barre syndrome within 6 weeks of previous flu vaccine. Immunosuppressed. Have epinephrine inj (1:1000) available. Pregnancy (Cat.C for IM and High-Dose; Cat.B for Intradermal). Nursing mothers.

Interactions: Immunosuppressants: may get suboptimal response.

Adverse reactions: Local reactions (eg, pain, tenderness, swelling, erythema), malaise, headache, myalgia, irritability.

How supplied: Fluzone, Fluzone Quadrivalent prefilled syringe (0.25mL, 0.5mL)-10; Single-dose vial (0.5mL)-10; Fluzone multi-dose vial (5mL)-1 (contains thimerosal); Fluzone High-Dose prefilled syringe (0.5mL)-10; Fluzone Intradermal single-dose prefilled microinjection system-10

MENINGITIS VACCINE

R

MENACTRA Sanofi Pasteur

Neisseria meningitidis polysaccharides 4mcg each of Group A, C, Y, and W-135; per 0.5mL; (diphtheria toxoid conjugate); soln for IM inj; preservative-free.

Indications: Meningitis immunization.

Adults and Children: <9mos: not recommended. Give by IM inj only in deltoid region. 9-23mos: 0.5mL given as 2-dose series three months apart. 2-55yrs: 0.5mL once.

Contraindications: Severe allergic reaction to any previous meningococcal capsular polysaccharide, diphtheria toxoid- or CRM₁₉₇-containing vaccine. History of Guillain-Barre syndrome.

Warnings/Precautions: Have epinephrine inj (1:1000) available. Immunosuppressed. Latex allergy. Adults >55yrs old. Pregnancy (Cat.C). Nursing mothers.

Interactions: Immunosuppressants (eg, irradiation, antimetabolites, alkylating agents, cytotoxic drugs, high-dose steroids) may get suboptimal response. Concomitant vaccines: see literature.

Adverse reactions: Local reactions, headache, fatigue, malaise, arthralgia, GI upset, anorexia, chills, fever, rash, irritability, drowsiness; children: also, abnormal crying.

Note: To register pregnant patients or to report adverse events call (800) 822-2463. Refer to www.cdc.gov for ACIP guidelines on vaccinating acutely ill patients.

How supplied: Vials-5

MENINGITIS VACCINE

R

MENVEO Novartis

Neisseria meningitidis oligosaccharide conjugate vaccine (*Corynebacterium diphtheriae* CRM197 protein); 10mcg of Group A + 5mcg each of Group C, Y, and W-135 + 32.7-64.1mcg of diphtheria CRM197 protein; per 0.5mL; lyophilized pwd for IM inj after reconstitution; preservative-free.

Indications: Meningitis immunization.

Adults and Children: <2yrs: not recommended. Give by IM inj only in deltoid muscle. 2-55yrs: 0.5mL once. Monitor 15min post-dose. For children 2-5yrs: if continued high risk, may give 2nd dose 2mos after the 1st dose.

Contraindications: Life-threatening reaction to any previous CRM197 or other diphtheria toxoid or meningococcal-containing vaccine.

Warnings/Precautions: Immunodeficiency. Bleeding disorders (eg, hemophilia, thrombocytopenia, during anticoagulant therapy). Have epinephrine inj

(1:1000) available. Possible risk of Guillain-Barre Syndrome. Labor & delivery. Pregnancy (Cat.B).

Nursing mothers.

Interactions: Immunosuppressants (eg, irradiation, antimetabolites, alkylating agents, cytotoxic drugs, high-dose steroids) may get suboptimal response. Concomitant vaccines: see literature.

Adverse reactions: Inj site pain, erythema, induration; irritability, headache, malaise, nausea, myalgia, arthralgia; syncope (transient tonic-clonic movements, other seizure-like activity possible post-dose).

How supplied: Vials-5 doses (1 vial of lyophilized MenA conjugate component + 1 vial of liquid MenCYW-135 conjugate component)

PNEUMOCOCCAL 13-VALENT VACCINE

R

PREVNAR 13 Pfizer

PCV. Pneumococcal 13-valent conjugate vaccine (diphtheria CRM₁₉₇ protein) 30.8micrograms of saccharides per 0.5mL; susp for IM inj; contains aluminum.

Indications: Immunization of children age 6 weeks to 5 years of age (before 6th birthday) against invasive disease caused by *S. pneumoniae* due to serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F; and against otitis media due to serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F. Immunization of children 6-17 years of age (before 18th birthday) against invasive disease caused by *S. pneumoniae* due to serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F. Immunization of adults ≥50 years of age against pneumonia and invasive disease caused by *S. pneumoniae* due to serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F.

Adults and Children: Each dose is 0.5mL IM into the anterolateral thigh for infants or the deltoid muscle for toddlers, children and adults; avoid nerves and blood vessels. May pretreat with antipyretic. <6 weeks: not established. ≥6 weeks: 4 doses usually given at 2, 4, 6, and 12-15 months of age (may start at 6 weeks of age: give first 3 doses 4-8 weeks apart, and 4th dose at least 2 months after 3rd dose). Previously unvaccinated older infants and children: 7-11 months of age: 3 doses (2nd dose at least 4 weeks after 1st dose, 3rd dose after 1st birthday and at least 2 months after 2nd dose); 12-23 months of age: 2 doses at least 2 months apart; 2-5 years of age: 1 dose once. Previously vaccinated with Prevnar: may complete 4-dose series with Prevnar 13; if series is completed and 15 months-5 years of age: may receive 1 dose of Prevnar 13, given at least 8 weeks after final dose of Prevnar. 6-17 years of age: a single dose; if previously vaccinated with Prevnar, then at least 8 weeks should elapse before receiving Prevnar 13. ≥50 years: a single dose.

Contraindications: Allergies to any diphtheria toxoid-containing vaccine.

Warnings/Precautions: Not for protection against disease caused by *S. pneumoniae* serotypes that are not in the vaccine. Immunocompromised. Have epinephrine inj available. Premature infants. Pregnancy (Cat.B). Nursing mothers.

Interactions: Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may get suboptimal response. Antibody responses may be diminished with concomitant inactivated influenza virus vaccine.

Adverse reactions: Inj site reactions, fever, decreased appetite, irritability, increased or decreased sleep, drowsiness, diarrhea, vomiting, rash, hives, fatigue, headache, chills, muscle and joint pain.

How supplied: Pre-filled syringe-10

PNEUMOCOCCAL VACCINE

R

PNEUMOVAX 23 Merck

Pneumococcal vaccine 25mcg; each of 23 polysaccharide isolates; inj; contains phenol.

Indications: Immunization against pneumococcal disease caused by approximately 85–90% of common U.S. isolates.

Adults and Children: <2yrs: not recommended. ≥2yrs: 0.5mL IM or SC once in deltoid muscle or lateral mid-thigh.

Contraindications: Not for routine revaccination after previous pneumococcal vaccination in immunocompetent patients. Within 14 days of immunosuppressive therapy.

Warnings/Precautions: Severe cardiac or pulmonary disease where a systemic reaction would pose a significant risk. May defer in acute febrile respiratory illness or other active infection. Do not discontinue antipneumococcal prophylactic antibiotic therapy. Have epinephrine inj (1:1000) available. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Inj site reactions, low grade fever.

How supplied: Multidose vials-1,10; Single-dose vials-10

POLIOVIRUS VACCINE, INACTIVATED

R

IPOL Sanofi Pasteur

IPV. Trivalent poliovirus vaccine; inactivated; whole virus grown in monkey kidney cells; IM or SC inj.

Indications: Poliomyelitis immunization (virus Types 1, 2, and 3).

Adults: Inject IM or SC in deltoid area. Each dose is 0.5mL. Previously unvaccinated: Two doses at a 1–2 month interval and a third dose 6–12 months later. Incompletely vaccinated: give 1–2 doses to complete series. Completely vaccinated: may give booster dose.

Children: Inject IM or SC in midlateral thigh. Each dose is 0.5mL. Under 6 wks: not recommended. Full IPV schedule: One dose at 2 months, 4 months, 6–18 months, and 4–6 years of age. Sequential

schedule with oral polio vaccine (OPV) (do not use OPV for immunocompromised patients or patients with immunocompromised household contacts): One dose of IPOL at 2 months and at 4 months of age, then 1 dose of OPV at 12–18 months and 1 dose of OPV at 4–6 years of age.

Contraindications: Hypersensitivity to neomycin, streptomycin, or polymyxin B. May defer in acute febrile illness.

Warnings/Precautions: Have epinephrine inj (1:1000) available. Immunodeficiency. Pregnancy (Cat.C). Nursing mothers.

Interactions: Immunosuppressants: may get suboptimal response.

Adverse reactions: Local irritation, fever, sleepiness, fussiness, decreased appetite.

How supplied: Syringe 0.5mL (w. needle)-1, 10 Multidose vial (10 doses)-1

RABIES VACCINE

R

RABAVERT Novartis

Rabies vaccine, inactivated 2.5IU/mL; pld for IM inj after reconstitution; may contain trace amounts of bovine gelatin, chicken protein, neomycin, chlortetracycline, and amphotericin B.

Indications: Preexposure immunization and post-exposure prophylaxis of rabies.

Adults and Children: Adults: inject into deltoid area. Small children: inject into thigh. Preexposure immunization: 3 inj of 1mL IM each on day 0, 7, and either day 21 or 28. Booster: 1 dose as needed to maintain antibody titer (see literature). Post-exposure prophylaxis: a 5-dose regimen of 1mL IM given on days 0, 3, 7, 14, and 28 (give 1st dose with human rabies immunoglobulin at a separate site). If previously immunized: 2 inj of 1mL each on days 0 and 3 (no immune globulin needed).

Warnings/Precautions: Immunocompromised: may get suboptimal response (monitor titers). Postpone preexposure immunization during acute febrile illness or infection. Egg allergy. Have epinephrine inj (1:1000) available. Pregnancy (Cat.C).

Interactions: Immunosuppressants: may get suboptimal response.

Adverse reactions: Local reactions, lymphadenopathy, headache, myalgia, malaise, dizziness, neuromuscular events, anaphylaxis.

How supplied: Single-dose vial-1 (w. diluent)

ROTAVIRUS VACCINE

R

ROTATEQ Merck

Pentavalent, live rotavirus vaccine; oral susp; contains fetal bovine serum (trace); preservative- and thimerosal-free.

Indications: Rotavirus gastroenteritis vaccination in infants 6–32 weeks of age.

Adults: Not recommended.

Children: <6 weeks or >32 weeks: not recommended. Each dose is 1 tube. Give 1st dose orally at 6–12 weeks of age; give 2nd and 3rd dose

at 4–10 week intervals for a total of 3 doses. If incomplete dose is given, do not give replacement dose; continue with remaining doses in the recommended series.

Warnings/Precautions: Immunocompromised. Febrile illness. Active or history of GI disorders. Chronic diarrhea. Failure to thrive. History of congenital abdominal disorders. Abdominal surgery. Intussusception. Immunodeficient close contacts.

Interactions: Immunosuppressants (eg, irradiation, chemotherapy, high-dose steroids): may get suboptimal response. Concomitant vaccines: see literature; oral polio vaccine: not recommended.

Adverse reactions: Diarrhea, vomiting, otitis media, nasopharyngitis, bronchospasm; rare: intussusception, hematochezia, seizures, Kawasaki disease.

How supplied: Single-use tube (2mL)–1, 10

TETANUS TOXOID

R

TETANUS TOXOID ADSORBED Sanofi Pasteur *Tetanus vaccine*. Tetanus toxoid; aluminum adsorbed; susp for IM inj; multi-dose vial preserved with thimerosal, single-dose vials contain trace amounts of thimerosal.

Indications: Tetanus immunization.

Adults and Children: <7yrs: not recommended. Give IM in anterolateral thigh or deltoid. ≥7yrs: Previously unvaccinated: three 0.5mL doses at elected date, then 4–8 weeks after first dose, and 6–12 months after second dose. Give booster dose at 11–12 yrs of age if last dose of tetanus and diphtheria toxoid-containing vaccine was given ≥5yrs ago. Other: give booster every 10 years.

Warnings/Precautions: Latex allergy. Previous arthus-type hypersensitivity reaction: do not give more frequently than every 10 years. Defer in moderate or severe active respiratory or other febrile infection (may vaccinate if mild or minor illness) or during polio outbreak. Guillain-Barre syndrome within 6 weeks of last tetanus vaccine. Bleeding disorders. Immunosuppressed. Have epinephrine (1:1000) available. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May get suboptimal response with immunosuppressants (eg, chemotherapy, high dose corticosteroids ≥2 weeks, radiation); consider deferring.

Adverse reactions: Local reactions (eg, erythema, tenderness), malaise, fever, hypotension, pain, nausea, arthralgia; rare: neurological disorders.

How supplied: Single-dose vials (latex free)–10
Multi-dose vial (5mL)–1

TETANUS TOXOID

R

TETANUS TOXOID BOOSTER Sanofi Pasteur *Tetanus vaccine*. Tetanus toxoid booster vaccine; for IM or SC inj; contains thimerosal.

Indications: Tetanus immunization booster.

Adults and Children: <7yrs: not recommended. Give IM or SC in lateral mid-thigh or deltoid. ≥7yrs: After completion of primary immunization: 0.5mL every 10 years. Tetanus prophylaxis: see literature.

Contraindications: Not for primary immunization. History of systemic allergic or neurologic reactions to a previous dose of DT.

Warnings/Precautions: Latex allergy. Previous arthus-type hypersensitivity reaction: do not give more frequently than every 10 years. Defer in moderate or severe active respiratory or other febrile infection (may vaccinate if mild or minor illness) or during polio outbreak. Bleeding disorders (use SC route). Immunosuppressed. History of Guillain-Barre syndrome within 6 weeks of last tetanus vaccine. Have epinephrine (1:1000) available. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May get suboptimal response with immunosuppressants (eg, chemotherapy, high dose corticosteroids ≥2 weeks, radiation); consider deferring.

Adverse reactions: Local reactions (eg, erythema, tenderness), malaise, fever, hypotension, pain, nausea, arthralgia; rare: neurological disorders.

How supplied: Vial (7.5mL)–1

TETANUS TOXOID + DIPHTHERIA TOXOID

R

DECAVAC Sanofi Pasteur *Td vaccine*. Tetanus and diphtheria toxoids; aluminum adsorbed; susp for IM inj; contains thimerosal (trace).

Indications: Tetanus and diphtheria immunization in patients ≥7yrs.

Adults and Children: <7yrs: not recommended. ≥7yrs: Give IM in deltoid muscle. Previously unvaccinated: three 0.5mL doses at elected date, then 4–8 weeks after first dose, and 6–12 months after second dose. Give booster dose at 11–12 yrs of age if last dose of tetanus and diphtheria toxoid-containing vaccine was given ≥5yrs ago. Other: give booster every 10 years. Diphtheria and tetanus prophylaxis: see literature.

Contraindications: Anaphylaxis associated with a previous dose.

Warnings/Precautions: Guillain-Barre syndrome within 6 weeks of previous tetanus toxoid vaccine. Previous Arthus-type hypersensitivity reaction: not recommended until ≥10yrs after prior dose of tetanus toxoid-containing vaccine. Immunodeficiency. Have epinephrine (1:1000) available. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant vaccines: see literature. Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may get suboptimal response.

Adverse reactions: Local reactions (eg, erythema, tenderness), headache, malaise, fever; rare: neurological disorders.

How supplied: Single-dose vials (0.5mL)–10
Single-dose prefilled syringe (0.5mL)–10

TETANUS TOXOID + DIPHTHERIA TOXOID

R

DIPHTHERIA AND TETANUS TOXOIDS ADSORBED (FOR PEDIATRIC USE) Sanofi Pasteur

DT vaccine. Tetanus and diphtheria toxoids; aluminum adsorbed; susp for IM inj; multi-dose vial preserved with thimerosal, single-dose vials contain trace amounts of thimerosal.

Indications: Tetanus and diphtheria immunization in patients 6 weeks to 7 yrs of age when pertussis vaccine cannot be used.

Children: <6wks and ≥7yrs: not recommended. Give IM in anterolateral thigh or deltoid. 6wks–1yr: three 0.5mL doses 4–8 weeks apart, then 4th dose 6–12 months after third dose. 1–6yrs (up to 7yrs): two 0.5mL doses 4–8 weeks apart, then 3rd dose 6–12 months after the second dose (if >7yrs, use Td vaccine). Booster dose: see literature.

Contraindications: History of systemic allergic or neurologic reactions to a previous dose of DT.

Warnings/Precautions: Defer in moderate or severe active respiratory or other febrile infection (may vaccinate if mild or minor illness) or during polio outbreak. Bleeding disorders. Immunosuppressed. Have epinephrine (1:1000) available.

Interactions: May get suboptimal response with immunosuppressants (eg, chemotherapy, high dose corticosteroids ≥2 weeks, radiation); consider deferring.

Adverse reactions: Local reactions (eg, erythema, edema), malaise, fever, hypotension, arthralgia, nausea; rare: neurologic disorders.

How supplied: Single-dose vials–10
Multi-dose vial (5mL)–1

TETANUS TOXOID + DIPHTHERIA TOXOID + PERTUSSIS VACCINE

R

ADACEL Sanofi Pasteur

Vaccine (Tdap). Tetanus and reduced diphtheria toxoids, acellular pertussis vaccine; aluminum phosphate adsorbed; susp for IM inj; contains 2-phenoxyethanol and traces of formaldehyde, glutaraldehyde.

Indications: Diphtheria, tetanus, and pertussis booster immunization in persons 11–64 years of age.

Adults and Children: <11yrs or ≥65yrs: not recommended. 11–64yrs (≥5yrs after last dose of tetanus toxoid, diphtheria toxoid, and/or pertussis-containing vaccine): 0.5mL IM once into deltoid muscle.

Contraindications: Anaphylaxis associated with any previous diphtheria, tetanus, pertussis vaccine. Encephalopathy within 7 days after previous pertussis-containing vaccine.

Warnings/Precautions: Progressive neurologic disorders (eg, uncontrolled epilepsy, progressive encephalopathy). Unstable neurologic conditions (eg, cerebrovascular events). Guillain-Barre syndrome

(within 6 weeks) of previous tetanus vaccination. Previous Arthus-type hypersensitivity reaction: not recommended until ≥10yrs after prior dose of tetanus toxoid-containing vaccine. Acute illness. Immunodeficiency. Have epinephrine inj (1:1000) available. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant vaccines: see literature. Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may get suboptimal response.

Adverse reactions: Local reactions, headache, fever, fatigue, arthralgia, GI upset.

Note: Register pregnant patients exposed to Adacel by calling (800) 822-2463.

How supplied: Single-dose vials–5, 10; Single-dose prefilled syringes–5

TETANUS TOXOID + DIPHTHERIA TOXOID + PERTUSSIS VACCINE

R

BOOSTRIX GlaxoSmithKline

Tdap. Tetanus and reduced diphtheria toxoid, acellular pertussis vaccine (aluminum hydroxide adsorbed); susp for IM inj; preservative-free.

Indications: Diphtheria, tetanus, and pertussis booster immunization in patients ≥10 years of age.

Adults and Children: <10yrs: not recommended. ≥10yrs (≥5yrs after last childhood DTaP or DTaP or adult Td vaccine): 0.5mL IM once into deltoid muscle.

Contraindications: Encephalopathy within 7 days after previous DTaP or DTaP vaccination.

Warnings/Precautions: Guillain-Barre syndrome (within 6 weeks) after previous tetanus toxoid vaccine: see literature. Progressive or unstable neurologic disorders (eg, cerebrovascular events, acute encephalopathic conditions). Previous Arthus-type hypersensitivity reaction: not recommended until ≥10yrs after prior dose of tetanus toxoid-containing vaccine. Immunosuppressed. Have epinephrine available. Latex allergy. Pregnancy (Cat.C). Nursing mothers.

Interactions: Concomitant vaccines: see literature. Immunosuppressants (eg, radiation, chemotherapy, high-dose steroids): may get suboptimal response.

Adverse reactions: Local reactions (eg, pain), fever, headache, fatigue, GI upset.

Note: Register pregnant patients exposed to Boostrix by calling (888) 452-9622. Report adverse events to VAERS by calling (800) 822-7967.

How supplied: Vials (single dose)–10; Prefilled syringes (without needles)–1, 5, 10

VARICELLA VIRUS VACCINE

R

VARIVAX Merck

VAR. Varicella virus vaccine live, attenuated (Oka/Merck) (human and guinea pig cell cultures) with 1350 plaque-forming units (PFU) minimum per 0.5mL after reconstitution; for SC inj; lyophilized; preservative-free.

Indications: Varicella (chickenpox) vaccination.

Adults: Give SC in deltoid area. 1 dose of 0.5mL at elected date and a 2nd dose of 0.5mL 4–8 weeks later.

Children: Give SC in deltoid area. Under 12 months: not recommended. 12 months–12 years: 1 dose of 0.5mL.

Contraindications: See literature. Hypersensitivity to gelatin or neomycin. Active febrile infection. Active untreated tuberculosis. Primary or acquired immune deficiency. Immunosuppressant therapy. Blood dyscrasias. Bone marrow or lymphatic malignancy. Pregnancy (Cat.C) during and for 3 months after vaccination.

Warnings/Precautions: Have epinephrine inj available. Defer vaccination for at least 5 months after blood or plasma transfusions, immune globulins, or varicella zoster immune globulin (VZIG); avoid VZIG and other immune globulins for 2 months after immunization whenever feasible. HIV infection: see literature. Nursing mothers: not recommended.

Interactions: See Contraindications and Precautions. Avoid salicylates for 6 weeks after vaccination, immune globulins, transfusions.

Adverse reactions: Fever, local reactions, rash; others.

How supplied: Single-dose vials–1, 10 (w. diluent)

VARICELLA ZOSTER VACCINE

ZOSTAVAX Merck

Varicella zoster vaccine, live, attenuated; minimum of 19,400 PFU/0.65mL dose; pld for SC inj after reconstitution; contains porcine gelatin, neomycin and bovine serum (trace); preservative-free.

Indications: Prevention of herpes zoster (shingles) in adults ≥ 50 years of age.

Adults: < 50 yrs: not recommended. ≥ 50 yrs: one 0.65mL dose by SC inj once in upper arm. Administer immediately upon reconstitution.

Children: Not recommended.

Contraindications: Immunodeficiency (eg, HIV, leukemia, lymphoma, bone marrow or lymphatic cancer, immunosuppressive therapy). Pregnancy (during and 3 months after vaccination).

Warnings/Precautions: Not for treating zoster or postherpetic neuralgia. Not for preventing primary varicella infection. Defer in untreated tuberculosis. Consider deferral in acute illness. Have epinephrine inj (1:1000) available. May not protect 100% of recipients. Virus transmission may occur between recipients and susceptible contacts. Nursing mothers.

Interactions: See Contraindications. Immunosuppressants may cause disseminated disease.

Adverse reactions: Inj site reactions (eg, erythema, pain, swelling, pruritus), headache, cardiovascular diseases (eg, CHF, pulmonary edema).

Note: To register pregnant patients exposed to Zostavax: (800) 986-8999. To report adverse events to VAERS: (800) 822-7967.

How supplied: Single-dose vials–1, 10 (w. diluent)

SECTION 9:

INFECTIOUS DISEASES

9A Bacterial infections

AMIKACIN

AMIKACIN INJECTION (various)

Aminoglycoside. Amikacin sulfate 100mg/2mL, 500mg/2mL, 1g/4mL; soln for IM inj or IV infusion after dilution; contains sulfites.

Indications: Short-term treatment of serious susceptible infections, including septicemia, respiratory tract, bones and joints, CNS (eg, meningitis), skin and skin structure, intra-abdominal (eg, peritonitis), burns and postoperative infections, complicated and recurrent UTIs or uncomplicated UTIs not susceptible to other antibiotics.

Adults: Give by IM inj; or IV infusion over 30–60 mins. 15mg/kg per day in 2–3 divided doses (7.5mg/kg every 12 hours or 5mg/kg every 8 hours); max 15mg/kg/day. Heavier wt. patients: max 1.5g/day. Usual duration: 7–10 days. Uncomplicated UTIs: 250mg twice daily. Renal impairment: adjust dose based on serum levels or reduce frequency; see literature.

Children: Infants: give by IM inj; or IV infusion over 1–2 hours. Newborns: loading dose: 10mg/kg; then follow with 7.5mg/kg every 12 hours. All other children and older infants: give by IM inj; or IV infusion over 30–60 mins. 15mg/kg per day in 2–3 divided doses (7.5mg/kg every 12 hours or 5mg/kg every 8 hours); max 15mg/kg/day. Usual duration: 7–10 days. Renal impairment: adjust dose based on serum levels or reduce frequency; see literature.

Warnings/Precautions: Monitor for nephro- and neurotoxicity; avoid peak serum levels > 35 micrograms/mL and trough levels > 10 micrograms/mL. Discontinue or adjust dose if auditory, vestibular, or renal dysfunction develops; monitor serum levels periodically. Monitor BUN, CrCl, serum creatinine levels before, frequently during, and after therapy. Perform audiogram in high-risk patients. Maintain adequate hydration. Prolonged use or excessive doses. Asthma. Muscular disorders (eg, myasthenia gravis, parkinsonism, or infant botulism). Elderly. Premature or neonatal infants. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid concomitant furosemide, ethacrynic acid. Diuretics may increase toxicity. Increased risk of neurotoxicity and/or nephrotoxicity with concurrent or sequential polymyxin B, colistin, amphotericin B, other nephrotoxic or neurotoxic drugs; avoid. May potentiate neuromuscular blockade, respiratory paralysis with anesthetics, neuromuscular blockers. May be antagonized by concomitant penicillins, cephalosporins.

Adverse reactions: Nephrotoxicity (eg, azotemia, oliguria), ototoxicity, neurotoxicity, neuromuscular

blockade (eg, muscular paralysis, apnea); rare: rash, drug fever, headache, tremor, GI upset, paresthesia, eosinophilia, arthralgia, anemia, hypotension, hypomagnesemia.

How supplied: Contact supplier.

AMOXICILLIN

AMOXICILLIN TABLETS (various)

Broad-spectrum penicillin. Amoxicillin (as trihydrate) 500mg, 875mg; tabs.

Indications: Susceptible infections including ear/nose/throat (ENT), genitourinary tract, skin and skin structures, lower respiratory, acute uncomplicated gonorrhea.

Adults: >40kg: ENT: mild/moderate: 500mg every 12hrs; severe: 875mg every 12hrs. Lower respiratory tract: 875mg every 12hrs. Skin/skin structure: mild/moderate: 500mg every 12hrs; severe: 875mg every 12hrs. Genitourinary tract: mild/moderate: 500mg every 12hrs; severe: 875mg every 12hrs. Gonorrhea, acute uncomplicated anogenital and urethral infections: 3g as single oral dose.

Children: ≤3 months: max 30mg/kg per day in 2 divided doses every 12 hrs. >3 months (<40kg): ENT, genitourinary, skin: 25mg/kg/day in divided doses every 12hrs. Severe infections, or lower respiratory infections: 45mg/kg/day in divided doses every 12hrs. Gonorrhea: <2 yrs: not recommended; prepubertal: amoxicillin 50mg/kg + probenecid 25mg/kg as a single dose.

Warnings/Precautions: Cephalosporin, imipenem or other allergy: not recommended. Monitor blood, renal, and hepatic function in long-term use. Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: May cause false (+) glucose test with Clinitest, Benedict's or Fehling's soln. Serum levels increased by probenecid.

Adverse reactions: GI upset, hypersensitivity reactions (eg, urticaria, rash, Stevens-Johnson syndrome, anaphylaxis), hyperactivity, blood dyscrasias.

How supplied: Contact supplier.

AMOXICILLIN

AMOXIL Dr. Reddy's

Broad-spectrum penicillin. Amoxicillin (as trihydrate) 500mg; caps.

Also: Amoxicillin

AMOXIL ORAL SUSPENSION

Amoxicillin (as trihydrate) 250mg/5mL, 400mg/5mL; bubble-gum flavor.

Also: Amoxicillin

AMOXIL PEDIATRIC DROPS

Amoxicillin (as trihydrate) 50mg/mL; bubble-gum flavor.

Indications: Susceptible infections including ear/nose/throat (ENT), lower respiratory tract, skin and skin structure, genitourinary tract, acute uncomplicated gonorrhea.

Adults: Mild to moderate ENT, skin, or genitourinary: 500mg every 12hrs or 250mg every 8hrs. Lower respiratory or severe ENT, skin, or genitourinary: 875mg every 12hrs or 500mg every 8hrs. Gonorrhea: 3g once. Severe renal impairment (CrCl <30mL/min): 875mg tabs not recommended; CrCl 10–30mL/min: 250–500mg every 12hrs; CrCl <10mL/min: 250–500mg every 24hrs (give additional doses during and after hemodialysis).

Children: For treating acute otitis media: The AAP recommends 80–90mg/kg per day in divided doses (note: this is not an FDA-approved dose). Do not exceed recommended adult dose. >40kg: dose as adults. Neonates and infants ≤3months:

max 30mg/kg per day in divided doses every 12hrs. >3months: Mild to moderate ENT, skin, or genitourinary: 25mg/kg per day in divided doses every 12hrs or, 20mg/kg per day in divided doses every 8hrs. Lower respiratory or severe ENT, skin, or genitourinary: 45mg/kg per day in divided doses every 12hrs or, 40mg/kg per day in divided doses every 8hrs. Gonorrhea: ≤2yrs: not recommended; >2yrs: 50mg/kg with 25mg/kg probenecid once. Renal dysfunction: not recommended.

Warnings/Precautions: Cephalosporin, imipenem, other allergy or mononucleosis: not recommended. Monitor blood, renal, and hepatic function in long-term use. Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by probenecid. May cause false (+) glucose test with Clinitest, Benedict's or Fehling's soln.

Adverse reactions: GI upset, hypersensitivity reactions (eg, urticaria, rash, Stevens-Johnson syndrome, anaphylaxis), hyperactivity, blood dyscrasias.

How supplied: Caps–500; Susp 250mg/5mL–100mL, 150mL; Susp 400mg/5mL–100mL; Drops 50mg/mL–30mL

AMOXICILLIN + CLAVULANIC ACID

AUGMENTIN XR Dr. Reddy's

Broad-spectrum penicillin + β-lactamase inhibitor. Amoxicillin 1000mg, clavulanic acid (as potassium) 62.5mg; scored ext-rel tabs.

Indications: Susceptible infections including community-acquired pneumonia and acute bacterial sinusitis (see full labeling).

Adults: Take with meals. May split scored tabs; do not reduce dose. Two Augmentin 500mg tabs are not equivalent to one XR tab. ≥16yrs: 2 tabs every 12 hrs. Sinusitis: treat for 10 days. CAP: treat for 7–10 days.

Children: <16yrs: not recommended.

Also: Amoxicillin + Clavulanic acid

AUGMENTIN

Amoxicillin, clavulanic acid (as potassium); 250mg/125mg, 500mg/125mg, 875mg/125mg; tabs.

Also: Amoxicillin + Clavulanic acid
AUGMENTIN SUSPENSION

Amoxicillin, clavulanic acid (as potassium)
125mg/31.25mg banana flavor; 200mg/28.5mg
orange flavor, contains phenylalanine;
250mg/62.5mg orange flavor; 400mg/57mg orange
flavor, contains phenylalanine; per 5mL.

Also: Amoxicillin + Clavulanic acid
AUGMENTIN CHEWABLE

Amoxicillin, clavulanic acid (as potassium);
125mg/31.25mg lemon-lime flavor; 200mg/28.5mg
cherry-banana flavor, contains phenylalanine;
250mg/62.5mg lemon-lime flavor; 400mg/57mg cherry-
banana flavor, contains phenylalanine; chew tabs.

Indications: Susceptible infections including
sinusitis due to β -lactamase producing organisms,
otitis media, lower respiratory or skin and skin
structure infections, UTIs.

Adults: Take with meals. Base dose on amoxicillin
component. Due to clavulanic acid component: two
250mg tabs are not equivalent to one 500mg tab;
also, the 250mg tab and the 250mg chewable tab
are not interchangeable. May use 125mg/5mL
or 250mg/5mL susp in place of 500mg tab; or
200mg/5mL or 400mg/5mL susp in place of 875mg
tab. Severe infections or respiratory tract infections:
875mg every 12 hrs or 500mg every 8 hrs. Others:
500mg every 12 hrs or 250mg every 8 hrs. Renal
impairment: CrCl<30mL/min: do not use 875mg
tabs. CrCl: 10–30mL/min: 250–500mg every 12 hrs.
CrCl<10mL/min: 250mg–500mg every 24 hrs;
hemodialysis: give additional doses during and after
dialysis.

Children: Take with meals. Base dose on amoxicillin
component. <12 weeks: 30mg/kg/day in 2 divided
doses every 12 hrs (use 125mg/5mL). $\geq$ 12 weeks:
Twice-daily regimen: use 200mg/5mL or 400mg/5mL.
Three times daily regimen: use 125mg/5mL or
250mg/5mL. Less severe infections: 25mg/kg/day
in 2 divided doses every 12 hrs or 20mg/kg/day in
3 divided doses every 8 hrs. Others: 45mg/kg/day in
2 divided doses every 12 hrs or 40mg/kg/day in 3
divided doses every 8 hrs. $\geq$ 40kg: see Adult dose.

Also: Amoxicillin + Clavulanic acid
AUGMENTIN ES-600 SUSPENSION

Amoxicillin 600mg, clavulanic acid (as potassium)
42.9mg; per 5mL; strawberry cream flavor (may add
FLAVORx); contains phenylalanine.

Indications: Susceptible recurrent or persistent
acute otitis media (see full labeling).

Adults: Not recommended.

Children: Take with food. Base dose on amoxicillin
component. Due to clavulanic acid component,
ES-600 is not interchangeable with other susp
formulations. <3months: not recommended.
 $\geq$ 3months (<40kg): 90mg/kg per day in 2 divided
doses every 12 hours for 10 days. $\geq$ 40kg: not
recommended.

Contraindications: History of Augmentin-
associated cholestatic jaundice/hepatic dysfunction.

R XR: Severe renal impairment (CrCl <30mL/min) or
hemodialysis.

Warnings/Precautions: Cephalosporin, imipenem,
or other allergy: not recommended. Monitor blood,
renal, and hepatic function in long-term use. Hepatic
dysfunction. Mononucleosis. Elderly (consider
monitoring renal function). Labor & delivery.
Pregnancy (Cat.B). Nursing mothers.

Interactions: May cause false (+) glucose
test with Clinitest, Benedict's or Fehling's soln.
Probenecid potentiates amoxicillin. May potentiate
oral anticoagulants (monitor). May antagonize oral
contraceptives.

Adverse reactions: Diarrhea, nausea, abdominal
pain, rash, urticaria, vomiting, vaginitis; anaphylaxis.

How supplied: XR tabs—28, 40; Tabs 250mg–30;
Tabs 500mg, 875mg–20; Susp 125mg/5mL,
250mg/5mL–75mL, 100mL, 150mL; Susp
200mg/5mL, 400mg/5mL–50mL, 75mL, 100mL;
Chew tabs 125mg, 250mg–30; Chew tabs 200mg,
400mg–20; Susp ES-600 600mg/5mL–50mL, 75mL,
100mL, 125mL, 150mL, 200mL

AMPICILLIN**R**

AMPICILLIN CAPSULES (various)

Broad-spectrum penicillin. Ampicillin 250mg, 500mg;
caps.

Also: Ampicillin**R**

AMPICILLIN SUSPENSION

Ampicillin 125mg/5mL, 250mg/5mL; fruit flavor.

Indications: Ampicillin-sensitive infections.

Adults: 250–500mg 4 times daily. Continue therapy
for 3 days after symptoms improve. *N. gonorrhoeae*:
3.5g with 1g probenecid once.

Children: <20kg: 50–100mg/kg per day in 3–4
divided doses. $\geq$ 20kg: as adult. Continue therapy for
3 days after symptoms improve.

Also: Ampicillin**R**

AMPICILLIN SODIUM INJECTION

Ampicillin sodium 125mg, 250mg, 500mg, 1g, 2g,
10g; per vial; pwd for IV or IM inj after reconstitution
and dilution.

Adults and Children: Give IV inj slowly over at least
10–15 minutes; rapid IV administration may result in
convulsive seizures. Respiratory tract and soft tissue
infections: <40kg: 25–50mg/kg per day in equally
divided doses every 6–8 hours. $\geq$ 40kg: 250–500mg
every 6 hours. GI or GU tract infections (including *N.*
gonorrhoeae in women): <40kg: 50mg/kg per day
in equally divided doses every 6–8 hours. $\geq$ 40kg:
500mg every 6 hours. Urethritis in males due to *N.*
gonorrhoeae: two doses of 500mg each at interval
of 8–12 hours. Meningitis: Initiate with IV drip, then
continue IM. 150–200mg/kg per day in equally divided
doses every 3–4 hours. Septicemia: Initiate IV for
at least 3 days, then continue IM every 3–4 hours.
150–200mg/kg per day; treat for at least 10 days if
caused by Group A β -hemolytic streptococci.

Warnings/Precautions: Cephalosporin, imipenem,
other allergy or mononucleosis: not recommended.

Monitor blood, renal, and liver function in long-term use. Pregnancy (Cat.B). Nursing mothers.

Interactions: May cause false (+) glucose test with Clinitest, Benedict's or Fehling's soln. Potentiated by probenecid. May increase risk of rash with allopurinol.

Adverse reactions: Anaphylaxis, urticaria, GI upset, blood dyscrasias.

How supplied: Contact supplier.

AZITHROMYCIN

ZITHROMAX Pfizer
Macrolide (azalide). Azithromycin (as dihydrate)
250mg, 500mg, 600mg; tabs.

Also: Azithromycin
ZITHROMAX ORAL SUSPENSION

Azithromycin (as dihydrate) 100mg/5mL,
200mg/5mL; cherry flavor.

Also: Azithromycin
ZITHROMAX PACKETS

Azithromycin (as dihydrate) 1g/packet (single dose);
banana-cherry flavor.

Indications: Mild to moderate susceptible infections including acute bacterial exacerbations of COPD, acute bacterial sinusitis, acute otitis media, community-acquired pneumonia, pharyngitis/tonsillitis, uncomplicated skin and skin structure, urethritis, cervicitis, chancroid in men. Treatment and prophylaxis of *Mycobacterium avium* complex (MAC) infection.

Adults: Use packets only for doses equal to 1gram. COPD: 500mg once daily for 3 days; or 500mg once daily for 1 day, then 250mg once daily for 4 days. Sinusitis: 500mg once daily for 3 days. Community-acquired pneumonia, pharyngitis/tonsillitis, skin and skin structure: 500mg once daily for 1 day, then 250mg once daily for 4 days. Nongonococcal urethritis, cervicitis, chancroid: 1g as a single dose. Urethritis, cervicitis due to *N. gonorrhoeae*: 2g as a single dose. MAC prevention (alone or combined with rifabutin): 1200mg once weekly. MAC treatment (combined with ethambutol): 600mg once daily.

Children: Use oral susp (not packets). Otitis media: <6 months: not recommended; ≥6 months: 30mg/kg as a single dose (max 1.5g); or 10mg/kg (max 500mg) once daily for 3 days; or 10mg/kg (max 500mg) once then 5mg/kg (max 250mg) per day for 4 days. Sinusitis: <6 months: not recommended; ≥6 months: 10mg/kg (max 500mg) once daily for 3 days. Community-acquired pneumonia: <6 months: not recommended; ≥6 months: 10mg/kg (max 500mg) once daily for 1 day, then 5mg/kg (max 250mg) once daily for 4 days. Pharyngitis/tonsillitis: <2 yrs: not recommended; ≥2 yrs: 12mg/kg (max 500mg) once daily for 5 days.

Also: Azithromycin
ZITHROMAX INJECTION

Azithromycin 500mg/vial; for IV infusion after reconstitution and dilution.

Indications: Susceptible infections including community-acquired pneumonia, pelvic inflammatory disease (PID).

Adults: Give by IV infusion 1mg/mL over 3 hrs or 2mg/mL over 1hr. ≥16yrs: Pneumonia: 500mg once daily for at least 2 days, switch to 500mg orally once daily, for a total of 7–10 days combined therapy. PID: 500mg once daily for 1–2 days, switch to 250mg orally once daily for a total of 7 days combined therapy.

Children: <16yrs: not recommended.

Contraindications: Ketolide or related allergy.

Warnings/Precautions: Pneumonia: oral treatment is for mild, community-acquired cases suitable for outpatient therapy only. Discontinue if signs/symptoms of hepatitis occur. Hepatic or renal impairment. Known QT prolongation, proarrhythmic conditions, clinically significant bradycardia: avoid. Myasthenia gravis. Hepatic or renal impairment. Hypersensitivity reactions may recur after initial successful symptomatic treatment. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid concomitant aluminum- or magnesium-containing antacids. Monitor digoxin, cyclosporine, ergots, triazolam, hexobarbital, phenytoin, warfarin. Monitor for azithromycin toxicity (eg, liver dysfunction, ototoxicity) with nelfinavir. Concomitant Class 1A (eg, quinidine, procainamide), or Class III (eg, dofetilide, amiodarone, sotalol) antiarrhythmics, or others known to prolong the QT interval: avoid.

Adverse reactions: Diarrhea, nausea, vomiting, abdominal pain, rash, chest pain; hepatotoxicity, allergy (eg, angioedema, cholestatic jaundice), torsade de pointes (esp. elderly), *C. difficile* associated diarrhea.

How supplied: Tabs–30; Z-Pak (6 × 250mg tabs)–3; Tri-Pak (3 × 500mg tabs)–3; Susp 100mg/5mL–15mL; 200mg/5mL–15mL, 22.5mL, 30mL; Single Dose Packets–3, 10; Inj (500mg vials)–10

AZTREONAM

AZACTAM Elan

Monobactam. Aztreonam 500mg, 1g, 2g; for IM or IV inj after reconstitution; sodium-free.

Indications: Susceptible bacterial infections, including septicemia, lower respiratory tract, complicated or uncomplicated urinary tract, skin and skin structure, gynecologic, intraabdominal. Surgical adjunct.

Adults: UTI: 500mg–1g every 8–12 hours. Other infections: moderately severe: 1–2g every 8–12 hours. Severe: 2g every 6–8 hours. Max 1g/dose IM. Renal impairment (CrCl 10–30mL/min): Halve dose after loading dose; CrCl <10mL/min: see literature.

Children: <9 months: not recommended. Not for septicemia or certain skin and skin structure infections; see literature. 9 months–16 years (normal renal function only): Urinary tract, lower respiratory tract, intraabdominal, gynecologic infections: mild-to-moderate: 30mg/kg IV every 8 hours; moderate-to-severe: 30mg/kg IV every 6–8 hours; max

120mg/kg/day. May need higher dose in patients with cystic fibrosis.

Warnings/Precautions: Penicillin, cephalosporin, carbapenem, or other allergy. Renal or hepatic impairment. Monitor renal function in prolonged use or with high doses. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: May potentiate nephrotoxicity of concomitant aminoglycosides. Avoid concomitant β -lactamase-inducing drugs (eg, cefoxitin, imipenem).

Adverse reactions: Local reactions (eg, phlebitis, discomfort), GI upset, rash, anaphylaxis, blood dyscrasias, elevated liver enzymes or serum creatinine.

How supplied: Single-dose vials-10

BACITRACIN

BACIIM X-GEN

Antibacterial. Bacitracin 50,000units/vial; pwd for IM inj after reconstitution.

Indications: Susceptible infections due to staphylococci, including pneumonia and empyema in infants.

Adults: Not applicable.

Children: Give by IM inj into upper outer quadrant of buttocks. Infants: <2.5kg: 900units/kg per day in 2-3 divided doses; >2.5kg: 1,000units/kg per day in 2-3 divided doses.

Warnings/Precautions: Renal impairment. Monitor renal function before and daily during therapy; discontinue if renal toxicity occurs. Ensure adequate hydration.

Interactions: Avoid other nephrotoxic drugs (eg, aminoglycosides, polymyxin B, colistin).

Adverse reactions: Nephrotoxicity (eg, albuminuria, azotemia, cylinduria), nausea, vomiting, rash, inj site pain.

How supplied: Vials-10

CEFACLOX

CEFACLOX EXTENDED-RELEASE TABLETS (various) *Cephalosporin.* Cefaclor 375mg, 500mg; ext-rel tabs.

Indications: Susceptible mild to moderate infections including acute exacerbations of chronic bronchitis, secondary infections of acute bronchitis, pharyngitis/tonsillitis, uncomplicated skin and skin structures.

Adults: Take with meals. Swallow whole. Cefaclor ext-rel tab 500mg twice daily clinically equivalent to caps 250mg three times daily. ≥ 16 ys: Bronchitis: 500mg every 12 hrs for 7 days. Pharyngitis/tonsillitis: 375mg every 12 hrs for 10 days. Skin and skin structures: 375mg every 12 hrs for 7-10 days.

Children: ≤ 16 ys: not recommended.

Also: Cefaclor

CEFACLOX CAPSULES

Cefaclor 250mg, 500mg; caps.

Also: Cefaclor

CEFACLOX SUSPENSION

Cefaclor 125mg/5mL, 187mg/5mL, 250mg/5mL, 375mg/5mL; strawberry flavor.

Indications: Susceptible infections including otitis media, lower respiratory or urinary tract, pharyngitis/tonsillitis, skin and skin structure.

Adults: 250-500mg every 8 hrs.

Children: <1month: not recommended. ≥ 1 month: 20mg/kg per day in 3 equally divided doses. Otitis media, more serious or less susceptible infections: 40mg/kg per day in 3 equally divided doses (may give in 2 divided doses for pharyngitis or otitis media); max 1g/day.

Warnings/Precautions: Penicillin or other allergy. Discontinue if colitis occurs and treat. Severe renal dysfunction. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: May cause false (+) Coomb's test or glucose test with Clinitest or Benedict's or Fehling's soln. Potentiated by probenecid. Monitor warfarin. ER: antagonized by concomitant (within 1 hr) aluminum or magnesium-containing antacids.

Adverse reactions: Headache, GI upset, rash, blood dyscrasias, hepatic dysfunction, cough, CNS stimulation, serum-sickness-like reactions.

How supplied: Contact supplier.

CEFADROXIL

CEFADROXIL (various)

Cephalosporin. Cefadroxil 500mg; caps.

Also: Cefadroxil

CEFADROXIL TABLETS

Cefadroxil 1g.

Also: Cefadroxil

CEFADROXIL SUSPENSION

Cefadroxil 250mg/5mL, 500mg/5mL; orange-pineapple flavor.

Indications: Susceptible urinary tract, skin and skin structure infections, pharyngitis/tonsillitis, impetigo.

Adults: Uncomplicated UTI: 1-2g once daily or in 2 divided doses. Complicated UTI: 2g/day in 2 divided doses. Skin and skin structure infections: 1g once daily or in 2 divided doses. Pharyngitis/tonsillitis: 1g once daily or in 2 divided doses for 10 days. Renal dysfunction (CrCl <50mL/min): 1g loading dose, then 500mg at increased dosing intervals (see literature). Continue for 3 days after symptoms improve.

Children: UTI, skin and skin structure infections: 30mg/kg/day in 2 divided doses every 12 hours. Pharyngitis/tonsillitis, impetigo: 30mg/kg once daily or in 2 divided doses for 10 days. Renal dysfunction: reduce dose (see literature). Continue for 3 days after symptoms improve.

Warnings/Precautions: Penicillin or other allergy. Discontinue if colitis occurs and treat. Impaired renal function (CrCl <50mL/min). GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by probenecid. May cause false (+) Clinitest or Coomb's test.

Adverse reactions: GI upset, anaphylaxis, rash; blood dyscrasias (rare).

How supplied: Contact supplier.

CEFDINIR

CEFDINIR CAPSULES (various)
Cephalosporin. Cefdinir 300mg; caps.

Also: Cefdinir**CEFDINIR FOR ORAL SUSPENSION**

Cefdinir 125mg/5mL, 250mg/5mL; pwd for reconstitution; strawberry-cream flavor.

Indications: Susceptible mild-to-moderate infections, including community-acquired pneumonia, acute exacerbations of chronic bronchitis, acute maxillary sinusitis, pharyngitis/tonsillitis, uncomplicated skin and skin structure infections, acute otitis media.

Adults: Use caps. ≥ 13 yrs: Pneumonia, skin and skin structure: 300mg every 12 hrs for 10 days. Bronchitis, pharyngitis/tonsillitis: 300mg every 12 hrs for 5–10 days, or 600mg every 24 hrs for 10 days. Sinusitis: 300mg every 12 hrs, or 600mg every 24 hrs, for 10 days. Renal insufficiency (CrCl < 30 mL/min): 300mg once daily. Hemodialysis: 300mg (or 7mg/kg) at end of session then 300mg (or 7mg/kg) every other day.

Children: Use susp. < 6 months: not recommended. 6 months–12 yrs: Otitis media, pharyngitis/tonsillitis: 7mg/kg every 12 hrs for 5–10 days, or 14mg/kg every 24 hrs for 10 days. Sinusitis: 7mg/kg every 12 hrs, or 14mg/kg every 24 hrs, for 10 days. Skin and skin structure: 7mg/kg every 12 hrs for 10 days. For all: max 600mg/day; see literature for chart. Renal insufficiency (CrCl < 30 mL/min per 1.73 m²): 7mg/kg (max 300mg) once daily. Hemodialysis: give initial and subsequent doses at end of session (see literature).

Warnings/Precautions: Penicillin or other allergy. Renal insufficiency. History of colitis. Labor & delivery. Pregnancy (Cat.B).

Interactions: Antagonized by magnesium- or aluminum-containing antacids or iron supplements (except iron-fortified infant formulas); separate dosing by 2 hrs. Potentiated by probenecid. May cause false (+) glucose test with Clinitest, Fehling's or Benedict's soln, or direct Coomb's test.

Adverse reactions: GI disturbances, abdominal pain, headache, rash.

How supplied: Contact supplier.

CEFEPIME

MAXIPIME Hospira

Cephalosporin. Cefepime (as HCl) 500mg, 1g, 2g; pwd for IV infusion or IM inj after reconstitution.

Indications: Susceptible infections, including moderate-to-severe pneumonia, uncomplicated skin and skin structure infections, complicated and uncomplicated urinary tract infections (UTIs) including pyelonephritis, complicated intraabdominal in adults (w. metronidazole). Empiric therapy in febrile neutropenia.

Adults: When giving IV, infuse over 30 minutes.

Pneumonia: 1–2g IV every 12 hrs for 10 days. Skin and skin structures, severe UTIs: 2g IV every 12 hrs

for 10 days. Mild-to-moderate UTIs: 500mg–1g IV or IM every 12 hrs for 7–10 days (IM only for UTIs caused by *E. coli*). Intraabdominal (use w. metronidazole): 2g IV every 12 hrs for 7–10 days. Febrile neutropenia: 2g IV every 8 hrs for 7 days or until neutropenia resolves. CrCl ≤ 60 mL/min: reduce dose; see full labeling. Hemodialysis: repeat initial dose after each session. Continuous ambulatory peritoneal dialysis: give usual doses at 48-hour intervals.

Children: < 2 months: not recommended. Not for use in serious infection when pathogen is or may be *H. influenzae* type b. 2 months–16 yrs (≤ 40 kg): 50mg/kg per dose, given every 12 hrs; do not exceed recommended adult dose. Severe UTIs, pneumonia, skin and skin structure: give IV for 10 days. Mild-to-moderate UTIs: give IV or IM for 7–10 days (IM only for UTIs caused by *E. coli*). Febrile neutropenia: give IV every 8 hours for 7 days or until neutropenia resolves.

Contraindications: Penicillin or other β -lactam allergy.

Warnings/Precautions: Renal impairment. Risk of neurotoxicity (esp. in renally-impaired); consider discontinuing or making appropriate dose adjustments. Renal or hepatic dysfunction, poor nutritional state, prolonged antimicrobial therapy: monitor prothrombin time. History of GI disease (esp. colitis). Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: Aminoglycosides may potentiate oto- or nephrotoxicity. Possible nephrotoxicity with diuretics (eg, furosemide). May cause false (+) Coomb's, Clinitest.

Adverse reactions: Local reactions (eg, pain, phlebitis, inflammation), rash, nausea, vomiting, diarrhea, pruritus, fever, headache, seizures, encephalopathy, blood dyscrasias, anemia, renal dysfunction; *C. difficile* associated diarrhea, hypersensitivity reactions.

How supplied: Vials (500mg)–10; 1g, 2g–10, 25

CEFOTAXIME

CLAFORAN Sanofi Aventis

Cephalosporin. Cefotaxime sodium 500mg, 1g, 2g, 10g; IM or IV inj; sodium content 2.2mEq/g.

Indications: Susceptible bacteremia, septicemia, lower respiratory and genitourinary tracts, skin and skin structure, bone and joint, gynecologic, CNS (eg, meningitis), intraabdominal infections. Surgical prophylaxis.

Adults: Uncomplicated infections: 1g every 12 hours. Moderate to severe infections: 1–2g every 8 hours. Infections commonly needing a higher dosage (eg, septicemia): 2g IV every 6–8 hours. Life-threatening infections: 2g IV every 4 hours. Gonococcal urethritis or cervicitis: 0.5g IM once. Rectal gonorrhea: 0.5g (women) or 1g (men) IM once. All: max 12g/day. Post-op prophylaxis: give 1g as single dose 30–90mins before surgery. Cesarean section: 1st dose: 1g IV as soon as umbilical cord clamped; 2nd and 3rd dose: 1g at 6 and 12 hours

after 1st dose. CrCl <20mL/min/1.73m²: consider reducing dose by one-half.

Children: Neonates up to 1 week of age: 50mg/kg IV every 12 hours. 1–4 weeks of age: 50mg/kg IV every 8 hours. Over 1 month of age (<50kg): 50–180mg/kg in 4–6 equally divided doses. ≥50kg: as adult; max 12g/day.

Warnings/Precautions: Penicillin or other allergy. Severe renal impairment, reduce dose. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: Increased nephrotoxicity with concomitant aminoglycosides. Potentiated by probenecid.

Adverse reactions: Local or hypersensitivity reactions, diarrhea; blood dyscrasias, elevated liver enzymes (rare).

How supplied: Vials (500mg)–10 (1g, 2g)–10, 25, 50
Infusion bottles (1g, 2g)–10
Bottles (10g)–1
Premixed inj soln–12

CEFOXITIN

R

CEFOXITIN INJECTION (various)
Cephalosporin. Cefoxitin sodium 1g, 2g; for IV inj; sodium content 2.3mEq/g.

Indications: Susceptible bacterial septicemia, lower respiratory or urinary tract, skin and skin structure, bone and joint, gynecologic, intraabdominal infections. Surgical prophylaxis.

Adults: Usually 1–2g every 6–8 hrs. Uncomplicated: 1g every 6–8 hrs. Moderately severe to severe: 1g every 4 hrs or 2g every 6–8 hrs. Max 2g every 4 hrs or 3g every 6 hrs. Prophylaxis: see literature.

Children: <3months: not recommended.
≥3months: 80–160mg/kg per day in 4–6 equal divided doses; max 12g/day. Prophylaxis: see literature.

Warnings/Precautions: Penicillin or other allergy. Renal impairment (CrCl <50mL/min), reduce dose: see literature. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: Aminoglycosides may potentiate nephrotoxicity. Potentiated by probenecid. May cause false (+) Clintest. May interfere with creatinine tests.

Adverse reactions: Local reactions, rash, pruritus, drug fever, GI upset, anaphylaxis, blood dyscrasias, elevated liver enzymes.

How supplied: Contact supplier.

CEFPROZIL

R

CEFZIL (various)
Cephalosporin. Cefprozil 250mg, 500mg; tabs.

Also: Cefprozil

CEFZIL ORAL SUSPENSION

Cefprozil 125mg/5mL, 250mg/5mL; bubble-gum flavor; contains phenylalanine.

Indications: Susceptible mild to moderate infections, including pharyngitis/tonsillitis, secondary

bacterial infection of acute bronchitis, acute bacterial exacerbation of chronic bronchitis, acute sinusitis, skin and skin structure, otitis media.

Adults: ≥13yrs: Pharyngitis/tonsillitis: 500mg every 24 hrs. Acute sinusitis: 250mg (mild) or 500mg (moderate to severe) every 12 hrs. Bronchitis: 500mg every 12 hrs. Skin and skin structure: 250mg every 12 hrs or 500mg every 12–24 hrs. All: for 10 days. CrCl<30mL/min: 50% of standard dose.

Children: Otitis media: <6months: not recommended; 6months to 12yrs: 15mg/kg every 12 hrs. Acute sinusitis: <6months: not recommended; 6months to 12yrs: 7.5mg/kg (mild) or 15mg/kg (moderate to severe) every 12 hrs. Pharyngitis/tonsillitis: <2yrs: not recommended; 2–12yrs: 7.5mg/kg every 12 hrs. Skin and skin structure: <2yrs: not recommended; 2–12yrs: 20mg/kg every 24 hrs. All: for 10 days.

Warnings/Precautions: Penicillin or other allergy. Renal impairment, reduce dose. Monitor renal function. GI disease (esp. colitis). Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid diuretics, other nephrotoxic drugs, including aminoglycosides. Potentiated by probenecid. May cause false (+) Clintest.

Adverse reactions: GI upset, elevated liver enzymes, dizziness.

How supplied: Contact supplier.

CEFTAROLINE FOSAMIL

R

TEFLARO Forest

Cephalosporin. Ceftaroline fosamil 400mg/vial, 600mg/vial; pvd for IV infusion after reconstitution.

Indications: Susceptible bacterial community-acquired pneumonia and acute skin and skin structure infections.

Adults: ≥18yrs: Give by IV infusion over 1hr. Treat skin and skin structure for 5–14 days; treat pneumonia for 5–7days. CrCl >50mL/min: 600mg every 12hrs. Renal impairment (CrCl >30–≤50mL/min): 400mg every 12hrs; (CrCl ≥15–≤30mL/min): 300mg every 12hrs; ESRD (including hemodialysis): 200mg every 12hrs (dose after dialysis on dialysis days).

Children: <18yrs: not recommended.

Warnings/Precautions: Penicillin or other allergy. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: GI upset, rash, (+) Coombs test (evaluate for hemolytic anemia if occurs), pseudomembranous colitis, superinfection.

How supplied: Vials–1, 10

CEFTAZIDIME

R

FORTAZ Covis

Cephalosporin. Ceftazidime 500mg, 1g, 2g; IM or IV inj; sodium content 2.3mEq/g.

Indications: Susceptible infections including septicemia, pneumonia, skin and skin structure, bone and joint, gynecologic, intraabdominal, meningitis, urinary tract.

Adults: Uncomplicated pneumonia, mild skin or skin structure: 500mg–1g IV or IM every 8 hours. Serious gynecologic, intraabdominal, meningitis, or very severe life-threatening (esp. immunocompromised): 2g IV every 8 hours. Bone and joint: 2g IV every 12 hours. Uncomplicated UTIs: 250mg IV or IM every 12 hours. Complicated UTIs: 500mg IV or IM every 8–12 hours. Renal dysfunction: CrCl 31–50mL/min: 1g every 12 hours; CrCl 16–30mL/min: 1g every 24 hours; CrCl 6–15mL/min: 500mg every 24 hours; CrCl <5mL/min: 500mg every 48 hours. Hemodialysis: 1g loading dose then 1g after dialysis session. Peritoneal dialysis: 1g loading dose then 500mg every 24 hours.

Children: Neonates: 30mg/kg IV every 12 hours. 1 month–12 years: 30–50mg/kg IV every 8 hours; max 6g/day. Renal impairment: reduce dose.

Warnings/Precautions: Penicillin or other allergy. Renal impairment. Monitor prothrombin time in renal or hepatic dysfunction, poor nutritional states, or long-term use. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: May potentiate nephrotoxicity of aminoglycosides or diuretics. Antagonized by chloramphenicol. False (+) glucose test with Clinitest, Benedict's, or Fehling's soln.

Adverse reactions: Hypersensitivity reactions (eg, rash, pruritus, fever), local reactions, GI upset, elevated liver enzymes.

How supplied: Vials–10

CEFTAZIDIME

R

TAZICEF Hospira

Cephalosporin. Ceftazidime 1g, 2g; pwd for IM or IV inj, or IV infusion after reconstitution; sodium content 2.3mEq/g.

Indications: Susceptible infections including lower respiratory tract (eg, pneumonia), skin and skin structure, UTIs, septicemia, bone and joint, gynecologic (eg, endometritis, pelvic cellulitis), meningitis, intraabdominal (eg, peritonitis).

Adults: Administer in upper outer quadrant of the gluteus maximus or lateral part of the thigh. Usual dose: 1g IV or IM every 8–12 hours. Uncomplicated UTIs: 250mg IV or IM every 12 hours. Complicated UTIs: 500mg IV or IM every 8–12 hours. Bone and joint: 2g IV every 12 hours. Uncomplicated pneumonia, mild skin and skin structure: 500mg–1g IV or IM every 8 hours. Serious gynecologic, intraabdominal, meningitis, or very severe life threatening (eg, immunocompromised): 2g IV every 8 hours. Lung infections: 30–50mg/kg IV every 8 hours; max of 6g/day. Renal dysfunction: CrCl 31–50mL/min: 1g every 12 hours; CrCl 16–30mL/min: 1g every 24 hours; CrCl 6–15mL/min: 500mg every 24 hours; CrCl <5mL/min: 500mg every 48 hours. Hemodialysis: 1g loading dose then 1g after each dialysis session. Peritoneal dialysis: 1g loading dose then 500mg every 24 hours.

Children: Neonates: 30mg/kg IV every 12 hours. 1 month–12 years: 30–50mg/kg IV every 8 hours, max of 6g/day. Renal impairment: reduce dose.

Warnings/Precautions: Penicillin or other allergy. Renal or hepatic impairment, poor nutritional state, long term use: monitor prothrombin time. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: Nephrotoxicity with concomitant aminoglycosides, diuretics (eg, furosemide). Antagonized by chloramphenicol. False (+) glucose test with Clinitest, Benedict's, or Fehling's soln.

Adverse reactions: Hypersensitivity reactions (eg, rash, pruritus, fever), local reactions, GI upset, elevated liver enzymes.

How supplied: Vials 1g–1, 10, 25
2g–1, 10

CEFTRIAXONE

R

ROCEPHIN Roche

Cephalosporin. Ceftriaxone sodium 250mg, 500mg, 1g, 2g; IM or IV inj; sodium content 3.6mEq/g.

Indications: Susceptible bacterial septicemia, acute bacterial otitis media, lower respiratory tract, UTIs, skin and skin structure, bone and joint, pelvic inflammatory disease (PID), intraabdominal infections, meningitis, uncomplicated gonorrhea. Surgical prophylaxis.

Adults: 1–2g IM or IV once daily or in 2 equally divided doses; max 4g/day. Gonorrhea: 250mg IM once. Surgery: 1g IV ½–2 hours pre-op.

Children: 50–75mg/kg per day in equally divided doses every 12 hours; max 2g/day. Skin and skin structures: may give as a single dose or in 2 equally divided doses every 12 hours; max 2g/day. Meningitis: 100mg/kg (max 4g) for 1 dose, then 100mg/kg per day (max 4g/day) once daily or in 2 equally divided doses every 12 hours for 7–14 days. Otitis media: 50mg/kg (max 1g) IM once.

Contraindications: Hyperbilirubinemic neonates (esp. prematures). Concomitant calcium-containing solutions or products in newborns.

Warnings/Precautions: Penicillin or other allergy. Discontinue if gallbladder sonographic abnormalities, symptoms or disease occur. Renal failure: monitor; decrease dose if drug accumulation occurs. Chronic hepatic disease or malnutrition (impaired Vit. K synthesis or storage), monitor prothrombin time. Both renal and hepatic impairment: usual max 2g/day. GI disease (esp. colitis). Pregnancy (Cat.B). Nursing mothers.

Interactions: See Contraindications. Potentiated by probenecid.

Adverse reactions: Inj site reactions, hematologic effects (eg, eosinophilia), rash, diarrhea, elevated liver enzymes; rare: allergic pneumonitis, seizures, anaphylaxis.

How supplied: Vials (250mg, 500mg, 1g)–1, 10; 2g–10

CEFUROXIME**CEFTIN** GlaxoSmithKline*Cephalosporin.* Cefuroxime (as axetil) 250mg, 500mg; tabs.**Indications:** Susceptible mild to moderate infections including pharyngitis/tonsillitis, acute maxillary sinusitis, bronchitis, acute otitis media; uncomplicated skin and skin structure, UTIs, gonorrhea; early Lyme disease.**Adults:** ≥ 13 years: Pharyngitis/tonsillitis, sinusitis: 250mg twice daily for 10 days. Acute bacterial exacerbations of chronic bronchitis, skin and skin structure infections: 250–500mg twice daily for 10 days. Secondary bacterial infections of acute bronchitis: 250–500mg twice daily for 5–10 days. UTIs: 250mg twice daily for 7–10 days. Gonorrhea: 1g as a single dose. Lyme disease: 500mg twice daily for 20 days.**Children:** Swallow tab whole, or use susp. Otitis media, sinusitis: 250mg twice daily for 10 days.**Also: Cefuroxime****CEFTIN ORAL SUSPENSION***Cefuroxime (as axetil)* 125mg/5mL, 250mg/5mL; pwd for reconstitution; contains phenylalanine; tutti-frutti flavor.**Indications:** Susceptible infections including pharyngitis/tonsillitis, otitis media, impetigo, acute maxillary sinusitis.**Adults: Not applicable.****Children:** Give with food. < 3 months: not recommended. 3 months–12 years: Pharyngitis/tonsillitis: 20mg/kg per day in 2 divided doses for 10 days; max 500mg/day. Otitis media, impetigo, sinusitis: 30mg/kg per day in 2 divided doses for 10 days; max 1g/day.**Warnings/Precautions:** Tabs and susp not bioequivalent; do not interchange on a mg/mg basis. Penicillin or other allergy. History of colitis; discontinue if colitis occurs and treat. Renal impairment. Monitor prothrombin time in renal or hepatic dysfunction, stabilized on anticoagulant, poor nutritional state, or long-term use. Labor & delivery. Pregnancy (Cat.B). Nursing mothers: consider discontinuing nursing during treatment.**Interactions:** May cause false (+) Fehling's or Benedict's soln, Clinistest, or Coomb's test. Antacids, others that decrease gastric acidity may inhibit absorption. Potentiated by probenecid. Caution with potent diuretics, other nephrotoxic drugs.**Adverse reactions:** GI disturbances, transient increase of AST, ALT, LDH, eosinophilia, bitter taste; convulsions (overdose).**How supplied:** Tabs–20, 60; Susp 125mg/5mL–100mL; Susp 250mg/5mL–50mL, 100mL**CEFUROXIME****ZINACEF** Covis*Cephalosporin.* Cefuroxime (as sodium) 750mg, 1.5g; IM or IV inj; sodium content 2.4mEq/g.**Indications:** Susceptible bacterial septicemia, lower respiratory or urinary tract, skin and skin structure,

R

meningitis, bone and joint infections, gonorrhea. Surgical prophylaxis.

Adults: Use IV route for serious infections. Usual duration of therapy: 5–10 days. Uncomplicated UTIs, skin and skin structure, disseminated gonorrhea, or uncomplicated pneumonia: 750mg every 8 hours. Severe or complicated infections, bone and joint: 1.5g every 8 hours; life-threatening: 1.5g every 6 hours; meningitis: max 3g every 8 hours. Uncomplicated gonorrhea: 1.5g IM once (divide into 2 injections) with 1g oral probenecid. Prophylaxis: see literature. Renal dysfunction: CrCl 10–20mL/min: 750mg every 12 hours; CrCl < 10 mL/min: 750mg every 24 hours. Coincide a dose for end of dialysis.**Children:** < 3 months: not recommended. Give in equally divided doses. ≥ 3 months: usual range: 50–100mg/kg per day every 6–8 hours. Bone and joint: 150mg/kg per day every 8 hours. Meningitis: 200–240mg/kg per day IV every 6–8 hours. Renal dysfunction: reduce dose.

R

Warnings/Precautions: Penicillin allergy. Renal impairment, reduce dose. Monitor prothrombin time (in patients at risk), renal function. GI disease (esp. colitis). Elderly. Pregnancy (Cat.B). Nursing mothers.**Interactions:** Avoid aminoglycosides, furosemide, ethacrynic acid, other nephrotoxic drugs. May cause false (+) glucose test with Clinistest, Benedict's or Fehling's soln. Potentiated by probenecid.**Adverse reactions:** Local reactions, blood dyscrasias, elevated liver enzymes; rarely: GI upset, rash (may be serious, eg, Stevens-Johnson syndrome), drug fever, anaphylaxis, interstitial nephritis, seizures, hearing loss in children treated for meningitis.**How supplied:** Vials–10**CEPHALEXIN****KEFLEX** Shionogi*Cephalosporin.* Cephalixin 250mg, 500mg, 750mg; caps.**Indications:** Susceptible infections including otitis media, skin and skin structure, bone, respiratory or genitourinary tract.**Adults:** 1–4g/day in divided doses. Usual dose: 250mg every 6 hours. Strep pharyngitis, skin and skin structure, and uncomplicated cystitis (> 15 years of age): 500mg every 12 hours. Treat cystitis for 7–14 days. Max 4g/day.**Children:** 25–50mg/kg per day in divided doses; max 100mg/kg per day. Otitis media: 75–100mg/kg per day in 4 divided doses. Strep pharyngitis (> 1 year of age) or skin and skin structure: may give in 2 divided doses every 12 hours.**Warnings/Precautions:** Penicillin or other allergy. Severe renal dysfunction. GI disease (esp. colitis). Discontinue if colitis occurs and treat. Pregnancy (Cat.B). Nursing mothers.**Interactions:** Potentiates metformin (monitor and adjust metformin dose). Potentiated by probenecid.

R

May cause false (+) Coomb's test or glucose test with Clinitest or Benedict's or Fehling's soln.

Adverse reactions: Diarrhea, other GI disturbances, dizziness, fatigue, headache, hypersensitivity reactions, itch; rare: blood dyscrasias, elevated liver enzymes.

How supplied: Caps 250mg, 500mg–20, 100; 750mg–50

CIPROFLOXACIN

CIPRO Bayer

Quinolone. Ciprofloxacin (as HCl) 250mg, 500mg; tabs.

Also: Ciprofloxacin

CIPRO ORAL SUSPENSION

Ciprofloxacin 5% (250mg/5mL), 10% (500mg/5mL); microcapsules for susp after reconstitution; strawberry flavor.

Indications: Susceptible infections, including lower respiratory tract, skin and skin structures, bone and joint, acute sinusitis, complicated intraabdominal (w. metronidazole), UTIs, chronic bacterial prostatitis. Postexposure prophylaxis and treatment of anthrax. Infectious diarrhea, typhoid fever, uncomplicated cervical and urethral gonorrhea: oral form only. Nosocomial pneumonia, empiric therapy in febrile neutropenia: IV form only.

Adults: See full labeling. Swallow tabs whole, do not chew microcapsules for susp. ≥ 18 yrs: Sinusitis, typhoid fever: 500mg every 12 hrs for 10 days. Lower respiratory tract, skin and skin structure: 500–750mg every 12 hrs for 7–14 days. Intraabdominal (w. metronidazole): 500mg every 12 hrs for 7–14 days. Bone and joint: 500–750mg every 12 hrs for at least 4–6 weeks. Infectious diarrhea: 500mg every 12 hrs for 5–7 days. Acute uncomplicated cystitis due to *E. coli*, *S. saprophyticus* in females: 250mg every 12 hrs for 3 days (oral forms only). Other UTIs: 250–500mg every 12 hrs for 7–14 days. Prostatitis: 500mg every 12 hrs for 28 days. Gonorrhea: 250mg once. Postexposure prophylaxis of inhalational anthrax: 500mg every 12 hrs for 60 days (start as soon as possible after exposure). Treatment of inhalational, cutaneous, GI, or oropharyngeal anthrax: see CDC recommendations. Renal dysfunction (CrCl 30–50mL/min): 250–500mg every 12 hrs; (CrCl 5–29mL/min): 250–500mg every 18 hrs; hemo- or peritoneal dialysis: 250–500mg every 24 hrs (after dialysis).

Children: < 18 yrs: usually not recommended. Swallow tabs whole, do not chew microcapsules for susp. 1–17 yrs: Complicated UTIs or pyelonephritis: 10–20mg/kg (max 750mg) every 12 hrs for 10–21 days (see full labeling). Postexposure prophylaxis of inhalational anthrax: 15mg/kg (max 500mg/dose) every 12 hrs for 60 days (start as soon as possible after exposure). Treatment of inhalational, cutaneous, GI, or oropharyngeal anthrax: see CDC recommendations.

Also: Ciprofloxacin

CIPRO IV CONCENTRATE

Ciprofloxacin 10mg/mL; soln for IV infusion after dilution.

Also: Ciprofloxacin

CIPRO IV PREMIXED

Ciprofloxacin 2mg/mL; soln for IV infusion.

Adults: See full labeling. Infuse over 60 minutes. Switch to oral form when appropriate. ≥ 18 yrs: Lower respiratory tract, skin and skin structure: 400mg every 8–12 hrs for 7–14 days. Nosocomial pneumonia: 400mg every 8 hrs for 10–14 days. Intraabdominal (w. metronidazole): 400mg every 12 hrs for 7–14 days. Bone and joint: 400mg every 8–12 hrs for ≥ 4 –6 weeks. Sinusitis: 400mg every 12 hrs for 10 days. UTIs: 200–400mg every 12 hrs for 7–14 days. Prostatitis: 400mg every 12 hrs for 28 days. Febrile neutropenia: 400mg every 8 hrs (+ piperacillin sodium 50mg/kg IV every 4 hrs; max 24g/day) for 7–14 days. Postexposure prophylaxis of inhalational anthrax: 400mg every 12 hrs for 60 days (start as soon as possible after exposure). Treatment of inhalational, GI, or oropharyngeal anthrax, or cutaneous anthrax with systemic involvement, extensive edema, or head/neck lesions: see CDC recommendations. Renal dysfunction (CrCl 5–29mL/min): 200–400mg every 18–24 hours.

Children: < 18 yrs: usually not recommended. See full labeling. Infuse over 60 minutes. Switch to oral form when appropriate. 1–17 yrs: Complicated UTIs or pyelonephritis: 6–10mg/kg (max 400mg) IV every 8 hrs for 10–21 days (see literature). Postexposure prophylaxis of inhalational anthrax: 10mg/kg (max 400mg/dose) every 12 hrs for 60 days (start as soon as possible after exposure). Treatment of inhalational, GI, cutaneous, or oropharyngeal anthrax: see CDC recommendations.

Also: Ciprofloxacin

CIPRO XR

Ciprofloxacin (as HCl and betaine) 500mg, 1000mg; ext-rel tabs.

Indications: Susceptible infections including UTIs, acute uncomplicated pyelonephritis.

Adults: Swallow whole. ≥ 18 yrs: Uncomplicated UTIs: 500mg once daily for 3 days. Complicated UTIs, acute uncomplicated pyelonephritis: 1000mg once daily for 7–14 days; renal impairment (CrCl < 30 mL/min): 500mg once daily for 7–14 days. Coincide dose for end of dialysis.

Children: < 18 yrs: not recommended.

Contraindications: Concomitant tizanidine.

Warnings/Precautions: XR not interchangeable with other forms. Renal (except XR tabs for uncomplicated UTIs) or hepatic dysfunction: reduce dose. Increased risk of tendinitis or tendon rupture esp. in patients > 60 yrs, or those with kidney, heart or lung transplants. Discontinue if tendon pain, inflammation, or rupture occurs; if rash, phototoxicity, or other sign of hypersensitivity occurs; or if CNS disorders or neuropathy occurs. History of

myasthenia gravis; avoid. Conditions that increase seizure risk. History of prolonged QT interval. Hypokalemia. History of joint-related disorders (esp. children). Maintain adequate hydration, avoid alkaline urine to avoid crystalluria. Avoid excessive sun and UV light. May mask symptoms of syphilis; test for syphilis before treating gonorrhea, then follow-up after 3 months. Monitor blood, renal, hepatic function in prolonged use. Elderly. Pregnancy (Cat.C), nursing mothers: usually not recommended.

Interactions: Avoid theophylline (increases theophylline levels; may potentiate other CYP1A2 substrates), urinary alkalinizers; oral forms with antacids, calcium, iron, zinc, sucralfate, buffered forms of didanosine, other highly buffered drugs (may give ciprofloxacin 2 hrs before or 6 hrs after); high ciprofloxacin doses with NSAIDs (increases seizure risk). Potentiates caffeine. Potentiated by probenecid. Severe hypoglycemia with glyburide (rare). Increased serum creatinine with cyclosporine. Monitor methotrexate, oral anticoagulants (potentiation), phenytoin (variable effects). Increased risk of tendinitis and tendon rupture with corticosteroids. Caution with other drugs that lower seizure threshold. Increased risk of QT prolongation with Class IA or III antiarrhythmics. Reduced absorption with omeprazole (XR).

Adverse reactions: GI upset, headache, CNS disturbances (eg, convulsions, dizziness, nervousness, insomnia, nightmares, paranoia), rash, eosinophilia, elevated liver enzymes, photosensitivity, Stevens-Johnson syndrome, myalgia, tendinitis/rupture, joint-related disorders (children), local reactions (inj); rare: increased intracranial pressure, toxic psychosis; peripheral neuropathy, *C. difficile*-associated diarrhea.

Note: See MMWR Vol 50, No.42 (Oct. 26, 2001) for more information on anthrax.

How supplied: Tabs 250mg, 500mg-100; Oral Susp-100mL; Inj Conc (20mL, 40mL)-1; Infusion (100mL, 200mL)-1; XR Tabs-50, 100

CLARITHROMYCIN

BIAXIN XL AbbVie

Macrolide. Clarithromycin 500mg; ext-rel tabs.

Indications: Mild to moderate susceptible acute maxillary sinusitis, acute bacterial exacerbation of chronic bronchitis, community-acquired pneumonia.

Adults: Swallow whole. Take with food. 1g once daily. Sinusitis: for 14 days. Bronchitis, pneumonia: for 7 days.

Children: Not recommended.

Also: Clarithromycin

BIAXIN

Clarithromycin 250mg, 500mg; tabs.

Also: Clarithromycin

BIAXIN ORAL SUSPENSION

Clarithromycin 125mg/5mL, 250mg/5mL; granules for oral susp; fruit-punch flavor.

Indications: Mild to moderate susceptible pharyngitis/tonsillitis, acute bacterial exacerbation of

chronic bronchitis, community-acquired pneumonia, acute maxillary sinusitis, acute otitis media, uncomplicated skin and skin structure infections. Disseminated *M. intracellulare*. Treatment (with other antimycobacterials) and prophylaxis of disseminated *Mycobacterium avium* complex (MAC).

Adults: Pharyngitis/tonsillitis: 250mg every 12 hours for 10 days. Bronchitis: 250mg-500mg every 12 hours for 7-14 days. CAP, skin and skin structures: 250mg every 12 hours for 7-14 days. Sinusitis: 500mg every 12 hours for 14 days. MAC: 500mg every 12 hours continue indefinitely if improvement occurs. CrCl <30mL/min: ½ dose. Concomitant atazanavir: ½ dose; consider alternative antibacterial therapy for indications other than MAC.

Children: <6 months: not recommended. Otitis media, pharyngitis/tonsillitis, pneumonia, sinusitis, skin and skin structures: 7.5mg/kg every 12 hours for 10 days. MAC (see literature): 7.5mg/kg every 12 hours; max 500mg twice daily, continue indefinitely if improvement occurs. CrCl <30mL/min: ½ dose. Concomitant atazanavir: ½ dose; consider alternative antibacterial therapy for indications other than MAC.

Contraindications: Concomitant cisapride, pimozide, ergots, HMG-CoA reductase inhibitors extensively metabolized by CYP3A4 (lovastatin or simvastatin). History of QT prolongation or ventricular cardiac arrhythmia (including torsades de pointes). Concomitant colchicine (in renal or hepatic impairment). Cholestatic jaundice/hepatic dysfunction with prior clarithromycin use.

Warnings/Precautions: Discontinue immediately if hepatitis occurs. Severe renal impairment. Proarrhythmic conditions (eg, hypokalemia, hypomagnesemia, bradycardia); avoid. Myasthenia gravis. Elderly. Pregnancy (Cat.C): usually not recommended. Nursing mothers.

Interactions: See Contraindications. Class IA (quinidine, procainamide) or Class III (dofetilide, amiodarone, sotalol) antiarrhythmics: not recommended. Sildenafil, tadalafil, vardenafil: not recommended. Antagonized by CYP3A inducers (eg, efavirenz, nevirapine, rifampicin, rifapentine); use alternative antibacterial treatment. Doses >1000mg/day should not be coadministered with protease inhibitors. Concomitant atazanavir: reduce clarithromycin dose by 50%. Potentiated by CYP3A inhibitors (eg, itraconazole, saquinavir). May potentiate theophylline, omeprazole, phenytoin, digoxin, midazolam, alprazolam, triazolam, cyclosporine, hexobarbital, tacrolimus, alfentanil, disopyramide, bromocriptine, valproate, carbamazepine, tolterodine, itraconazole, methylprednisolone, cimetidine, vinblastine; monitor these and other drugs metabolized by CYP3A. Myopathy/rhabdomyolysis with statins; max 20mg atorvastatin/day, 40mg pravastatin/day; consider use of statin not dependent on CYP3A metabolism (eg, fluvastatin). Reduce colchicine dose if coadministration is necessary. Hypoglycemia with oral hypoglycemics/insulin; carefully

monitor glucose. Oral anticoagulants: frequently monitor INR and prothrombin times. Hypotension with calcium channel blockers metabolized by CYP3A4 (eg, verapamil, amlodipine, diltiazem).

Adverse reactions: GI upset, abnormal taste, headache, rash, increased BUN; hepatotoxicity, QT prolongation, *C. difficile* associated diarrhea, hypersensitivity reactions.

How supplied: XL tabs, tabs-60; Biaxin XL-Pac (14 × 500mg XL tabs)-4; Susp-50mL, 100mL

CLINDAMYCIN

CLEOCIN Pfizer

Lincosamide. Clindamycin (as HCl) 75mg +, 150mg +, 300mg; caps; + contains tartrazine.

Indications: Serious susceptible infections where less toxic antibiotics are inappropriate, including respiratory, skin and soft tissue, septicemia, intraabdominal, female pelvic or genital; bone and joint (inj).

Adults: Take with full glass water. Serious:

150–300mg every 6 hours. More severe:

300–450mg every 6 hours.

Children: Take with full glass water. Serious:

8–16mg/kg per day. More severe: 16–20mg/kg per day. Divide into 3–4 equal doses.

Also: Clindamycin

CLEOCIN PEDIATRIC GRANULES

Clindamycin (as palmitate HCl) 75mg/5mL; for oral soln; cherry flavor.

Children: Take with full glass water. <10kg: at least 37.5mg 3 times daily. Serious: 8–12mg/kg per day. Severe: 13–16mg/kg per day. More severe: 17–25mg/kg per day. Divide into 3–4 equal doses.

Also: Clindamycin

CLEOCIN INJECTION

Clindamycin (as phosphate) 150mg/mL; contains benzyl alcohol.

Adults: Serious: 0.6–1.2g daily. More severe: 1.2–2.7g/day IM or IV. Both: give in 2–4 equally divided doses; max 600mg per IM inj and 4.8g/day.

Children: Neonates: 15–20mg/kg per day. >1 month: 20–40mg/kg per day IM or IV. Both: give in 3–4 equally divided doses. Or: serious infections: 350mg/m² per day; more severe: 400mg/m² per day.

Warnings/Precautions: Not for treatment of meningitis. Discontinue if colitis occurs and treat. Monitor neonates. Allergy. Asthma (75mg, 150mg caps). GI disease (esp. colitis). Monitor blood, renal, and hepatic function in long-term use and in children. Renal or hepatic disease with metabolic aberrations. Pregnancy (Cat.B). Nursing mothers.

Interactions: May potentiate neuromuscular blocking agents. May antagonize erythromycin. Antiperistaltic agents may worsen colitis.

Adverse reactions: Pseudomembranous colitis, diarrhea, GI upset, rash, anaphylaxis, jaundice, renal dysfunction, blood dyscrasias, polyarthritis.

How supplied: Caps 75mg–100; 150mg, 300mg–16, 100; Granules (100mL)–1; Inj (2mL, 4mL vials)–25

DAPTOMYCIN

CUBICIN Cubist

Cyclic lipopeptide. Daptomycin 500mg/vial; lyophilized pwd for IV inj after reconstitution or IV infusion after reconstitution and dilution; preservative-free.

Indications: Susceptible complicated skin and skin structure infections, and *S. aureus* bacteremia including MRSA and MSSA right-sided endocarditis.

Adults: Give by IV inj over 2 minutes or IV infusion over 30 minutes. Skin and skin structure: 4mg/kg once every 24 hours for 7–14 days. *S. aureus* bacteremia: 6mg/kg once every 24 hours for at least 2–6 weeks. Renal impairment (CrCl <30mL/min): increase dosing interval to once every 48 hours; coincide dose for after dialysis.

Children: <18yrs: not recommended.

Warnings/Precautions: Monitor CPK weekly; discontinue if CPK (≥5×ULN) and myopathy occur, or if CPK (≥10×ULN) without myopathy occurs. Monitor for neuropathy, eosinophilic pneumonia. Decreased efficacy observed in patients with moderate baseline renal impairment. Severe hepatic impairment. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Consider suspending statins. Caution with tobramycin. Monitor warfarin.

Adverse reactions: Abnormal liver function tests, elevated CPK, dyspnea; eosinophilic pneumonia (discontinue if develops), peripheral neuropathy, myopathy, rhabdomyolysis.

How supplied: Single-use vials–1

DICLOXACILLIN

DICLOXACILLIN (various)

Penicillinase-resistant penicillin. Dicloxacillin sodium 250mg, 500mg; caps.

Indications: Susceptible infections caused by penicillinase-producing staphylococci. Not for initial therapy in serious, life-threatening infections.

Adults: Take on an empty stomach. ≥40kg: Mild to moderate infections: 125mg every 6hrs. Severe infections: 250mg every 6hrs.

Children: Take on an empty stomach. <40kg: Mild to moderate infections: 12.5mg/kg/day in divided doses every 6hrs. Severe: 25mg/kg/day in divided doses every 6hrs.

Warnings/Precautions: Significant allergy/asthma. Monitor blood, renal, and hepatic function in long-term use. Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid concomitant tetracyclines, aminoglycosides. Serum levels increased by probenecid. May reduce anticoagulant response: monitor PT.

Adverse reactions: GI upset, hypersensitivity reactions, neurotoxic reactions, blood dyscrasias; *C. difficile* associated diarrhea.

How supplied: Contact supplier.

DORIPENEM**DORIBAX** Janssen

Carbapenem. Doripenem (as monohydrate) 250mg/vial, 500mg/vial; pwd; for IV infusion after constitution and dilution; preservative-free.

Indications: Susceptible complicated intra-abdominal and complicated urinary tract infections (including pyelonephritis).

Adults: Give by IV infusion over 1hr; may switch to oral antibiotics after 3 days. ≥ 18 yrs (CrCl > 50 mL/min): Intra-abdominal: 500mg every 8hrs for 5–14 days. UTI, pyelonephritis: 500mg every 8hrs for 10–14 days. CrCl 30–50 mL/min: 250mg every 8hrs; CrCl > 10 – < 30 mL/min: 250mg every 12hrs.

Children: < 18 yrs: not established.

Contraindications: Beta-lactam allergy.

Warnings/Precautions: Do not administer by inhalation. CNS disorders. Renal impairment. Pregnancy (Cat.B). Nursing mothers.

Interactions: Antagonizes valproic acid (monitor valproate frequently). Potentiated by probenecid (not recommended).

Adverse reactions: Headache, nausea, diarrhea (may be serious; evaluate if occurs), rash, phlebitis, anemia, elevated hepatic enzymes; hypersensitivity reactions, *C. difficile*-associated diarrhea, seizures, pneumonitis with inhalation use.

How supplied: Single-use vials–1, 10

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for 1 day; then 1–2mg/lb daily in 1–2 doses; max 2mg/lb daily. > 100 lbs: 100 mg orally every 12 hours. Postexposure prophylaxis of inhalational anthrax, or treatment of cutaneous anthrax: > 8 years (> 45 kg): as adult; > 8 years (≤ 45 kg) or ≤ 8 years: 2.2 mg/kg orally every 12 hours. Treatment of inhalational, GI, or oropharyngeal anthrax, or cutaneous anthrax with systemic involvement, extensive edema, or head/neck lesions: > 8 years (> 45 kg): use an IV form first at 100 mg every 12 hours (w. 1 or 2 other antimicrobials), then switch to oral form at same dose; > 8 years (≤ 45 kg) or ≤ 8 years: 2.2 mg/kg IV every 12 hours (w. 1 or 2 other antimicrobials), then switch to oral form at same dose. Treat for a total of 60 days.

Warnings/Precautions: Monitor blood, renal, and hepatic function in long-term use. Sunlight or UV light. Asthma (syrup). Pregnancy (Cat.D), nursing mothers: usually not recommended.

Interactions: May increase digoxin levels. Antacids, iron, zinc, calcium, magnesium, urinary alkalizers reduce absorption. Avoid concomitant penicillins, methoxyflurane. Carbamazepine, hydantoin may decrease effectiveness. Monitor prothrombin time with oral anticoagulants. Oral contraceptives may be less effective.

Adverse reactions: Photosensitivity, GI upset, rash, blood dyscrasias, hepatotoxicity.

How supplied: Caps 50mg–50; 100mg–50, 500; Syrup–10z, pt; Susp–20z; Tabs–Contact supplier.

DOXYCYCLINE**VIBRAMYCIN** Pfizer

Tetracycline. Doxycycline (as hyclate) 50mg, 100mg; caps.

Also: Doxycycline

VIBRAMYCIN SYRUP

Doxycycline (as calcium) 50mg/5mL; raspberry-apple flavor; contains sulfites.

Also: Doxycycline

VIBRAMYCIN SUSPENSION

Doxycycline 25mg/5mL; raspberry flavor.

Also: Doxycycline

VIBRA-TABS (various)

Doxycycline (as hyclate) 100mg; tabs.

Indications: Tetracycline-susceptible infections including respiratory, genitourinary, rickettsial, trachoma. Postexposure prophylaxis and treatment of anthrax.

Adults: Take with fluids. 100mg every 12 hours for 1 day; then 100mg daily; max 200mg daily. Postexposure prophylaxis of inhalational anthrax, or treatment of cutaneous anthrax: 100mg orally every 12 hours (start as soon as possible after exposure). Treatment of inhalational, GI, or oropharyngeal anthrax, or cutaneous anthrax with systemic involvement, extensive edema, or head/neck lesions: use an IV form initially at 100mg IV every 12 hours (w. 1 or 2 other antimicrobials), then switch to oral form at 100mg every 12 hours. Treat for a total of 60 days.

Children: < 8 years: usually not recommended. ≥ 8 years (≤ 100 lbs): 2mg/lb divided in 2 doses

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ERTAPENEM**INVANZ** Merck

Carbapenem. Ertapenem (as sodium) 1g; pwd for IV infusion after reconstitution and dilution; or for IM inj after reconstitution; sodium content 6mEq/g.

Indications: Susceptible moderate to severe infections including complicated intraabdominal, complicated skin and skin structure, community-acquired pneumonia, complicated UTIs, acute pelvic infections. Prevention of surgical site infection following elective colorectal surgery in adults.

Adults and Children: Give by IV infusion over 30 minutes for up to 14 days; or, give by IM inj for up to 7 days (for IM: see note). < 3 months: not recommended. 3 months–12 yrs: 15mg/kg twice daily (max 1g/day). ≥ 13 yrs: 1g once daily; renal dysfunction (CrCl ≤ 30 mL/min): 500mg once daily (give supplemental 150mg after session if dosed within 6 hours of hemodialysis). Intraabdominal: treat 5–14 days. Skin and skin structure: treat 7–14 days. Pneumonia, UTIs: treat 10–14 days (may switch to oral antibiotic after 3 days). Pelvic: treat 3–10 days. Adult prophylaxis in colorectal surgery: 1g single IV dose given 1 hour prior to surgical incision.

Contraindications: Penicillin, cephalosporin, or other β -lactam allergy.

Warnings/Precautions: CNS disorders (eg, brain lesions, seizure history). Renal dysfunction. Avoid extravasation. Monitor renal, hepatic, and

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hematopoietic function in prolonged use. Elderly. Labor & delivery. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by probenecid: not recommended. Antagonizes valproic acid or divalproex sodium: not recommended; consider other antibacterials.

Adverse reactions: GI upset, inj site reactions (thrombophlebitis/phlebitis), headache, CNS effects (dizziness, altered mental state, rarely: seizures), edema, dyspnea, fever.

Note: For IM use, reconstitute with lidocaine 1% only; see literature.

How supplied: Vials (1g)-10

ERYTHROMYCIN

ERY-TAB Arbor

Macrolide. Erythromycin (as base) 250mg, 333mg, 500mg; e-c tabs.

Indications: Susceptible infections including upper and lower respiratory, skin and soft tissue, genitourinary, Legionnaires' disease, pertussis, listeriosis.

Adults: 250mg every 6 hours, 500mg every 12 hours, or 333mg every 8 hours; max 4g/day; twice daily dosing max 1g/day. Legionnaires: 1-4g/day in divided doses.

Children: 30-50mg/kg/day in divided doses; max 100mg/kg/day.

Contraindications: Concomitant cisapride, pimozide.

Warnings/Precautions: Hepatic dysfunction.

Myasthenia gravis. Pregnancy (Cat.B). Nursing mothers.

Interactions: See Contraindications. May potentiate or be potentiated by drugs metabolized by CYP450 (eg, carbamazepine, cyclosporine, tacrolimus, hexobarbital, phenytoin, alfenitil, disopyramide, bromocriptine, valproate). May potentiate warfarin, triazolam, midazolam, methylprednisolone, digoxin, theophylline, ergotamine. Avoid use with statins (rhabdomyolysis).

Adverse reactions: GI upset, abdominal pain, anorexia, hepatic dysfunction, rash, superinfection; pseudomembranous colitis, (rare).

How supplied: 250mg-30, 40, 100, 500; 333mg-30, 100, 500; 500mg-100

GENTAMICIN

GENTAMICIN INJECTION (various)

Aminoglycoside. Gentamicin sulfate 40mg/mL; IM, or IV inj after dilution; contains sulfites.

Indications: Serious susceptible infections.

Adults: Obesity: Base dose on lean body mass. Usual duration 7-10 days. 1mg/kg IM or IV every 8 hours; max 5mg/kg/day. For alternative dosing regimens (eg, extended intervals) see literature.

Children: Premature and infants <1 week: 2.5mg/kg every 12 hours. Neonates: 2.5mg/kg every 8 hours. Others: 2-2.5mg/kg every 8 hours.

Warnings/Precautions: Monitor for nephro- and neurotoxicity; avoid peak serum levels >12micrograms/mL (when dosed at conventional

intervals) and trough levels >2micrograms/mL. Renal impairment: reduce dose, see literature; maintain adequate hydration. Prolonged use or excessive doses. Asthma. Neuromuscular disorders. Elderly. Pregnancy (Cat.D): not recommended.

Interactions: Avoid concomitant furosemide, ethacrynic acid, other nephro/neurotoxic drugs including cephalosporins. May potentiate neuromuscular blockade.

Adverse reactions: Nephro- or neurotoxicity, respiratory depression, lethargy, confusion, depression, visual disturbances, elevated liver enzymes, blood dyscrasias.

How supplied: Contact supplier.

IMIPENEM + CILASTATIN SODIUM

PRIMAXIN IV 250 Merck

Carbapenem (thienamycin) + dehydropeptidase I inhibitor. Imipenem 250mg, cilastatin sodium 250mg; IV inj; sodium content 3.2mEq/g imipenem.

Also: Imipenem + Cilastatin sodium

PRIMAXIN IV 500

Imipenem 500mg, cilastatin sodium 500mg; IV inj; sodium content 3.2mEq/g imipenem.

Indications: Serious susceptible infections including bacterial septicemia, lower respiratory tract, urinary tract, skin and skin structure, bone and joint, intraabdominal, gynecologic, polymicrobial infections, endocarditis.

Adults: See literature. Base dose on imipenem component. Give by IV infusion. Uncomplicated UTI: 250mg every 6 hours. Complicated UTI: 500mg every 6 hours. Other infections: Mild: 250-500mg every 6 hours; moderate: 500mg every 6-8 hours or 1g every 8 hours; severe: 500mg-1g every 6 hours or 1g every 8 hours; max 50mg/kg per day or 4g/day (whichever is less). Reduce dose if CrCl ≤70mL/min or body wt <70kg. CrCl ≤5mL/min: not recommended unless hemodialysis starts within 48 hours.

Children: <30kg and renal dysfunction: not recommended. Give by IV infusion. CNS infections: not recommended (seizure risk). Non-CNS infections (if ≥1.5kg): <1week of age: 25mg/kg every 12hours; 1-4weeks: 25mg/kg every 8hours; 4weeks-3months: 25mg/kg every 6hours; ≥3months: 15-25mg/kg every 6hours. Max 2g/day if susceptible or 4g/day if moderately susceptible; doses up to 90mg/kg per day have been used in older children with cystic fibrosis.

Also: Imipenem + Cilastatin sodium

PRIMAXIN IM 500

Imipenem 500mg, cilastatin sodium 500mg; IM inj; sodium content 2.8mEq/g imipenem.

Indications: Susceptible mild to moderate infections including lower respiratory tract, intraabdominal, skin and skin structure, gynecologic. IM form not for severe or life-threatening infections.

Adults: Base dose on imipenem component.

Lower respiratory tract, skin and skin structure, gynecologic: mild to moderate: 500–750mg every 12 hours. Intraabdominal: 750mg every 12 hours. CrCl <20mL/min: not recommended.

Children: Not recommended.

Contraindications: IM: Allergy to amide-type local anesthetics. Heart block. Severe shock.

Warnings/Precautions: Penicillin, cephalosporin, or other allergy. CNS disorders (esp. brain lesions or seizures). Renal impairment: reduce dose.

Hemodialysis: see literature. GI disease (esp. colitis). IM: prepare with lidocaine (see literature). Pregnancy (Cat.C): Nursing mothers.

Interactions: Concomitant ganciclovir (increased seizure risk), probenecid: not recommended. May antagonize valproic acid; monitor (consider alternative therapy).

Adverse reactions: Local reactions, GI upset, confusion, myoclonia, seizures, changes in serum electrolytes, dizziness, somnolence, anaphylaxis, blood dyscrasias, elevated liver enzymes, fever, rash, hypotension.

How supplied: Vials (IV)–25

Vials (IM)–10

KANAMYCIN

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KANAMYCIN INJECTION (various)

Aminoglycoside. Kanamycin sulfate 500mg/vial, 1g/vial; soln for IM inj or IV infusion, intraperitoneal, nebulization, irrigation after dilution; contains sulfites.

Indications: Short-term treatment of serious susceptible infections.

Adults and Children: Obesity: base dose on lean body mass. IM: inject into upper outer quadrant of gluteal muscle. 15mg/kg/day in divided doses every 12 hours; or 15mg/kg/day in divided doses every 6–8 hours if continuously high blood levels desired. IV: infuse slowly over 30–60 mins; 15mg/kg/day in 2–3 divided doses. Usual duration: 7–10 days. Intraperitoneal, nebulization, irrigation: see literature. All routes: max 1.5g/day. Renal impairment: adjust dose based on serum levels or reduce frequency; see literature.

Warnings/Precautions: Monitor for nephro- and neurotoxicity; avoid peak serum levels >35micrograms/mL and trough levels >10micrograms/mL. Discontinue or adjust dose if auditory, vestibular, or renal dysfunction develops; monitor serum levels periodically. Monitor BUN, CrCl, serum creatinine levels before, frequently during, and after therapy. Perform audiogram in high-risk patients. Maintain adequate hydration. Prolonged use or excessive doses. Asthma. Muscular disorders (eg, myasthenia gravis, parkinsonism, or infant botulism). Elderly. Premature or neonatal infants. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Avoid concomitant furosemide, ethacrynic acid, mannitol. Diuretics may increase toxicity. Increased risk of neurotoxicity and/or

nephrotoxicity with concurrent or sequential polymyxin B, colistin, amphotericin B, other nephrotoxic or neurotoxic drugs; avoid. May potentiate neuromuscular blockade, respiratory paralysis with anesthetics, neuromuscular blockers. May be antagonized by concomitant penicillins, cephalosporins.

Adverse reactions: Nephro- or ototoxicity, neurotoxicity, neuromuscular blockade (eg, muscular paralysis, apnea), local irritation or pain; rare: rash, drug fever, headache, GI upset, paresthesia.

How supplied: Contact supplier.

LEVOFLOXACIN

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LEVAQUIN TABS Janssen

Quinolone. Levofloxacin 250mg, 500mg, 750mg.

Also: Levofloxacin

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LEVAQUIN ORAL SOLUTION

Levofloxacin 25mg/mL; contains benzyl alcohol.

Also: Levofloxacin

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LEVAQUIN INJECTION CONCENTRATE

Levofloxacin 25mg/mL; soln for slow IV infusion after dilution; preservative-free.

Also: Levofloxacin

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LEVAQUIN INJECTION PREMIXED

Levofloxacin 5mg/mL; soln for slow IV infusion; preservative-free.

Indications: Susceptible bacterial infections including acute sinusitis, acute exacerbations of chronic bronchitis, nosocomial or community-acquired pneumonia (CAP), UTIs, acute pyelonephritis, chronic bacterial prostatitis, skin and skin structure infections. Inhalation anthrax (post-exposure): to reduce incidence or progression of disease (see literature).

Adults: ≥18yrs: Regimen depends on pathogen type (see literature). Tabs: take with water. Oral soln: take on empty stomach. IV: infuse over 60 minutes (250mg or 500mg), or over 90 minutes (750mg). Bronchitis: 500mg once daily for 7 days. Nosocomial pneumonia: 750mg once daily for 7–14 days. CAP: 500mg once daily for 7–14 days or 750mg once daily for 5 days. Sinusitis: 500mg once daily for 10–14 days or 750mg once daily for 5 days. Uncomplicated skin and skin structure: 500mg once daily for 7–10 days; complicated: 750mg once daily for 7–14 days. Prostatitis: 500mg once daily for 28 days. Uncomplicated UTIs: 250mg once daily for 3 days. Complicated UTIs, acute pyelonephritis: 250mg once daily for 10 days or 750mg once daily for 5 days. Postexposure inhalational anthrax: 500mg once daily for 60 days (start as soon as possible after exposure). Renal impairment (CrCl <50mL/min): reduce dose; see literature.

Children: Inhalation anthrax (post-exposure): ≥6months: <50kg: 8mg/kg twice daily for 60 days; max 250mg/dose. >50kg: 500mg once daily for 60 days.

Warnings/Precautions: Increased risk of tendinitis and tendon rupture esp. in patients

>60yrs, or those with kidney, heart or lung transplants. Maintain adequate hydration. Renal impairment. CNS disorders (eg, cerebral arteriosclerosis, epilepsy) that increase seizure risk. Avoid in proarrhythmic conditions (eg, bradycardia, cardiomyopathy) or hypokalemia. Discontinue if rash, jaundice, other signs of hypersensitivity, hypoglycemic reactions, phototoxicity, CNS stimulation, or hepatitis occurs. Discontinue if tendon pain, inflammation or rupture occurs. Monitor blood, renal, hepatic, and hematopoietic function. Reevaluate if peripheral neuropathy occurs. Avoid excessive sun or UV light. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Avoid drugs that prolong QT interval (eg, Class IA or Class III antiarrhythmics). Avoid oral form with antacids containing magnesium or aluminum, sucralate, didanosine, iron, zinc, other metal cations (separate dosing by at least 2 hours). Increased risk of tendonitis and tendon rupture with corticosteroids. Monitor theophylline, warfarin, antidiabetic agents. Caution with other drugs that may lower seizure threshold (eg, NSAIDs).

Adverse reactions: GI upset, CNS stimulation, dizziness, headache, pruritus, rash, abdominal pain, tendonitis/rupture, local reactions (inj); rarely: peripheral neuropathy, hepatotoxicity, photosensitivity, convulsions. Children: also musculoskeletal disorders.

How supplied: Tabs 250mg, 500mg-50; 750mg-20; LEVA-Pak (5 × 750mg tabs)-1; Oral soln-480mL; Inj conc (single-use vials) 20mL, 30mL-1; Inj premixed 50mL, 100mL, 150mL-1

LINEZOLID

ZYVOX Pfizer

Oxazolidinone. Linezolid 400mg, 600mg; tabs.

Also: Linezolid

ZYVOX FOR ORAL SUSPENSION

Linezolid 100mg/5mL; pwd for reconstitution; orange flavor; contains phenylalanine.

Also: Linezolid

ZYVOX I.V. INJECTION

Linezolid 2mg/mL; soln for IV infusion; sodium content 0.38mg/mL.

Indications: Susceptible vancomycin-resistant *E. faecium* (VREF) infections, nosocomial and community-acquired pneumonia, complicated skin and skin structure infections (including diabetic foot infections) without osteomyelitis, uncomplicated skin and skin structure infections.

Adults: Infuse inj over 30–120 minutes; switch to oral form when appropriate. VREF: 600mg every 12 hrs for 14–28 days. Pneumonia, complicated skin and skin structure: 600mg every 12 hrs for 10–14 days. Uncomplicated skin and skin structure (oral forms only): 12–17yrs: 600mg every 12 hrs; >17yrs: 400mg every 12 hrs; both for 10–14 days. MRSA: 600mg every 12 hrs.

Children: Infuse inj over 30–120 minutes; switch to oral form when appropriate. Neonates <7 days: see literature. 0–11yrs: VREF: 10mg/kg every 8 hrs for 14–28 days; pneumonia, complicated skin and skin structure: 10mg/kg every 8 hrs for 10–14 days. Uncomplicated skin and skin structure (oral forms only): <5yrs: 10mg/kg every 8 hrs; 5–11yrs: 10mg/kg every 12 hrs; both for 10–14 days.

Contraindications: Uncontrolled hypertension. Pheochromocytoma. Thyrotoxicosis. Carcinoid syndrome. During or within 2 weeks of MAOIs (eg, phenelzine, isocarboxazid). Concomitant sympathomimetics (eg, pseudoephedrine), vasopressive agents (eg, epinephrine, norepinephrine), dopaminergics (eg, dopamine, dobutamine), SSRIs, tricyclic antidepressants, triptans, meperidine, buspirone.

Warnings/Precautions: History of seizures. Monitor CBC's weekly (esp. if otherwise at risk). Consider discontinuing if myelosuppression occurs or worsens. Therapy >28 days. Peripheral and optic neuropathy. Monitor visual function if treatment ≥3 months and if new visual symptoms occur. Diabetes; monitor for hypoglycemia, if occurs, reduce dose or discontinue. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Avoid large amounts of dietary tyramine (keep <100mg/meal). May be antagonized by carbamazepine, phenytoin, phenobarbital. Possible serotonin syndrome with serotonergic agents. Caution with myelosuppressants.

Adverse reactions: GI upset, headache, insomnia, constipation, rash, dizziness, pruritus, tongue discoloration, taste alteration, myelosuppression (eg, anemia, thrombocytopenia), lactic acidosis, hypoglycemia, blurred vision, convulsion.

How supplied: Tabs-20, 100; Susp-150mL; Inj (100mL, 200mL, 300mL)-1

MEROPENEM

MERREM AstraZeneca

Carbapenem. Meropenem 500mg, 1g; pwd for IV inj after reconstitution; sodium content 3.92mEq/g.

Indications: Susceptible infections including complicated skin and skin structure, intraabdominal infections, bacterial meningitis.

Adults: Give by IV infusion over 15–30 mins or IV bolus over 3–5 mins (for doses = 1g). Skin and skin structure: 500mg every 8hrs. Intraabdominal: 1g every 8hrs. Renal impairment: CrCl 26–50mL/min: give recommended dose every 12hrs; CrCl 10–25mL/min: give ½ of recommended dose every 12hrs; CrCl <10mL/min: give ½ of recommended dose every 24hrs.

Children: Give by IV infusion over 15–30 mins or IV bolus over 3–5 mins. <3 months: not recommended. ≥3 months: Skin and skin structure: 10mg/kg (max 500mg) every 8hrs. Intraabdominal: 20mg/kg (max 1g) every 8hrs. Meningitis: 40mg/kg (max 2g) every 8hrs.

Contraindications: Penicillin, cephalosporin, or other β-lactam allergy.

Warnings/Precautions: CNS disorders. History of seizures. Renal impairment. Monitor renal, hepatic, and hematopoietic function in long-term use. Evaluate if diarrhea develops. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by probenecid: not recommended. May antagonize valproic acid; monitor (consider alternative therapy).

Adverse reactions: Local reactions, headache, nausea, vomiting, diarrhea, constipation, rash, pruritus, apnea, sepsis, anemia, pain; *C. difficile*-associated diarrhea, possible neuromotor impairment (eg, seizures, paresthesias).

How supplied: Single-use vials-1

METRONIDAZOLE

FLAGYL Pfizer

Nitroimidazole. Metronidazole 250mg, 500mg; scored tabs.

Also: Metronidazole

FLAGYL 375

Metronidazole 375mg; caps.

Indications: Susceptible anaerobic infections, including intraabdominal, skin and skin structures, gynecologic, bacterial septicemia, bone and joint, CNS, lower respiratory tract, endocarditis.

Adults: Parenteral form usually used first. 7.5mg/kg every 6 hours for 7-10 days; max 4g/day.

Children: Not recommended.

Also: Metronidazole

FLAGYL I.V. INJECTION

Metronidazole 500mg/100mL.

Indications: Susceptible anaerobic infections. Surgical prophylaxis.

Adults: Infuse over 1 hour. Anaerobic infections: 15mg/kg (loading dose), then 7.5mg/kg every 6 hours; max 4g/day. Prophylaxis: see literature.

Children: Not recommended.

Contraindications: Pregnancy (1st trimester for trichomoniasis).

Warnings/Precautions: CNS disease. Discontinue if neurological symptoms occur. Severe hepatic disease: reduce dose. Candidiasis. History of blood dyscrasias. Monitor leukocytes before and after therapy. Elderly: monitor serum levels. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid alcohol during and for 3 days after use. Do not give within 2 weeks of disulfiram (possible psychotic reactions). May potentiate oral anticoagulants, phenytoin, lithium. Antagonized by phenobarbital, phenytoin, other hepatic enzyme inducers. May impair phenytoin clearance. Potentiated by cimetidine, other hepatic enzyme inhibitors. Interferes with serum chemistry tests.

Adverse reactions: Seizures, peripheral neuropathy, GI upset, anorexia, constipation, headache, metallic taste, ECT changes, dysuria.

How supplied: Tabs-50, 100; Caps 375mg-50; IV-24

MOXIFLOXACIN

AVELOX Bayer

Quinolone. Moxifloxacin (as HCl) 400mg; tabs.

Also: Moxifloxacin

AVELOX I.V.

Moxifloxacin 400mg/250mL; soln for IV infusion; preservative-free.

Indications: Susceptible bacterial infections including acute sinusitis, acute exacerbations of chronic bronchitis, community acquired pneumonia, skin and skin structure, complicated intra-abdominal infections.

Adults: ≥18yrs: 400mg once daily. Sinusitis: treat for 10 days. Bronchitis: treat for 5 days. Pneumonia: treat for 7-14 days. Skin and skin structure: treat for 7 days, if complicated: 7-21 days. Intra-abdominal: treat for 5-14 days; use IV form first. IV form: infuse over 60 minutes.

Children: <18yrs: not recommended.

Warnings/Precautions: Increased risk of tendinitis and tendon rupture esp. in patients >60yrs, or those with kidney, heart or lung transplants. CNS disorders (eg, seizures). Discontinue if tendon pain, inflammation, or rupture occurs; or if allergic reaction or CNS events occur. Severe hepatic impairment. History of QT prolongation or proarrhythmic conditions (eg, hypokalemia, bradycardia, acute myocardial ischemia). Do not exceed recommended dose or infusion rate; may increase QT prolongation. Maintain adequate hydration. Avoid excessive sun or UV light. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Avoid drugs that prolong QTc interval (eg, Class IA or Class III antiarrhythmics, erythromycin, antipsychotics, tricyclics). Oral forms: take at least 4 hours before or 8 hours after iron, zinc, magnesium, aluminum, sucralose, didanosine (buffered forms). Increased risk of tendinitis and tendon rupture with corticosteroids. Monitor warfarin. Concomitant NSAIDs may increase seizure risk.

Adverse reactions: GI upset, dizziness, headache, convulsions, other CNS effects, abdominal pain, inj site reaction, taste perversion; hypersensitivity reactions, abnormal liver function tests, rash, phototoxicity (discontinue if occurs), tendinitis/rupture; rare: peripheral neuropathy.

How supplied: Tabs-30; ABC Pack (5 tabs)-1; Premixed IV soln (250mL)-1

NAFCILLIN

NAFCILLIN INJECTION (various)

Penicillinase-resistant penicillin. Nafcillin sodium 1g/vial, 2g/vial, 10g/vial; pld for deep IM inj after reconstitution, IV inj or IV drip after reconstitution and dilution.

Indications: Susceptible infections due to penicillinase-producing staphylococci.

Adults: Give by deep IM gluteal inj, or IV inj over 5-10 mins, or short-term IV drip for 24-48 hours. IM:

500mg every 4–6 hours. IV: 500mg every 4 hours. Severe infections: 1g IM or IV every 4 hours; treat for at least 14 days, then continue for at least 48 hours after becoming afebrile, asymptomatic, or (–) cultures. Endocarditis or osteomyelitis: may need longer therapy; see literature. Switch to oral therapy as soon as clinically indicated.

Children: Give by deep IM gluteal inj only. Neonates: 10mg/kg twice daily. Infants and children <40kg: 25mg/kg twice daily.

Warnings/Precautions: Cephalosporin or other allergy: not recommended. Asthma. Renal impairment: consider dose reduction. Do CBCs, BUN, urinalysis, creatinine levels prior to and weekly during therapy. Monitor renal, hepatic and hematopoietic function in prolonged use. Elderly (esp. IV route). Newborns (monitor). Pregnancy (Cat.B). Nursing mothers.

Interactions: May be antagonized by tetracycline; avoid. Potentiated by probenecid.

Adverse reactions: Inj site reactions, rash, serum sickness, GI upset, anaphylaxis, neuropathy, nephropathy, blood dyscrasias.

How supplied: Contact supplier.

NEOMYCIN + POLYMYXIN B

NEOSPORIN G.U. King

Neomycin (as sulfate) 40mg, polymyxin B sulfate 200000units; per mL; soln for bladder irrigation after dilution; amp; vial (contains parabens).

Indications: Short-term (up to 10 days) prophylaxis of bacteriuria and gram (–) rod septicemia associated with indwelling urinary catheters.

Adults: Dilute 1mL in 1L of normal saline and use daily as continuous bladder irrigant; max 10 days.

Children: Not recommended.

Contraindications: Nonintact bladder. Irrigation of wounds, burns. Recent lower urinary tract surgery.

Warnings/Precautions: Impaired renal function. Dehydration. Monitor urine cultures. Elderly. Infants. Pregnancy (Cat.D).

Adverse reactions: Superinfection, local irritation, ototoxicity, nephrotoxicity.

How supplied: Amps (1mL)–10, 50
Multidose vial (20mL)–1

NITROFURANTOIN

MACRODANTIN Warner Chilcott

Antibiotic. Nitrofurantoin macrocrystals 25mg, 50mg, 100mg; caps.

Indications: Susceptible UTIs.

Adults: Take with food. 50–100mg 4 times a day for at least 7 days. Long-term use: 50–100mg at bedtime.

Children: Take with food. <1month: not recommended. ≥1month: 5–7mg/kg per day in 4 divided doses for at least 7 days. Long-term use: 1mg/kg per day in 1–2 divided doses.

Contraindications: Anuria, oliguria, creatinine clearance <60mL/min. Neonates <1 month of age. Labor & delivery. Pregnancy at term. Nursing mothers.

Warnings/Precautions: Renal insufficiency. G6PD or Vit. B deficiency. Anemia. Diabetes. Electrolyte imbalance. Asthma. Discontinue if pulmonary, hepatic disorders, hemolysis, or peripheral neuropathy occur. Monitor renal function in long-term use. Debilitated. Pregnancy (Cat.B).

Interactions: Avoid antacids containing magnesium trisilicate. May be antagonized by uricosurics. May cause false (+) glucose test with Benedict's or Fehling's solution.

Adverse reactions: GI disturbances, headache, pulmonary disorders, hepatic damage, peripheral neuropathy, hemolytic anemia, dizziness, anorexia, alopecia, exfoliative dermatitis, Stevens-Johnson syndrome, anaphylaxis, blood dyscrasias, aplastic anemia.

How supplied: Caps 25mg–100; 50mg, 100mg–100, 500, 1000

OFLOXACIN

OFLOXACIN TABLETS (various)

Quinolone. Ofloxacin 200mg, 300mg, 400mg; tabs.

Indications: Susceptible infections including acute bacterial exacerbation of chronic bronchitis, community-acquired pneumonia, acute pelvic inflammatory disease (PID), acute, uncomplicated cervical and urethral gonorrhea, urethritis, cervicitis, uncomplicated cystitis, uncomplicated skin and skin structure, complicated UTIs, prostatitis.

Adults: ≥18yrs: Take with full glass water. Bronchitis, pneumonia, uncomplicated skin and skin structure: 400mg every 12 hours for 10 days. Urethritis, cervicitis: 300mg every 12 hours for 7 days. Gonorrhea: 400mg once as a single dose. PID: 400mg every 12 hours for 10–14 days. Uncomplicated cystitis due to *E. coli* or *K. pneumoniae*: 200mg every 12 hrs for 3 days. Other uncomplicated cystitis: 200mg every 12 hrs for 7 days. Complicated UTIs: 200mg every 12 hrs for 10 days. Prostatitis due to *E. coli*: 300mg every 12 hours for 6 weeks. Severe hepatic impairment: max 400mg/day. Renal impairment: CrCl 20–50mL/min: give normal dose (loading dose) and increase dosing interval to 24 hours. CrCl <20mL/min: give normal dose once (loading dose) then ½ normal dose and increase dosing interval to 24 hours.

Children: <18yrs: not recommended.

Warnings/Precautions: Increased risk of tendinitis or tendon rupture esp. in patients >60yrs, or those with kidney, heart, or lung transplants. CNS disorders (eg, cerebral arteriosclerosis, epilepsy) that increase seizure risk. Discontinue if CNS effects, photosensitization, allergic reactions, peripheral neuropathy, or tendon pain, inflammation or rupture occurs. History of QT prolongation or proarrhythmic conditions (eg, hypokalemia, bradycardia, recent MI). May mask symptoms of syphilis; test for syphilis before treating gonorrhea then follow-up after 3 months. Maintain adequate hydration. Avoid excessive sun or UV light. Monitor blood, renal, and

hepatic function in prolonged use. Renal or severe hepatic impairment. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Avoid drugs that prolong QTc interval (eg, Class IA or Class III antiarrhythmics, erythromycin, antipsychotics, tricyclics). Separate dosing of magnesium- or aluminum containing antacids and didanosine, sucralfate, iron, zinc, other metal cations (separate dosing by 2hrs). Increased risk of seizures with NSAIDs. May potentiate cyclosporine, theophylline, warfarin; monitor. May potentiate insulin, oral hypoglycemics (discontinue ofloxacin if hypoglycemia occurs). Increased risk of tendinitis and tendon rupture with corticosteroids. Monitor drugs metabolized by CYP450.

Adverse reactions: GI upset, dizziness, rash, pruritus, dysgeusia; CNS stimulation (eg, convulsions, nervousness, anxiety), hypersensitivity reactions, phototoxicity, tendinitis/rupture; rarely: peripheral neuropathy.

How supplied: Contact supplier.

OXACILLIN

R

OXACILLIN INJECTION (various)

Penicillinase-resistant penicillin. Oxacillin sodium 1g/vial, 2g/vial, 10g/vial; pwd for IM or IV inj after reconstitution, or IV drip after reconstitution and dilution; sodium content 2.5mEq/g oxacillin sodium.

Indications: Susceptible infections due to penicillinase-producing staphylococci.

Adults: Give by IM gluteal inj, or slow IV inj over 10 mins, or IV drip. Mild-to-moderate infections: 250–500mg IM or IV every 4–6 hours. Severe infections: 1g IM or IV every 4–6 hours; treat for at least 14 days, then continue for at least 48 hours after becoming afebrile, asymptomatic, or (–) cultures. Endocarditis or osteomyelitis: may need longer therapy; see literature. Switch to oral therapy as soon as clinically indicated.

Children: Give by IM gluteal inj, or slow IV inj over 10 mins, or IV drip. Premature and neonates: 25mg/kg/day IM or IV. Infants and children <40kg: Mild-to-moderate infections: 50mg/kg/day IM or IV in divided doses every 6 hours; severe infections: 100mg/kg/day IM or IV in divided doses every 4–6 hours; treat for at least 14 days, then continue for at least 48 hours after becoming afebrile, asymptomatic, or (–) cultures. Endocarditis or osteomyelitis: may need longer therapy; see literature. Switch to oral therapy as soon as clinically indicated.

Warnings/Precautions: Cephalosporin or other allergy: not recommended. Asthma. Renal impairment: consider dose reduction. Do CBCs, BUN, urinalysis, creatinine levels prior to and weekly during therapy. Monitor renal, hepatic and hematopoietic function in prolonged use. Elderly (esp. IV route). Newborns (monitor). Pregnancy (Cat.B). Nursing mothers.

Interactions: May be antagonized by tetracycline; avoid. Potentiated by probenecid.

Adverse reactions: Inj site reactions, rash, serum sickness, GI upset, anaphylaxis, neuropathy, nephropathy, blood dyscrasias, hepatotoxicity.

How supplied: Contact supplier.

PENICILLIN VK

R

PENICILLIN VK TABLETS (various)

Penicillinase-sensitive penicillin. Penicillin V (as potassium) 250mg, 500mg; tabs.

Also: Penicillin VK

R

PENICILLIN VK ORAL SUSPENSION

Penicillin V (as potassium) 125mg/5mL, 250mg/5mL.

Indications: Penicillin-sensitive infections.

Adults: Take on an empty stomach. 125–500mg every 6–8 hours.

Children: Take on an empty stomach. 15–56mg/kg per day in 3–6 divided doses.

Warnings/Precautions: Cephalosporin, imipenem, or other allergy: not recommended. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid concomitant erythromycin, sulfonamides. Potentiated by probenecid.

Adverse reactions: GI upset, urticaria, anaphylaxis.

How supplied: Contact supplier.

PIPERACILLIN + TAZOBACTAM

R

ZOSYN 2.25g Pfizer

Broad-spectrum penicillin + β -lactamase inhibitor.

Piperacillin 2g, tazobactam 0.25g; IV; sodium content 2.35mEq/g of piperacillin.

Also: Piperacillin + Tazobactam

R

ZOSYN 3.375g

Piperacillin 3g, tazobactam 0.375g; IV; sodium content 2.35mEq/g of piperacillin.

Also: Piperacillin + Tazobactam

R

ZOSYN 4.5g

Piperacillin 4g, tazobactam 0.5g; IV; sodium content 2.35mEq/g of piperacillin.

Indications: Susceptible skin and skin structure infections, moderately severe community-acquired pneumonia, moderate to severe nosocomial pneumonia, postpartum endometritis, pelvic inflammatory disease, complicated appendicitis, peritonitis.

Adults: Infuse over 30 minutes. Usually 3.375g every 6 hrs for 7–10 days; renal impairment (CrCl 20–40mL/min): 2.25g every 6 hrs; CrCl <20mL/min: 2.25g every 8 hrs; hemodialysis or peritoneal dialysis: 2.25g every 12 hrs, give additional 0.75g at end of hemodialysis.

Nosocomial pneumonia: 4.5g every 6 hrs for 7–14 days (give with an aminoglycoside for *P. aeruginosa*); renal impairment (CrCl 20–40mL/min): 3.375g every 6 hrs; CrCl <20mL/min: 2.25g every 6 hrs; hemodialysis or

peritoneal dialysis: 2.25g every 8 hrs, give additional 0.75g at end of hemodialysis.

Children: Not recommended.

Contraindications: Cephalosporin or β -lactamase inhibitor allergy.

Warnings/Precautions: Renal dysfunction. Higher doses increase seizure risk. Cystic fibrosis (increased fever/rash risk). Monitor electrolytes, hematopoiesis; discontinue if bleeding disorders occur. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiated by probenecid. May potentiate non-depolarizing muscle relaxants (eg, vecuronium). Monitor methotrexate, heparin, anticoagulants. False (+) Clinitest or Coomb's test.

Adverse reactions: GI disturbances, headache, insomnia, rash, pruritus, agitation, pain, hypertension, dizziness, edema, local reactions; rare: bleeding.

How supplied: Single-dose vials-10

POLYMYXIN B

POLYMYXIN B INJECTION (various)

Antibiotic. Polymyxin B sulfate 500,000units/vial; pwd for IM, intrathecal inj, IV drip or ophthalmic use after reconstitution.

Indications: Susceptible infections due to *P. aeruginosa* including UTIs, meningitis, bloodstream, and eye infections. Other serious susceptible infections including *H. influenza* meningitis, *E. coli* UTIs, and bacteremia due to *A. aerogenes* and *K. pneumoniae*.

Adults and Children: Infants: up to 40,000units/kg per day IV or IM inj. Adults and children: IV: 15,000-25,000units/kg per day in divided doses every 12 hours; max 25,000units/kg per day. IM: 25,000-30,000units/kg per day in divided doses every 4-6 hours. *P. aeruginosa* meningitis: Give by intrathecal inj only. <2yrs: 20,000units once daily for 3-4 days or 25,000units once every other day, continue with 25,000units once every other day; >2yrs: 50,000units once daily for 3-4 days, then 50,000units once every other day; both: treat for at least 2 weeks after negative CSF cultures and sugar content normalized. Ophthalmic: see literature. Renal impairment: adjust or reduce dose.

Warnings/Precautions: Renal impairment. Monitor renal function before and during therapy; discontinue if nephrotoxicity occurs. Pregnancy: not recommended.

Interactions: Avoid other neurotoxic and/or nephrotoxic drugs (eg, bacitracin, aminoglycosides, colistin). May potentiate neuromuscular blockade with anesthetics and/or muscle relaxants.

Adverse reactions: Nephrotoxicity (eg, albuminuria, azotemia, cylindruria), neurotoxicity (eg, flushing, dizziness, paresthesias), meningeal irritation (intrathecal), drug fever, rash, inj site pain, thrombophlebitis; respiratory paralysis (discontinue if occurs).

How supplied: Contact supplier.

QUINUPRISTIN + DALFOPRISTIN R

SYNERCID King

Streptogramin. Quinupristin/dalfopristin 500mg per vial (as 150mg quinupristin and 350mg dalfopristin); pwd for IV infusion after reconstitution; preservative-free.

Indications: Treatment of serious or life-threatening susceptible infections associated with vancomycin resistant *E. faecium* (VREF) bacteremia. Complicated skin and skin structure infections due to *S. aureus* (methicillin-susceptible) or *S. pyogenes*.

Adults: ≥ 16 years: VREF bacteremia: 7.5 mg/kg every 8 hours; base duration of therapy on infection site and severity. Complicated skin and skin structure: 7.5 mg/kg every 12 hours for at least 7 days.

Children: <16 years: not recommended; doses of 7.5 mg/kg every 8 or 12 hours have been used in a limited number of children under emergency-use conditions (see literature).

Warnings/Precautions: Hepatic insufficiency. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid use with drugs that can cause QTc prolongation. Caution with these and with other drugs metabolized by CYP3A4 (eg, cyclosporine, midazolam, calcium channel blockers, cisapride, vinca alkaloids, steroids, non-nucleoside reverse transcriptase inhibitors, statins, protease inhibitors); monitor appropriately.

Adverse reactions: Inj site reactions, arthralgia, myalgia, GI upset, thrombophlebitis, rash, headache, pruritus.

How supplied: Single-dose vials-10

RIFAMPIN

RIFADIN Sanofi Aventis

Rifamycin. Rifampin 150mg, 300mg; caps.

Also: Rifampin

RIFADIN IV INJECTION

Rifampin 600mg/vial.

Indications: Asymptomatic carriers of *Neisseria meningitidis* to eliminate meningococci from nasopharynx.

Adults: 600mg twice daily for 2 days. Oral: give 1 hour before or 2 hours after meals with water.

Children: <1 month: 5mg/kg every 12 hours for 2 days. ≥ 1 month: 10mg/kg every 12 hours for 2 days; max 600mg per dose. Oral: give 1 hour before or 2 hours after meals with water. Preparation of suspension: see full labeling.

Contraindications: Concomitant ritonavir-boosted saquinavir (increased risk of severe hepatotoxicity). Concomitant atazanavir, darunavir, fosamprenavir, saquinavir, tipranavir.

Warnings/Precautions: Reserve drug for cases where high risk of meningococcal meningitis exists. Confirm diagnosis. Not recommended for intermittent therapy (risk of renal hypersensitivity reactions; rare). Impaired hepatic function; monitor LFTs at baseline and then every 2-4 weeks. Diabetes. May stain body

secretions and contact lenses. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Reduces serum levels of protease inhibitors: avoid concomitant use. Antagonizes anticonvulsants, digitoxin, antiarrhythmics, oral anticoagulants, antifungals, barbiturates, β -blockers, calcium channel blockers, chloramphenicol, clarithromycin, corticosteroids, cyclosporine, cardiac glycosides, clofibrate, oral or other hormonal contraceptives (consider nonhormonal methods), dapsone, diazepam, doxycycline, fluoroquinolones, haloperidol, oral hypoglycemics, levofloxacin, methadone, narcotic analgesics, progestins, quinine, tacrolimus, theophylline, tricyclic antidepressants, zidovudine, atovaquone, enalapril, sulfasalazine. May be potentiated by atovaquone, probenecid, cotrimoxazole. Concomitant ketoconazole decreases serum concentration of both drugs. Monitor prothrombin time with concomitant anticoagulants. Separate dosing of antacids by at least 1 hour. Avoid concomitant halothane. May cause false (+) urine tests for opiates. May inhibit assays for serum folate and Vit. B₁₂ (consider alternative methods). Perform LFTs and use contrast media prior to morning dose.

Adverse reactions: GI disturbances, jaundice, headache, fever, drowsiness, fatigue, ataxia, dizziness, inability to concentrate, mental confusion, muscular weakness, pain in extremities, generalized numbness, visual disturbances, elevated BUN and serum uric acid, menstrual disturbances, urticaria, rash; rare: hepatitis, abnormal LFTs, blood dyscrasias.

How supplied: 150mg-30; 300mg-60, 100; Vials-1

SULFAMETHOXAZOLE + TRIMETHOPRIM R

SEPTRA King

Sulfonamide + folic acid inhibitor. Sulfamethoxazole 400mg, trimethoprim 80mg; scored tabs.

Also: Sulfamethoxazole + Trimethoprim R

SEPTRA DS

Sulfamethoxazole 800mg, trimethoprim 160mg; scored tabs.

Also: Sulfamethoxazole + Trimethoprim R
SULFAMETHOXAZOLE/TRIMETHOPRIM ORAL SUSPENSION (various)

Sulfamethoxazole 200mg, trimethoprim 40mg; per 5mL; cherry or grape flavor; alcohol 0.26%.

Indications: Susceptible infections including UTIs (not for initial uncomplicated episodes), shigellosis, prophylaxis and treatment of *Pneumocystis carinii* pneumonia (PCP), travelers' diarrhea or acute exacerbations of chronic bronchitis in adults, acute otitis media in children.

Adults: 1 DS tab, 2 regular tabs, or 20mL of susp every 12 hours for 5 days (shigellosis, travelers' diarrhea), or 10-14 days (UTIs), or 14 days (bronchitis). PCP treatment: 15-20mg/kg per day of trimethoprim

(75-100mg/kg per day of sulfamethoxazole) in 4 divided doses at 6 hour intervals for 14-21 days; PCP prophylaxis: one DS tab daily.

Children: <2months: not recommended.

≥ 2 months: 8mg/kg per day trimethoprim (40mg/kg per day of sulfamethoxazole) in 2 divided doses at 12 hour intervals for 5 days (shigellosis) or 10 days (otitis media, UTIs). PCP treatment: as adult; PCP prophylaxis or renal impairment: see literature.

Also: Sulfamethoxazole + Trimethoprim R
SULFAMETHOXAZOLE/TRIMETHOPRIM INJECTION (various)

Sulfamethoxazole 80mg, trimethoprim 16mg; per mL; contains sulfites, benzyl alcohol.

Indications: Susceptible *Pneumocystis carinii* pneumonia (PCP), shigellosis, severe or complicated UTIs.

Adults and Children: Dilute (see literature); give IV over 60-90 minutes. <2months: not recommended. ≥ 2 months: PCP: 15-20mg/kg per day (of trimethoprim) in 3-4 equal divided doses every 6-8 hours for up to 14 days. Shigellosis, UTIs: 8-10mg/kg per day (of trimethoprim) in 2-4 equal divided doses every 6, 8, or 12 hours for up to 5 days (for shigellosis) or up to 14 days (for UTIs). Max 60mL/day.

Contraindications: Megaloblastic anemia due to folate deficiency. 3rd trimester pregnancy (Cat.C). Infants. Nursing mothers of ill, stressed, G6PD-deficient, premature, or hyperbilirubinemic infants.

Warnings/Precautions: Not for group A β -hemolytic strep. Avoid prolonged administration. Monitor blood, urine, and renal function. Hepatic or renal dysfunction. AIDS (increased risk of toxicity). Folate or G6PD deficiency. Allergy. Asthma (inj). Maintain adequate hydration. Discontinue if rash occurs. Elderly: CrCl 15-30mL/min: reduce dose by $\frac{1}{2}$; CrCl <15mL/min: not recommended.

Interactions: May potentiate oral anticoagulants, hypoglycemics, phenytoin, methotrexate. May increase risk of thrombocytopenic purpura with diuretics (esp. thiazides). May form insoluble precipitate with methenamine metabolites.

Adverse reactions: GI upset, allergic skin reactions, blood dyscrasias, hemolysis, hepatic or renal toxicity, crystalluria, pancreatitis, photosensitivity, drug fever, rash (may be serious, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), lupus-like syndrome, peripheral neuritis, depression, convulsions, ataxia.

How supplied: Tabs-100; DS tabs-20, 100, 500; Susp, Inj-contact supplier

TETRACYCLINE R

TETRACYCLINE (various)

Tetracycline antibiotic. Tetracycline HCl 250mg, 500mg; caps.

Indications: Tetracycline-sensitive infections, including respiratory, genitourinary, skin and soft tissue, and those caused by rickettsiae and

Mycoplasma pneumoniae; also cholera, psittacosis, plague, shigellosis.

Adults: Take with fluids, 1 hour before or 2 hours after meals. 250–500mg 4 times daily.

Children: <8yrs: not recommended. Take with fluids, 1 hour before or 2 hours after meals. ≥8yrs: 25–50mg/kg/day in 4 divided doses.

Warnings/Precautions: Renal impairment. Monitor blood, renal and hepatic function in long-term use. Avoid sun and UV light. Discontinue if skin erythema occurs. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Avoid methoxyflurane, photosensitizing agents. May antagonize bactericidal antibiotics; avoid. Reduced absorption with antacids, iron, zinc, calcium, magnesium, dairy products, urinary alkalinizers, other multivalent cations. May reduce effectiveness of oral contraceptives. Monitor prothrombin time with oral anticoagulants.

Adverse reactions: Photosensitivity, GI upset, rash, blood dyscrasias, increased BUN, hepatotoxicity; rare: esophagitis and esophageal ulceration.

How supplied: Contact supplier.

TICARCILLIN + CLAVULANIC ACID

TIMENTIN GlaxoSmithKline

Antipseudomonal penicillin + β-lactamase inhibitor. Ticarcillin (as disodium) 3g, clavulanate (as potassium) 0.1g; IV inj; sodium content 4.75mEq/g of ticarcillin; potassium content 0.15mEq/g of Timentin.

Indications: Susceptible bacterial septicemia (adults only), lower respiratory, bone and joint, skin and skin structure, urinary tract, gynecologic and intraabdominal infections.

Adults: By IV infusion over 30 minutes. >60kg: Systemic and UTI: 3.1g every 4–6 hours. Gynecologic: moderate: 200mg/kg/day of ticarcillin in divided doses every 6 hours; severe: 300mg/kg/day in divided doses every 4 hours. <60kg: 200–300mg/kg/day in divided doses every 4–6 hours. Renal impairment: reduce dose; see literature.

Children: <3months: not recommended. Give by IV infusion over 30 minutes. ≥3months: (<60kg): mild-to-moderate infections: 200mg/kg per day of ticarcillin in equal divided doses every 6 hrs; severe infections: 300mg/kg per day of ticarcillin in equal divided doses every 4 hours. ≥3months (≥60kg): mild-to-moderate infections: 3.1g every 6 hrs; severe infections: 3.1g every 4 hours. Renal impairment: reduce dose; see literature.

Warnings/Precautions: Cephalosporin, imipenem or other allergy. Not for use in children for septicemia or *H. influenzae* type b infections. Heart disease. Sodium restricted diets. Monitor serum electrolytes (esp. potassium) and renal, hepatic, hematopoietic function during prolonged therapy. Discontinue if

bleeding problems occur and treat. Pregnancy (Cat.B). Nursing mothers.

Interactions: Probenecid increases ticarcillin levels. May cause false (+) Coomb's test.

Adverse reactions: Inj site reactions, rash, pruritus, drug fever, GI upset, blood dyscrasias, hemorrhage, hypokalemia, superinfection, anaphylaxis, CNS stimulation, elevated liver enzymes.

How supplied: Vials (3.1g)–1

TIGECYCLINE

TYGACIL Pfizer

Glycylcycline. Tigecycline 50mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free.

Indications: Susceptible complicated skin and skin structure and intraabdominal infections. Community-acquired bacterial pneumonia (CABP).

Adults: ≥18yrs: Give by IV infusion over 30–60 minutes. 100mg once, then 50mg every 12 hours. Skin, skin structure, and intraabdominal infections: treat for 5–14 days. CABP: treat for 7–14 days. Severe hepatic impairment (Child Pugh C): 100mg once, then 25mg every 12 hours.

Children: <18yrs: not recommended.

Warnings/Precautions: Risk of increase in all-cause mortality. Monitor for hepatic dysfunction and pancreatitis; consider discontinuing if occurs. Ventilator-associated pneumonia. Intestinal perforation. Sepsis/septic shock. Avoid sun, UV light. Pregnancy (Cat.D): usually not recommended. Nursing mothers.

Interactions: Monitor warfarin. May antagonize oral contraceptives.

Adverse reactions: GI upset, abdominal pain, headache, increased SGPT, inj site reactions, photosensitivity, acute pancreatitis; superinfection.

How supplied: Single-use vials–10

TOBRAMYCIN

TOBI PODHALER Novartis

Aminoglycoside. Tobramycin 28mg/cap; dry pwd in caps for oral inhalation; with Podhaler device.

Indications: Management of cystic fibrosis patients with *P. aeruginosa*. Safety and efficacy have not been demonstrated in patients <6yrs, in those with FEV1 <25% or >80% predicted, or patients colonized with *B. cepacia*.

Adults and Children: <6yrs: not recommended.

For oral inhalation only. Give in alternate 28-day cycles (28 days on, 28 days off). ≥6yrs: Inhale 4 capsules twice daily, as close to every 12hrs as possible (must be at least 6hrs apart). Give last when using multiple inhalation therapies.

Warnings/Precautions: Known or suspected auditory, vestibular, renal, or neuromuscular dysfunction. Myasthenia gravis. Parkinson's disease. Consider performing an audiogram at baseline (esp. at risk of auditory dysfunction). Monitor serum tobramycin levels in auditory or renal dysfunction

patients, or if used with other aminoglycosides (or other nephrotoxic or ototoxic drugs) as needed. Discontinue if ototoxicity or nephrotoxicity occurs; may restart when serum tobramycin $<2\mu\text{g/mL}$. Monitor renal function as needed. Elderly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Concomitant ethacrynic acid, furosemide, urea, mannitol: not recommended. Diuretics may increase toxicity. Avoid concomitant and/or sequential use with other neurotoxic, nephrotoxic, or ototoxic drugs.

Adverse reactions: Cough, lung disorder, productive cough, dyspnea, pyrexia, oropharyngeal pain, dysphonia, hemoptysis, headache; hearing loss, tinnitus, nephrotoxicity, bronchospasm.

How supplied: Caps-224 (w. Podhaler devices)

TOBRAMYCIN

R

TOBRAMYCIN INJECTION (various)

Aminoglycoside. Tobramycin sulfate 10mg/mL, 40mg/mL; soln for IM inj or IV infusion after dilution; contains 1.56mg sodium per 20mg/mL vial; contains sulfites.

Indications: Serious susceptible infections, including lower respiratory tract, CNS (eg, meningitis), intraabdominal (eg, peritonitis), septicemia, bone, skin and skin structure, complicated and recurrent UTIs or uncomplicated UTIs not susceptible to other antibiotics.

Adults: Obesity: base dose on lean body mass. Give by IM inj; or IV infusion over 20–60 mins. Serious infections: 3mg/kg/day in 3 divided doses every 8 hours. Life-threatening infections: up to 5mg/kg/day in 3–4 divided doses; max 5mg/kg/day unless serum levels monitored; reduce to 3mg/kg/day as soon as clinically indicated. Usual duration: 7–10 days. Severe cystic fibrosis: initially 10mg/kg/day in 4 divided doses; adjust dose based on serum levels. Renal impairment: reduce dose; see literature.

Children: Give by IM inj; or IV infusion over 20–60 mins. Premature or neonates ≤ 1 week: up to 4mg/kg/day in 2 divided doses every 12 hours. All others >1 week: 6–7.5mg/kg/day in 3–4 divided doses (2–2.5mg/kg every 8 hours or 1.5–1.8mg/kg every 6 hours). Usual duration: 7–10 days. Renal impairment: reduce dose; see literature.

Warnings/Precautions: Monitor for nephro- and neurotoxicity; avoid peak serum levels >12 micrograms/mL and trough levels >2 micrograms/mL. Discontinue or adjust dose if auditory, vestibular, or renal dysfunction develops; monitor serum levels periodically. Do audiogram in high-risk patients. Maintain adequate hydration. Prolonged use or excessive doses. Asthma. Muscular disorders (eg, myasthenia gravis, parkinsonism). Elderly. Premature or neonatal infants. Pregnancy (Cat.D): not recommended.

Interactions: Avoid concomitant furosemide, ethacrynic acid, other nephro/neurotoxic drugs including cephalosporins. Diuretics may increase

toxicity. May potentiate neuromuscular blocking agents.

Adverse reactions: Nephro- or neurotoxicity, lethargy, confusion, headache, inj site reactions, GI upset, elevated liver enzymes, blood dyscrasias, electrolyte abnormalities, respiratory failure or paralysis, neuromuscular blockade; rare: serious allergic reactions (eg, anaphylaxis, exfoliative dermatitis, Stevens-Johnson Syndrome).

How supplied: Contact supplier.

TRIMETHOPRIM

R

TRIMETHOPRIM (various)

Folic acid inhibitor. Trimethoprim 100mg, 200mg; tabs.

Indications: Treatment of initial episodes of uncomplicated UTI due to susceptible strains (*E. coli*, *P. mirabilis*, *K. pneumoniae*, *Enterobacter* species, coagulase-negative *Staphylococcus* species, including *S. saprophyticus*).

Adults: Treat for 10 days. 100mg every 12 hours or 200mg every 24 hours. CrCl 15–30mL/min: 50mg every 12 hours. CrCl <15 mL/min: not recommended.

Children: Not recommended.

Contraindications: Megaloblastic anemia due to folate deficiency.

Warnings/Precautions: May interfere with hematopoieses (esp. when given in large doses and/or prolonged periods). Obtain CBCs if signs of serious blood disorder develop, discontinue if significant reduction in any formed blood element is found. Possible folate deficiency. Renal or hepatic impairment. Pregnancy (Cat.C). Nursing mothers.

Interactions: May potentiate phenytoin. May interfere with serum methotrexate assay, Jaffe alkaline picrate reaction assay for creatinine.

Adverse reactions: Rash, pruritus, GI upset, blood dyscrasias, hyperkalemia, hyponatremia, fever, increased BUN, serum creatinine; rare: aseptic meningitis, cholestatic jaundice, hypersensitivity reactions.

How supplied: Contact supplier.

VANCOMYCIN

R

VANCOMYCIN INJECTION (various)

Antibiotic. Vancomycin (as HCl) 500mg/vial, 1g/vial; lyophilized pwd for IV infusion after reconstitution and dilution.

Indications: Serious or severe infections due to susceptible methicillin-resistant (beta-lactam-resistant) staphylococci in penicillin-allergic patients; patients who cannot receive or have failed to respond to other drugs, including penicillins and cephalosporins; and for infections due to vancomycin-susceptible organisms resistant to other antimicrobials. Staphylococcal endocarditis, including septicemia, and infections of the lower respiratory tract, bone, and skin and skin structure. Streptococcal endocarditis due to *S. viridans* or *S. bovis* as monotherapy or in combination with an aminoglycoside. Enterococcal endocarditis due to

E. faecalis in combination with an aminoglycoside. Diphtheroid endocarditis. Early-onset prosthetic valve endocarditis due to *S. epidermidis* or diphtheroids in combination with rifampin, or an aminoglycoside, or both.

Adults: Give by intermittent IV infusion over at least 60 minutes or at a rate of 10mg/min or less, whichever is longer. 2g/day in divided doses (500mg every 6 hours or 1g every 12 hours). Renal impairment: adjust or reduce dose, obesity; see literature.

Children: Give by intermittent IV infusion over at least 60 minutes. Neonates: ≤ 1 month: initially 15mg/kg, then 10mg/kg every 12 hours (for neonates in the 1st week of life) and every 8 hours thereafter (up to 1 month of age). > 1 month: 10mg/kg per dose every 6 hours. Renal impairment: adjust or reduce dose, obesity; see literature.

Warnings/Precautions: Renal insufficiency. Monitor hearing, blood, renal function. Monitor vancomycin serum concentrations closely. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Monitor with other ototoxic, nephrotoxic, neurotoxic drugs (eg. aminoglycosides, amphotericin B, bacitracin, polymyxin B, colistin, viomycin, cisplatin). Erythema, histamine-like flushing, anaphylactoid reactions may occur with concomitant anesthetic agents.

Adverse reactions: Infusion-related events, nausea, drug fever, rash (may be serious, eg. Stevens-Johnson syndrome), ototoxicity, nephrotoxicity, thrombophlebitis, blood dyscrasias; rare: interstitial nephritis, vertigo.

How supplied: Contact supplier.

9B Fungal infections

AMPHOTERICIN B (AS LIPOSOME)

AMBISOME Astellas

Polyene. Amphotericin B (as liposome) 50mg/vial; p/wd for IV infusion after reconstitution, filtration, and dilution.

Indications: Empiric treatment of presumed fungal infections in febrile, neutropenic patients. Treatment of cryptococcal meningitis in HIV-infected patients. *Aspergillus*, *Candida*, or *Cryptococcus* infections in patients who are refractory to or intolerant of amphotericin B deoxycholate. Treatment of visceral leishmaniasis.

Adults and Children: Give by IV infusion over 2hrs; may reduce duration to 1 hr if well-tolerated or increase if discomfort occurs. Stop infusion immediately if severe anaphylactic reaction occurs.

< 1 month: consult manufacturer. ≥ 1 month: Empiric therapy in febrile neutropenia: 3mg/kg per day. Cryptococcal meningitis: 6mg/kg per day. *Aspergillus*, *Candida* or *Cryptococcus*: 3–5mg/kg per day. Visceral leishmaniasis: immunocompetent: 3mg/kg per day

on days 1–5, and 14, 21 (may repeat if parasites remain); immunocompromised: 4mg/kg per day on days 1–5, and 10, 17, 24, 31, 38 (obtain consult if parasites remain or relapse occurs).

Warnings/Precautions: Administer only by appropriately trained personnel. Be fully familiar with this drug's toxicity before use. Monitor renal and hepatic function, CBCs, and electrolytes (esp. K^+ , Mg^{++}). Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Caution with antineoplastics (renal toxicity, bronchospasm, hypotension), corticosteroids and ACTH (monitor electrolytes, cardiac function), azole antifungals (resistance), leukocyte transfusions (acute pulmonary toxicity), other nephrotoxic agents. May potentiate skeletal muscle relaxants, digitalis (monitor K^+). May increase flucytosine toxicity. Azoles may increase fungal resistance. May cause false elevations of serum phosphate with the PHOSm assay analyzer.

Adverse reactions: Infusion reactions, chills, bronchospasm, hypotension, GI disturbances, electrolyte disturbances; cardiovascular, respiratory, and dermatological effects; renal dysfunction, edema, increased liver enzymes, anaphylaxis, others.

How supplied: Vials–10

AMPHOTERICIN B LIPID COMPLEX

R

ABELCET Enzon

Polyene. Amphotericin B lipid complex 5mg/mL; susp for IV infusion after dilution; preservative-free.

Indications: Invasive fungal infections in patients who are refractory to, or intolerant of, conventional amphotericin B therapy.

Adults and Children: 5mg/kg daily as a single IV infusion, at a rate of 2.5mg/kg per hour. Renal impairment: reduce dose.

Warnings/Precautions: Be fully familiar with the use of this product. Administer under close supervision; cardiopulmonary resuscitation facilities should be available. Monitor CBC, serum creatinine, liver function, serum electrolytes (esp. magnesium and potassium). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Monitor other drugs; see literature. Caution with antineoplastics, corticosteroids, ACTH, cyclosporine, digitalis glycosides, flucytosine, imidazoles, nephrotoxic drugs, skeletal muscle relaxants, zidovudine. Concurrent leukocyte transfusion: not recommended.

Adverse reactions: Infusion reactions (1–2 hrs post-infusion, eg. transient chills/fever, rarely: bronchospasm, hypotension, arrhythmias, shock), nephrotoxicity, hepatotoxicity, anaphylaxis, respiratory/cardiac/neurological disorders, malaise, tinnitus, visual impairment, hearing loss, diarrhea; others: see literature.

How supplied: Single-use vials (50mg, 100mg)–1 (w. filter needle)

ANIDULAFUNGIN**ERAXIS** Pfizer*Glucan synthesis inhibitor (echinocandin).*

Anidulafungin 50mg/vial, 100mg/vial; pwd for IV infusion after reconstitution and dilution; preservative-free; contains fructose and mannitol.

Indications: Candidemia. Esophageal candidiasis. Other *Candida* infections (intra-abdominal abscess, peritonitis).**Adults:** Give by IV infusion; max rate 1.1mg/minute. Candidiasis, intra-abdominal abscess, peritonitis: 200mg on day 1, then 100mg/day for at least 14 days after last positive culture. Esophageal candidiasis: 100mg on day 1, then 50mg/day for at least 14 days and at least 7 days after symptom resolution.**Children:** ≤16yrs: not established.**Warnings/Precautions:** Follow-up if hepatic dysfunction develops. Discontinue and treat appropriately if anaphylactic reactions occur. Pregnancy (Cat.B). Nursing mothers.**Adverse reactions:** Hypokalemia, GI upset, pyrexia, insomnia, anemia, headache, dyspepsia; hepatic effects, infusion reactions, anaphylactic reactions.**How supplied:** Vial-1

R

ATOVAQUONE**MEPRON** GlaxoSmithKline*Naphthoquinone.* Atovaquone 750mg/5mL; susp; citrus flavor.**Indications:** Treatment of mild to moderate *Pneumocystis carinii* pneumonia (PCP) in patients intolerant to trimethoprim/sulfamethoxazole (TMP/SMX). Prevention of PCP in patients intolerant to TMP/SMX.**Adults:** Take with food. Treatment: 750mg twice daily for 21 days. Prophylaxis: 1500mg once daily.**Children:** See literature.**Warnings/Precautions:** GI disorders or inability to take with food. Monitor in severe hepatic impairment. Elderly. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Antagonized by rifampin. Caution with other highly protein-bound drugs.**Adverse reactions:** Rash, headache, GI upset, dyspnea, cough, rhinitis, infection, fever, elevated liver enzymes, insomnia, asthenia, oral moniliasis, pruritus, sinusitis, anorexia, depression, myalgia, pancreatitis, thrombocytopenia, allergic reactions.**How supplied:** Susp-210mL

R

CASPOFUNGIN**CANCIDAS** Merck*Glucan synthesis inhibitor (echinocandin).* Caspofungin acetate 50mg, 70mg; per vial; lyophilized pwd for IV infusion after reconstitution and dilution.**Indications:** Presumed fungal infections in febrile neutropenia, as empiric therapy. *Candida* infections of the esophagus, blood, peritoneum, intraabdominal abscess, pleural space. Invasive aspergillosis in patients refractory to or intolerant of other therapies (not for initial therapy).

R

Adults: Give by slow IV infusion over 1 hour.≥18yrs: Esophageal candidiasis: 50mg daily. Other *Candida* infections, aspergillosis, or empiric: 70mg once on day 1 then 50mg daily. Give 70mg daily if on concomitant rifampin, consider 70mg daily for concomitant nevirapine, efavirenz, carbamazepine, dexamethasone, phenytoin. For all: continue at least 14 days after last positive culture. Empiric: treat for at least 14 days; continue for at least 7 more days after resolution of neutropenia and clinical symptoms; may increase to 70mg/day. Moderate hepatic insufficiency: 35mg daily (may give 70mg on day 1 when indicated).**Children:** <3months: not recommended. Give by slow IV infusion over 1 hour. 3months-17yrs: 70mg/m² once on day 1, then 50mg/m² daily. May increase to 70mg/m² daily; max 70mg. Concomitant rifampin, efavirenz, nevirapine, phenytoin, carbamazepine, dexamethasone: consider 70mg/m² daily. Empiric: treat for at least 14 days; continue for at least 7 more days after resolution of neutropenia and clinical symptoms. All others: continue at least 14 days after last positive culture.**Warnings/Precautions:** Severe hepatic insufficiency. Monitor liver function tests. Discontinue if hypersensitivity reactions occur. Elderly. Pregnancy (Cat.C). Nursing mothers.**Interactions:** See Adults and Children dose. Cyclosporine: see literature. Monitor tacrolimus levels.**Adverse reactions:** Inj site reactions, diarrhea, pyrexia, chills, rash, increased alkaline phosphatase, ALT/AST, decreased potassium, anaphylaxis, histamine-mediated symptoms. Children: also hypotension.**How supplied:** Single-use vials-1**CLOTRIMAZOLE****MYCELEX TROCHES** Janssen*Azole.* Clotrimazole 10mg.**Indications:** Prophylaxis and treatment of oropharyngeal candidiasis.**Adults and Children:** <3 yrs: not recommended.

≥3 yrs: Dissolve slowly in mouth. Treatment: 1 troche 5 times daily for 14 consecutive days.

Prophylaxis: 1 troche 3 times daily.

Warnings/Precautions: Not for treatment of systemic mycoses. Diagnosis should be confirmed by KOH smear and/or culture. Monitor hepatic function. Pregnancy (Cat.C). Nursing mothers.**Adverse reactions:** Elevated SGOT levels, nausea, vomiting.**How supplied:** Troches-70, 140

R

FLUCONAZOLE**DIFLUCAN** Pfizer*Azole.* Fluconazole 50mg, 100mg, 200mg; tabs.**Also: Fluconazole****DIFLUCAN ORAL SUSPENSION**

Fluconazole 10mg/mL, 40mg/mL; pwd for oral suspension; orange flavor.

R

R

Also: Fluconazole**DIFLUCAN INJECTION**

Fluconazole 2mg/mL; for IV infusion.

Indications: Oropharyngeal, esophageal, systemic candidiasis. Bone marrow transplant prophylaxis. Cryptococcal meningitis. *Candida* urinary tract infection (UTI), peritonitis.

Adults: Individualize. CrCl < 50mL/min: reduce dose, see literature. All doses are once daily. Oropharyngeal candidiasis: 200mg on day 1, then 100mg/day for at least 2 wks. Esophageal candidiasis: 200mg on day 1, then 100mg/day for at least 3 wks; treat for at least 2 wks after symptoms resolve; max 400mg/day. Systemic candidiasis: doses of up to 400mg/day have been used. Prophylaxis of candidiasis in bone marrow transplantation: 400mg/day. Cryptococcal meningitis: 400mg on day 1, then 200–400mg/day for 10–12 wks after spinal fluid negative; to suppress relapse in AIDS: 200mg/day. UTI, peritonitis: 50–200mg/day have been used. Renal impairment: see literature.

Children: Individualize. CrCl < 50mL/min: reduce dose, see literature. All doses are once daily. Neonates: see literature. Over 2 wks of age: Oropharyngeal candidiasis: 6mg/kg on day 1, then 3mg/kg/day for at least 2 wks. Esophageal candidiasis: 6mg/kg on day 1, then 3mg/kg/day for at least 3 wks; treat for at least 2 wks after symptoms resolve; max 12mg/kg/day. Systemic candidiasis: 6–12mg/kg/day have been used. Cryptococcal meningitis: 12mg/kg on day 1, then 6mg/kg/day for 10–12 wks after negative CSF cultures; max 12mg/kg/day; to suppress relapse in AIDS: 6mg/kg/day. Max for all: 600mg/day. Renal impairment: see literature.

Contraindications: Concomitant pimozide, quinidine.

Warnings/Precautions: Proarrhythmic conditions. Renal or hepatic impairment. Monitor liver function during therapy and for signs/symptoms of hepatic injury; discontinue if develop. Monitor closely for skin rashes; discontinue if lesions progress. Elderly. Pregnancy (Cat.D): may cause rare congenital anomalies in infants exposed in-utero to high doses (400–800mg/day) during 1st trimester. Nursing mothers: not recommended.

Interactions: See Contraindications. Risk of cardiotoxicity with erythromycin; avoid. Concomitant voriconazole: not recommended; if needed, monitor closely esp. when given within 24hrs after fluconazole. Potentiates warfarin, theophylline, oral hypoglycemics, midazolam. May increase serum levels of phenytoin, cyclosporine, zidovudine, sulfonyleureas, carbamazepine. Thiazides increase fluconazole levels. Monitor levels and/or effects of cyclosporine, phenytoin, sulfonyleureas, rifabutin, tacrolimus, theophylline, warfarin. Cimetidine (oral), rifampin may decrease fluconazole levels. Oral contraceptives: see literature. Avoid other hepatotoxic

drugs. Caution with other drugs metabolized by CYP450.

Adverse reactions: Nausea, headache, rash, vomiting, abdominal pain, diarrhea; hepatotoxicity, exfoliative dermatitis (rare).

How supplied: Tabs–30; Susp (35mL)–1; IV (200mg, 400mg)–6

GRISEOFULVIN

GRIFULVIN V Valeant

Griseofulvin (microsize) 500mg; scored tabs.

Also: Griseofulvin

GRISEOFULVIN ORAL SUSPENSION (various)

Griseofulvin (microsize) 125mg/5mL; contains alcohol 0.02%.

Indications: Ringworm infections of the skin, hair, and nails.

Adults: 500mg daily; max 1g daily.

Children: 30–50lbs: 125–250mg daily. Over 50lbs: 250–500mg daily.

Contraindications: Porphyria. Hepatocellular failure. Pregnancy.

Warnings/Precautions: Continue therapy until infection is eradicated. Periodic monitoring of renal, hepatic, and hematopoietic functions. Discontinue if granulocytopenia occurs. Penicillin sensitivity. Avoid exposure to sunlight or UV light. Nursing mothers.

Interactions: Antagonizes oral contraceptives, oral anticoagulants. Antagonized by barbiturates.

Adverse reactions: Oral thrush, GI distress, dizziness, confusion, peripheral neuritis, photosensitivity, granulocytopenia, leukopenia, proteinuria, lupus-like syndrome.

How supplied: Tabs–100, 500; Susp–contact supplier

ITRACONAZOLE

SPORANOX Janssen

Azole. Itraconazole 100mg; caps.

Indications: Blastomycosis. Histoplasmosis. Aspergillosis in patients who are intolerant of or refractory to amphotericin B. Onychomycosis of the fingernail or toenail in immunocompetent patients.

Adults: Take with full meal. Take with cola drink in achlorhydria or if on concomitant gastric acid suppressants. Treat systemic infections for at least 3 months. Give daily doses > 200mg in 2 divided doses. Blastomycosis, histoplasmosis: 200mg once daily, may increase by 100mg increments; max 400mg/day. Aspergillosis: 200–400mg daily. Life-threatening conditions: May give loading dose of 200mg 3 times daily for 1st 3 days. Onychomycosis (toenail): 200mg once daily for 12 consecutive weeks. Onychomycosis (fingernail): 200mg twice daily for 1 week, then 3 weeks off, then 200mg twice daily for 1 more week.

Children: Not recommended. Systemic infections: 3–16yrs: doses of 100mg/day have been used; see literature.

Also: Itraconazole

SPORANOX ORAL SOLUTION Janssen Biotech Itraconazole 10mg/mL; cherry-caramel flavor.

Indications: Oropharyngeal and esophageal candidiasis (not recommended for initiation of treatment if immediate risk of systemic candidiasis).

Adults: Take on empty stomach. Swish and swallow 10mL at a time. Oropharyngeal: 200mg daily for 1–2 weeks; fluconazole-resistant: 100mg twice daily. Esophageal: 100–200mg daily. Treat for at least 3 weeks, continue 2 weeks after symptoms resolve.

Children: Not recommended. Doses of 5mg/kg per day for 2 weeks have been used; see literature.

Contraindications: CHF. Concomitant cisapride, pimozone, nisoldipine, quinidine, dofetilide, triazolam, levacetylmethadol, ergots, felodipine, lovastatin, simvastatin, methadone, or oral midazolam. Do not use for onychomycosis if pregnant or contemplating pregnancy.

Warnings/Precautions: Use appropriate formulation; caps and soln are not interchangeable. Confirm diagnosis of onychomycosis with nail specimen. Renal impairment. Hepatic dysfunction; monitor and discontinue if hepatic dysfunction occurs. Ventricular dysfunction. CHF risk (eg, valvular disease, COPD, renal disease). Discontinue if CHF or neuropathy occurs. Achlorhydria (reduced bioavailability from capsules). Cystic fibrosis patients on oral solution: switch to alternative therapy if no response. Elderly. Pregnancy (Cat.C): use appropriate contraception during and for 2 months after therapy. Nursing mothers: not recommended.

Interactions: See Contraindications. Serious cardiac effects with cisapride, pimozone, methadone, levacetylmethadol, quinidine, others. Concomitant nevirapine, rifabutin, rifampin, isoniazid, others metabolized by CYP3A4: not recommended. Potentiates triazolam, midazolam, diazepam, alprazolam, cyclosporine, tacrolimus, sirolimus, carbamazepine, digoxin, rifabutin, anticoagulants and coumarin-type drugs, HIV protease inhibitors (eg, ritonavir, indinavir, saquinavir), disopyramide, dihydropyridine calcium channel blockers, verapamil, atorvastatin, cerivastatin, glucocorticoids (eg, budesonide, dexamethasone, methylprednisolone), vinca alkaloids, docetaxel, busulfan, others metabolized by CYP3A4 (eg, halofantrine, alfentanil, bupirone, cilostazole, eletriptan, fluticasone, trimetrexate, fentanyl). Severe hypoglycemia with oral hypoglycemics; monitor glucose. Antagonized by phenytoin, phenobarbital, carbamazepine, rifampin, rifabutin, isoniazid, nevirapine, other CYP3A4 inducers; monitor itraconazole if given concomitantly. Potentiated by clarithromycin, erythromycin, indinavir, ritonavir, others that inhibit CYP3A4. Monitor cyclosporine, tacrolimus, phenytoin, digoxin, warfarin, vinca alkaloids, non-nucleoside reverse transcriptase inhibitors. May inhibit trimetrexate metabolism. May alter fentanyl plasma levels: fatal respiratory depression possible. Tinnitus or hearing impairment with quinidine. May

inhibit polyene antifungals. Calcium channel blockers increase risk of edema; consider dose adjustment. Capsules: antagonized by gastric acid suppressants (eg, H₂ blockers, proton pump inhibitors). Take at least 1 hour before or 2 hours after antacids.

Adverse reactions: GI upset, edema, rash, fatigue, fever, headache, dizziness, hepatotoxicity, liver failure, CHF, hypokalemia, hearing loss.

How supplied: Caps–30; Caps PulsePak–28; Oral soln–150mL

KETOCONAZOLE

NIZORAL TABLETS Janssen

Azole. Ketoconazole 200mg.

Indications: Susceptible systemic fungal infections or refractory cutaneous dermatophyte infections.

Adults: Initially 200mg daily; max 400mg daily.

Children: Usually not recommended. >2 years: see literature.

Contraindications: Concomitant cisapride, triazolam.

Warnings/Precautions: Not for fungal meningitis. Monitor hepatic function before and during therapy. Discontinue if hepatotoxicity occurs. Achlorhydria (may impair absorption). History of hepatic dysfunction. Allergy. Children. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Serious cardiac effects with cisapride. Potentiates triazolam, midazolam, possibly oral anticoagulants, oral hypoglycemics. Avoid antacids, anticholinergics, H₂ blockers within 2 hrs after ketoconazole. Avoid rifampin, isoniazid. Monitor phenytoin, cyclosporine, tacrolimus, methylprednisolone, digoxin. Caution with other hepatically metabolized drugs.

Adverse reactions: Hepatotoxicity, anaphylaxis, urticaria, nausea, vomiting, abdominal pain, pruritus; hormonal effects (at higher doses).

How supplied: Tabs–100

MICAFUNGIN

MYCAMINE Astellas

Glucan synthesis inhibitor/echinocandin. Micafungin sodium 50mg/vial, 100mg/vial; pld for IV infusion after reconstitution and dilution; preservative-free.

Indications: Treatment of Candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses; and esophageal candidiasis. Prophylaxis of *Candida* infection in patients undergoing hematopoietic stem cell transplantation (HSCT).

Adults: Give by slow IV infusion over 1 hour. Candidemia, acute disseminated, peritonitis, abscesses: 100mg/day (usual range 10–47 days). Esophageal: 150mg/day (usual range 10–30 days). Prophylaxis in HSCT: 50mg/day (usual range 6–51 days).

Children: <4months: not established. Give by slow IV infusion over 1 hour. ≥4months: Candidemia, acute disseminated, peritonitis, abscesses: 2mg/kg once daily; max 100mg/day. Esophageal: (≤30kg):

3mg/kg once daily; (>30kg): 2.5mg/kg once daily. Max: 150mg/day. Prophylaxis in HSCT: 1mg/kg once daily; max 50mg/day.

Warnings/Precautions: Hepatic impairment. Renal dysfunction. Monitor for evidence of worsening hepatic or renal function. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates sirolimus, itraconazole, nifedipine; monitor and reduce doses.

Adverse reactions: Inj site reactions, diarrhea, nausea, vomiting, pyrexia, thrombocytopenia, headache, rash, pruritus, facial swelling, vasodilatation, phlebitis, increased alkaline phosphatase; hematological effects, abnormal liver function tests (eg, ALT/AST), acute renal failure, anaphylaxis.

How supplied: Single-use vials—10

MICONAZOLE

R

ORAVIG Vestiq

Azole. Miconazole 50mg; buccal tablet.

Indications: Local treatment of oropharyngeal candidiasis.

Adults: Do not crush, chew, or swallow. Alternate application site. Apply to upper gum region, hold in place for 30 seconds to ensure adhesion. ≥ 16 yrs: 50mg once daily in the AM for 14 consecutive days.

Children: <16 yrs: not recommended.

Contraindications: Allergy to milk protein concentrate.

Warnings/Precautions: History of hypersensitivity to azoles; monitor and discontinue if allergic reactions develop. Hepatic Impairment. Pregnancy (Cat.C). Nursing mothers.

Interactions: May potentiate anticoagulant effects with warfarin (monitor PT, INR, evidence of bleeding). Caution with drugs metabolized by CYP2C9 and CYP3A4 (eg, oral hypoglycemics, phenytoin, ergot alkaloids).

Adverse reactions: Diarrhea, headache, nausea, dysgeusia, upper abdominal pain, vomiting, possible allergic reactions.

How supplied: Buccal tabs—14

NYSTATIN

R

NYSTATIN ORAL SUSPENSION (various)

Polyene antifungal. Nystatin 100000Units/mL.

Indications: Oral candidiasis.

Adults: 4–6mL ($\frac{1}{2}$ of dose on each side of mouth) 4 times daily. Retain in mouth as long as possible before swallowing.

Children: Infants: 2mL 4 times daily (1mL on each side of mouth). Older children: as adult.

Also: Nystatin

R

NYSTATIN ORAL TABLETS

Nystatin 500000Units.

Indications: Intestinal candidiasis.

Adults: 1–2 tabs 3 times daily.

Children: Not recommended.

Warnings/Precautions: Not for treatment of systemic mycoses. Confirm diagnosis by KOH smear

and/or culture. Continue treatment for at least 48 hrs after clinical cure. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Diarrhea, GI distress, nausea, vomiting, oral irritation.

How supplied: Contact supplier.

POSACONAZOLE

R

NOXAFIL Merck

Triazole. Posaconazole 40mg/mL; oral susp; cherry flavor.

Indications: Prophylaxis against invasive *Aspergillus* and *Candida* infections, in patients at high risk due to being severely immunocompromised, such as hematopoietic stem cell transplant recipients with Graft vs. Host Disease (GVHD) or those with hematologic malignancies with prolonged neutropenia due to chemotherapy. Treatment of oropharyngeal candidiasis, including refractory to itraconazole and/or fluconazole.

Adults: Take within 20mins after a full meal or liquid nutritional supplement; or may take with an acidic carbonated beverage (eg, gingerale). ≥ 13 yrs: Invasive fungal prophylaxis: 200mg 3 times daily. Oropharyngeal candidiasis: 100mg twice daily on day 1, then 100mg once daily for 13 days; refractory: 400mg twice daily.

Children: <13 yrs: not recommended.

Contraindications: Hypersensitivity to other azole antifungal agents. Concomitant sirolimus, ergots, or HMG-CoA reductase inhibitors (eg, atorvastatin, lovastatin, simvastatin). Drugs that cause QT prolongation and are metabolized by CYP3A4 (eg, quinidine, pimozide).

Warnings/Precautions: Correct potassium, calcium, magnesium levels before starting. Monitor liver function tests before starting and during therapy. Proarrhythmic conditions. Patients who cannot eat a full meal or nutritional supplement or those with severe renal impairment, severe diarrhea, or vomiting: monitor for breakthrough fungal infections. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid drugs that lower posaconazole levels (eg, cimetidine, esomeprazole, rifabutin, phenytoin, efavirenz). Monitor for breakthrough fungal infections with metoclopramide, fosamprenavir. Potentiates CYP3A4 substrates (eg, cyclosporine, tacrolimus, midazolam, rifabutin, phenytoin, ritonavir, atazanavir, calcium channel blockers, vinca alkaloids, digoxin, other benzodiazepines); monitor and consider dose reduction. Monitor glucose levels with glipizide.

Adverse reactions: Fever, headache, rigors, GI upset, anorexia, abdominal pain, constipation, fatigue, hypokalemia, coughing, hypertension, lab abnormalities (eg, anemia, neutropenia, thrombocytopenia, bilirubinemia, increased liver enzymes), rash; arrhythmias, QT prolongation.

How supplied: Susp—105mL (w. dosing spoon)

TERBINAFINE**LAMISIL TABLETS** Novartis

Allylamine. Terbinafine (as HCl) 250mg.

Indications: Onychomycosis of the toenail or fingernail due to tinea unguium.**Adults:** ≥ 18 years: 250mg once daily for 6 weeks (fingernail) or 12 weeks (toenail).**Children:** < 18 yrs: not recommended.**Also: Terbinafine****LAMISIL ORAL GRANULES**

Terbinafine (as HCl) 125mg, 187.5mg; per packet.

Indications: Tinea capitis.**Adults:** Not applicable.**Children:** < 4 yrs: not recommended. Sprinkle granules on pudding or other soft, non-acidic food and swallow (do not chew); do not use applesauce or fruit-based foods. ≥ 4 yrs: Take once daily for 6 weeks. < 25 kg: 125mg/day. 25–35kg: 187.5mg/day. > 35 kg: 250mg/day.**Warnings/Precautions:** Onychomycosis: confirm diagnosis with nail specimen. Do baseline liver function test. Pre-existing hepatic disease or renal impairment (CrCl < 50 mL/min): not recommended. Discontinue if hepatobiliary dysfunction, progressive skin rash (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), or severe neutropenia occurs. Monitor CBCs if immunodeficient. Pregnancy (Cat.B), nursing mothers: not recommended.**Interactions:** Potentiated by cimetidine.

Antagonized by rifampin. May potentiate drugs metabolized by CYP2D6. May be potentiated by CYP2C9 and CYP3A4 inhibitors (eg, fluconazole, ketoconazole, amiodarone). Monitor cyclosporine.

Adverse reactions: GI disturbances, liver test abnormalities, rash, pruritus, taste disturbances, urticaria; also children: nasopharyngitis, headache, pyrexia, cough, upper respiratory infection; rare: hepatotoxicity, liver failure, lupus erythematosus.**How supplied:** Tabs–30, 100; Packets–14, 42**VORICONAZOLE****VFEND** Pfizer

Azole. Voriconazole 50mg, 200mg; tabs.

Also: Voriconazole**VFEND ORAL SUSPENSION**

Voriconazole 40mg/mL; pwd for reconstitution; orange flavor.

Also: Voriconazole**VFEND I.V. FOR INJECTION**

Voriconazole 200mg/vial; pwd for IV infusion after reconstitution and dilution; preservative-free.

Indications: Invasive aspergillosis. Nonneutropenic candidemia. Candida infections in abdomen, kidney, bladder, wounds, or skin (disseminated). Esophageal candidiasis. Serious infections caused by *Scedosporium apiospermum* and *Fusarium* species in patients refractory to, or intolerant of, other agents.**Adults:** See literature. Infuse IV over 1–2 hours; max rate 3mg/kg per hour. Aspergillosis, other serious

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infections: initially 6mg/kg IV every 12 hours for 2 doses, then 4mg/kg every 12 hours. Candidemia, other deep tissue candida infections: initially 6mg/kg IV every 12 hours for 2 doses, then 3–4mg/kg every 12 hours; treat for at least 14 days after symptoms resolve or following last positive culture, whichever is longer. Both: switch to oral form when tolerated; give 1 hour before or after meals. Oral forms: < 40 kg: 100mg every 12 hours; may increase to 150mg every 12 hours if inadequate response; ≥ 40 kg: 200mg every 12 hours; may increase to 300mg every 12 hours if inadequate response. Esophageal candidiasis: oral forms: < 40 kg: 100mg every 12 hours; ≥ 40 kg: 200mg every 12 hours; treat for at least 14 days and for at least 7 days after symptoms resolve. Concomitant efavirenz: increase voriconazole dose to 400mg every 12 hours and decrease efavirenz dose to 300mg every 24 hours. Concomitant phenytoin: increase voriconazole dose. Hepatic impairment (mild to moderate): reduce maintenance dose by $\frac{1}{2}$, (severe): see literature. Renal impairment (CrCl < 50 mL/min): oral forms preferred. Duration of therapy, and for dose adjustments if not tolerated: see literature.

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Children: Not recommended.**Contraindications:** Concomitant quinidine, sirolimus, rifampin, rifabutin, carbamazepine, long-acting barbiturates, ergot alkaloids, pimozone, cisapride, efavirenz (adjusted dose may be used; see Adult dose); ritonavir 400mg every 12 hours.**Warnings/Precautions:** Hepatic or renal dysfunction. Proarrhythmic conditions. Correct electrolyte disturbances before starting. Monitor visual function if used > 28 days; hepatic function (at baseline and during therapy; consider discontinuing if hepatic dysfunction develops); and renal function (see literature). May cause visual disturbances; do not drive at night. Avoid strong sunlight. Pregnancy (Cat.D): use appropriate contraception. Nursing mothers: not recommended.

R

Interactions: See Contraindications. Potentiates cyclosporine, tacrolimus, phenytoin, coumarin anticoagulants, methadone, other CYP3A4, CYP2C9, or CYP2C19 substrates (eg, triazolam, midazolam, alprazolam, vinca alkaloids, statins, NNRTIs, HIV protease inhibitors, calcium channel blockers, omeprazole, sulfonylureas). Antagonized by phenobarbital, phenytoin, possibly delavirdine, efavirenz, other CYP3A4 inducers. Monitor levels and/or effects of cyclosporine, tacrolimus, phenytoin, warfarin, sulfonylureas, HIV protease inhibitors, NNRTIs, vinca alkaloids, statins. May need dose adjustments; monitor closely.

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Adverse reactions: Visual disturbances, GI upset, abdominal pain, rash (eg, Stevens-Johnson syndrome), fever, headache, sepsis, edema, hepatotoxicity, cardiovascular or CNS effects, hypokalemia, infusion reactions.

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How supplied: Tabs–30; Susp–75mL (w. dispenser); Vials–1

9C Malaria

CHLOROQUINE

Rx

ARALEN Sanofi Aventis

Aminoquinoline. Chloroquine phosphate 500mg; tabs.

Indications: Suppression and treatment of susceptible malaria.**Adults:** Suppression: 500mg once every 7 days. Treatment: 1g once, then 500mg 6–8 hrs later; then 500mg once daily for next 2 days. Low body wt: use children's dose.**Children:** Suppression: 8.35mg/kg (max 500mg) once every 7 days. Treatment: 16.7mg/kg (max 1g) once, then 8.35mg/kg (max 500mg) 6, 24 and 36 hrs after 1st dose.**Contraindications:** Retinal or visual field changes.**Warnings/Precautions:** Suppression: start 2 wks before and continue for 8 wks after trip. Hepatic or auditory dysfunction. Alcoholism. Psoriasis. Porphyria. Seizure disorders. G6PD deficiency. Discontinue if hematologic, visual disorders or ototoxicity occurs. Monitor CBC, reflexes, vision in long-term use. Elderly. Children. Pregnancy (use adequate contraception in endemic areas). Nursing mothers: not recommended.**Interactions:** Avoid cimetidine. Separate ampicillin dose by 2 hours; dosing of antacids, kaolin by 4 hours. Potentiates cyclosporine (monitor). Caution with hepatotoxic drugs.**Adverse reactions:** Retinopathy, headache, pruritus, photosensitivity, GI or CNS disturbances (eg, seizures, psychosis, tinnitus, visual changes), blood dyscrasias, neuromyopathy, cardiomyopathy.**How supplied:** Tabs–25

HYDROXYCHLOROQUINE

Rx

PLAQUENIL Covis

Aminoquinoline. Hydroxychloroquine sulfate 200mg; tabs.

Indications: Suppression and treatment of susceptible malaria.**Adults:** Suppression (start 2 wks before and continue for 8 wks after trip): 400mg every 7 days. Treatment: initially 800mg; then 400mg 6, 24, and 48 hrs after 1st dose.**Children:** Suppression (start 2 wks before and continue for 8 wks after trip): 6.45mg/kg (max 400mg) every 7 days. Treatment: initially 12.9mg/kg (max 800mg); then 6.45mg/kg (max 400mg) 6, 24 and 48 hrs after 1st dose.**Contraindications:** Long-term use in children. Retinal or visual field changes.**Warnings/Precautions:** Before using this product, be fully familiar with its toxicity. Hepatic dysfunction. Alcoholism. Psoriasis. Porphyria. G6PD deficiency. Monitor ocular function, reflexes, and blood in long-term use. Discontinue if blood dyscrasias occur. Children. Pregnancy. Nursing mothers.**Interactions:** Avoid other hepatotoxic or dermatotoxic drugs.**Adverse reactions:** Headache, dizziness, GI upset.**How supplied:** Tabs–100

MEFLOQUINE

Rx

MEFLOQUINE TABLETS (various)

Aminoquinoline. Mefloquine (as HCl) 250mg; scored tabs.

Indications: Prophylaxis of *P. falciparum* (including chloroquine-resistant strains) and *P. vivax* malaria.Treatment of mild to moderate acute malaria due to susceptible strains of *P. falciparum* or *P. vivax*.**Adults:** Take with food and 8oz water. Prophylaxis: 250mg once weekly starting 1 week before departure, continuing during travel to endemic areas and for 4 weeks after return. Treatment: 1250mg as a single dose.**Children:** Give with food and water. May crush tab and mix in water. Prophylaxis: 3–5mg/kg once weekly starting 1 week before departure, continuing during travel to endemic areas and for 4 weeks after return. Treatment: ≤6months of age: contact manufacturer. ≥6months: 20–25mg/kg as single dose or as 2 doses 6–8 hours apart.**Contraindications:** Quinine, quinidine, or related allergy. Not for prophylactic use in patients with psychiatric disorders or history of depression or seizures.**Warnings/Precautions:** Do not use for life-threatening *P. falciparum* infection. After initial treatment for acute *P. vivax* infection, follow with an 8-aminoquinoline (eg, primaquine) to eliminate exoerythrocytic phase. Discontinue prophylactic therapy if unexplained CNS disturbances occur. Cardiac disease. Psychiatric disturbances. Seizure disorders. Hepatic impairment. Monitor liver, visual function in long-term use. Pregnancy (Cat.C); use adequate contraception. Nursing mothers: not recommended.**Interactions:** Do not use during or within 12 hours of quinine, quinidine, chloroquine (may cause seizures or ECG changes); caution with drugs that cause QTc prolongation (eg, β -blockers). Do not use halofantrine or ketoconazole during or within 15 weeks of last mefloquine dose. Caution with rifampin. May affect or be affected by CYP3A4 inhibitors or inducers, p-glycoprotein substrates. May antagonize antiepileptics. Complete live oral bacterial vaccinations (eg, typhoid) at least 3 days before 1st mefloquine dose. Monitor anticoagulants, antidiabetics, antiepileptics 2–3 weeks before departure.**Adverse reactions:** Vomiting, dizziness, vertigo, syncope, extrasystoles, myalgias, fever, headache, chills, diarrhea, rash, abdominal pain, fatigue, anorexia, tinnitus; rare: seizures, cardiac arrest, encephalopathy, CNS/emotional disturbances.**How supplied:** Contact supplier.

QUININE SULFATE

QUALAQUIN AR Scientific

Quinine (cinchona alkaloids). Quinine sulfate 324mg; caps.

Indications: Treatment of uncomplicated *P. falciparum* malaria (including chloroquine-resistant strains).

Adults: Take with food. ≥ 16 yrs: 648mg every 8hrs for 7 days. Severe renal failure: 648mg once, after 12hrs start 324mg every 12hrs. Hepatic impairment (severe): not recommended; (mild and moderate): monitor closely.

Children: < 16 yrs: not established.

Contraindications: Prolonged QT interval. G6PD deficiency. Myasthenia gravis. Mefloquine, quinidine or related allergy. History of thrombocytopenic purpura, hemolytic uremic syndrome, thrombocytopenia, blackwater fever associated with previous quinine use. Optic neuritis.

Warnings/Precautions: Not for treatment of severe or complicated *P. falciparum* malaria. Not for prevention of malaria. Not for treatment or prevention of nocturnal leg cramps; serious and life-threatening hematologic reactions may develop. Discontinue if any signs/symptoms of hypersensitivity occurs (eg, thrombocytopenic purpura, hemolytic uremic syndrome, thrombocytopenia, blackwater fever). Underlying structural heart disease. Preexisting conduction abnormalities. Cardiac arrhythmias. Atrial fibrillation or atrial flutter. MI. Hypoglycemia. Hypokalemia. Bradycardia. Severe hepatic impairment: use alternative therapy. Elderly with sick sinus syndrome. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid drugs that can prolong QT interval (eg, quinidine, procainamide, disopyramide, amiodarone, sotalol, dofetilide), other CYP3A4 substrates (eg, cisapride, terfenadine, pimozone, halofantrine, quinidine), erythromycin, troleandomycin. Avoid concomitant mefloquine, halofantrine (may cause seizures or ECG changes), rifampin, ritonavir, antacids. Potentiates warfarin, oral anticoagulants, neuromuscular blocking agents. Potentiated by urinary alkalinizers. May potentiate atorvastatin (monitor). May antagonize anticonvulsants (eg, carbamazepine, phenobarbital, phenytoin), CYP2D6 substrates (eg, flecainide, metoprolol, paroxetine, dextromethorphan). Increases digoxin levels (monitor). Monitor cimetidine, ranitidine, ketoconazole, tetracycline, theophylline, aminophylline.

Adverse reactions: Headache, vasodilation, sweating, nausea, tinnitus, hearing impairment, vertigo, dizziness, blurred vision, disturbances in color perception, cardiac rhythm or conduction, vomiting, diarrhea, abdominal pain, deafness, blindness, lupus-like syndrome, blood dyscrasias; rashes (may be serious, eg, Stevens-Johnson), cardiovascular effects (eg, chest pain, AV block, torsades de pointes), hypoglycemia (esp. in pregnancy).

How supplied: Caps-30, 100, 500, 1000

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9D Protozoal infections

CHLOROQUINE

R

ARALEN Sanofi Aventis

Aminoquinoline. Chloroquine phosphate 500mg; tabs.

Indications: Extraintestinal amebiasis (use with intestinal amebicide).

Adults: 1g daily for 2 days, then 500mg daily for at least 2-3 wks.

Children: See literature.

Contraindications: Retinal or visual field changes.

Warnings/Precautions: Suppression: start 2 wks before and continue for 8 wks after trip. Hepatic or auditory dysfunction. Alcoholism. Psoriasis. Porphyrria. Seizure disorders. G6PD deficiency. Discontinue if hematologic, visual disorders or ototoxicity occurs. Monitor CBC, reflexes, vision in long-term use. Elderly. Children. Pregnancy (use adequate contraception in endemic areas). Nursing mothers: not recommended.

Interactions: Avoid cimetidine. Separate ampicillin dose by 2 hours; dosing of antacids, kaolin by 4 hours. Potentiates cyclosporine (monitor). Caution with hepatotoxic drugs.

Adverse reactions: Retinopathy, headache, pruritus, photosensitivity, GI or CNS disturbances (eg, seizures, psychosis, tinnitus, visual changes), blood dyscrasias, neuromyopathy, cardiomyopathy.

How supplied: Tabs-25

METRONIDAZOLE

R

FLAGYL Pfizer

Nitroimidazole. Metronidazole 250mg, 500mg; scored tabs.

Also: Metronidazole

R

FLAGYL 375

Metronidazole 375mg; caps.

Indications: Amebic dysentery. Amebic liver abscess.

Adults: Dysentery: 750mg. Abscess: 500-750mg. Both: 3 times daily for 5-10 days.

Children: 35-50mg/kg/day in 3 divided doses for 10 days.

Contraindications: Pregnancy (1st trimester for trichomoniasis).

Warnings/Precautions: CNS disease. Discontinue if neurologic symptoms occur. Severe hepatic disease: reduce dose. History of blood dyscrasias. Candidiasis. Monitor leukocytes before and after therapy. Elderly: monitor serum levels. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid alcohol during and for 3 days after use. Do not give within 2 weeks of disulfiram (possible psychotic reactions). May potentiate oral anticoagulants, phenytoin, lithium. Antagonized by phenobarbital, phenytoin, other hepatic enzyme inducers. May impair phenytoin clearance. Potentiated by cimetidine, other hepatic enzyme inhibitors. Interferes with serum chemistry tests.

Adverse reactions: Seizures, peripheral neuropathy, GI upset, anorexia, constipation, headache, metallic taste, ECT changes, dysuria.
How supplied: Tabs-50, 100; Caps 375mg-50

TINIDAZOLE

TINDAMAX Mission
 Nitroimidazole. Tinidazole 250mg, 500mg; scored tabs.

Indications: Giardiasis. Intestinal amebiasis. Amebic liver abscess.

Adults: Take with food. Giardiasis: 2g as a single dose. Intestinal amebiasis: 2g once daily for 3 days. Amebic liver abscess: 2g once daily for 3-5 days. Hemodialysis: see literature.

Children: <3yrs: not recommended. Take with food. ≥3yrs: Giardiasis: 50mg/kg (max 2g) as a single dose. Intestinal amebiasis: 50mg/kg (max 2g) per day for 3 days. Amebic liver abscess: 50mg/kg (max 2g) per day for 3-5 days.

Contraindications: Pregnancy (1st trimester).

Warnings/Precautions: CNS disorders. Discontinue if neurological effects occur. Hepatic dysfunction. Candidiasis. Blood dyscrasias. Monitor leukocytes before and after therapy. Elderly. Pregnancy (Cat.C) (2nd and 3rd trimesters). Nursing mothers: not recommended during and for 3 days after last dose.

Interactions: Avoid alcohol during and for 3 days after use. Do not give within 2 weeks of disulfiram. May potentiate oral anticoagulants, lithium, phenytoin. Monitor cyclosporine, tacrolimus, fluorouracil. May be antagonized by CYP450 inducers (eg, phenobarbital, rifampin), others. May be potentiated by CYP450 inhibitors (eg, cimetidine, ketoconazole). May interfere with serum chemistry tests.

Adverse reactions: GI upset, abdominal pain, metallic taste, anorexia, constipation, fatigue, dizziness, headache, transient leukopenia/neutropenia; rare: seizures, peripheral neuropathy.

How supplied: Tabs 250mg-40; 500mg-20

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followed by 200mg three times weekly (≥48hrs between doses) for 22 weeks.

Children: <18yrs: not established.

Warnings/Precautions: Increased risk of mortality. Increased risk of QT prolongation in patients with history of Torsade de Pointes, congenital long QT syndrome, hypothyroidism, bradyarrhythmias, uncompensated heart failure, electrolyte abnormalities; monitor closely. Obtain ECG prior to therapy, and at least 2, 12, and 24 weeks after starting. Correct any electrolyte abnormalities at baseline and monitor if QT prolongation is detected. Discontinue Sirturo and all other QT prolonging drugs if ventricular arrhythmia or QTcF interval >500ms develops. Monitor ALT/AST, phosphatase, bilirubin at baseline, monthly during treatment, and as needed. Test for viral hepatitis and discontinue other hepatotoxic drugs if serum aminotransferases >3×ULN (repeat testing within 48 hours). Discontinue if aminotransferase elevation with total bilirubin >2×ULN, aminotransferase elevation >8×ULN, or aminotransferase elevations persist >2 weeks. Severe hepatic or severe renal impairment/ESRD. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid concomitant use with strong CYP3A4 inducers (eg, rifampin, rifapentine, rifabutin). Avoid concomitant use with strong CYP3A4 inhibitors (eg, ketoconazole) for >14 days; monitor. Additive QT prolongation with other drugs that prolong the QT interval (eg, fluoroquinolones, macrolides, clofazimine). Avoid alcohol and other hepatotoxic drugs. Sirturo exposure increased with Kaletra (caution).

Adverse reactions: Nausea, arthralgia, headache, hemoptysis, chest pain; arrhythmias, syncope (obtain ECG), hepatic dysfunction, QT prolongation.

How supplied: Tabs-188

ETHAMBUTOL

MYAMBUTOL Elan
 Ethambutol HCl 100mg, 400mg+; tabs; + scored.

Indications: Susceptible pulmonary tuberculosis with other antituberculars.

Adults: Give once daily. Initially 15mg/kg per day. Retreatment: 25mg/kg per day, after 60 days decrease to 15mg/kg per day. Renal dysfunction: reduce dose.

Children: <13yrs: not recommended.

Contraindications: Optic neuritis.

Warnings/Precautions: Test visual acuity before beginning therapy and periodically; monthly if dose exceeds 15mg/kg per day. Monitor blood, renal, and hepatic function in long-term use. Gout. Pregnancy. Nursing mothers.

Adverse reactions: Dermatitis, pruritus, joint pain, GI upset, fever, malaise, headache, dizziness, confusion, peripheral neuritis, gout, reduced visual acuity, optic neuritis.

How supplied: Tabs 100mg-100; 400mg-100, 1000

R

9E Tuberculosis

BEDAQUILINE

SIRTURO Janssen Therapeutics
 Diarylquinoline. Bedaquiline 100mg; tabs.

Indications: As part of combination therapy in pulmonary multi-drug resistant tuberculosis (MDR-TB) only when an effective treatment regimen cannot otherwise be provided. Limitations of use: the safety and efficacy for treatment of latent infection, drug-sensitive, or extra-pulmonary tuberculosis (eg, CNS) has not been established.

Adults: Administer by directly observed therapy and in combination with ≥3 other drugs to which the isolate is susceptible. Swallow whole with water. Take with food. ≥18yrs: 400mg once daily for 2 weeks

R

ISONIAZID

ISONIAZID (various)

Isonicotinic acid. Isoniazid 300mg; scored tabs.**Indications:** Prophylaxis and treatment of susceptible tuberculosis.**Adults:** Prophylaxis: 300mg once daily. Active infection: 5mg/kg daily; max 300mg once daily. Do not interrupt therapy.**Children:** Prophylaxis: 10mg/kg once daily; max 300mg daily. Active infection: 10–20mg/kg once daily; max 500mg daily. Do not interrupt therapy.**Contraindications:** Previous isoniazid-associated hepatic injury. Acute hepatic disease.**Warnings/Precautions:** Impaired renal or hepatic function. Monitor hepatic and ocular function. Alcoholism. Diabetes. Increased risk of liver damage with increasing age. Multiple drug therapy and concomitant pyridoxine may be necessary. Pregnancy. Nursing mothers.**Interactions:** Potentiates phenytoin. Alcohol increases risk of hepatitis. Pyridoxine deficiency increases risk of neuropathy.**Adverse reactions:** Hepatitis, peripheral neuropathy, hepatic injury, GI distress, blood dyscrasias, pyridoxine deficiency, hyperglycemia, rheumatic and SLE-like syndrome.**How supplied:** Contact supplier.**PYRAZINAMIDE**

PYRAZINAMIDE (various)

Nicotinamide analogue. Pyrazinamide 500mg; scored tabs.**Indications:** Susceptible pulmonary tuberculosis.**Adults and Children:** 15–30mg/kg once daily; max 2g daily. Or 50–70mg/kg twice weekly based on lean body weight.**Contraindications:** Severe hepatic damage. Acute gout.**Warnings/Precautions:** Use with other antituberculars. Monitor hepatic function and serum uric acid before and during therapy. Hepatocellular damage or hyperuricemia with acute gouty arthritis: discontinue. Patients at risk for hepatitis (eg, alcoholism). Diabetes (blood glucose may be harder to control). HIV: see literature. Pregnancy (Cat.C). Nursing mothers.**Interactions:** May interfere with Acetest or Ketostix.**Adverse reactions:** Hepatitis, liver dysfunction, gout, GI disturbances, arthralgia, myalgia, blood dyscrasias (rare).**How supplied:** Contact supplier.**RIFAMPIN**

RIFADIN Sanofi Aventis

Rifamycin. Rifampin 150mg, 300mg; caps.**Also: Rifampin**

RIFADIN IV INJECTION

Rifampin 600mg/vial.

Indications: Susceptible pulmonary tuberculosis.

R

Adults: 10mg/kg in a single dose; max 600mg/day. Oral: give 1 hr before or 2 hrs after meals with water.**Children:** 10–20mg/kg; max 600mg/day. Oral: give 1 hr before or 2 hrs after meals with water.

Preparation of suspension: see full labeling.

Contraindications: Concomitant ritonavir-boosted saquinavir (increased risk of severe hepatotoxicity). Concomitant atazanavir, darunavir, fosamprenavir, saquinavir, tipranavir.**Warnings/Precautions:** Use with other antituberculars. Not recommended for intermittent therapy (risk of renal hypersensitivity reactions; rare). Impaired hepatic function. Obtain baseline LFTs (then every 2–4 weeks), bilirubin, serum creatinine, CBC, platelets. Diabetes. May stain body secretions and contact lenses. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** See Contraindications. Reduces serum levels of protease inhibitors: avoid concomitant use. Antagonizes anticonvulsants, digitoxin, antiarrhythmics, oral anticoagulants, antifungals, barbiturates, β -blockers, calcium channel blockers, chloramphenicol, clarithromycin, corticosteroids, cyclosporine, cardiac glycosides, clofibrate, oral or other hormonal contraceptives (consider nonhormonal methods), dapsone, diazepam, doxycycline, fluoroquinolones, haloperidol, oral hypoglycemics, levothyroxine, methadone, narcotic analgesics, progestins, quinine, tacrolimus, theophylline, tricyclic antidepressants, zidovudine, atovaquone, enalapril, sulfasalazine. May be potentiated by atovaquone, probenecid, cotrimoxazole. Concomitant ketoconazole decreases serum concentration of both drugs. Monitor prothrombin time with concomitant anticoagulants. Separate dosing of antacids by at least 1 hour. Avoid concomitant halothane. May cause false (+) urine tests for opiates. May inhibit assays for serum folate and Vit. B₁₂ (consider alternative methods). Perform LFTs and use contrast media prior to morning dose.**Adverse reactions:** GI disturbances, jaundice, headache, fever, drowsiness, fatigue, ataxia, dizziness, inability to concentrate, mental confusion, muscular weakness, pain in extremities, generalized numbness, visual disturbances, elevated BUN and serum uric acid, menstrual disturbances, urticaria, rash; rare: hepatitis, abnormal LFTs, blood dyscrasias.**How supplied:** 150mg–30; 300mg–60, 100; Vials–1**9F Viral infections****ABACAVIR**

ZIAGEN GlaxoSmithKline

Nucleoside analogue (reverse transcriptase inhibitor). Abacavir (as sulfate) 300mg; tabs.**Also: Abacavir**

ZIAGEN ORAL SOLUTION

Abacavir (as sulfate) 20mg/mL; strawberry-banana flavor; contains parabens, propylene glycol.

Indications: HIV-1 infection.

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Adults: >16 years: 300mg twice daily or 600mg once daily. Mild hepatic impairment: 200mg twice daily.

Children: <3 months: not recommended. ≥3 months–16 years: 8mg/kg twice daily; max 300mg twice daily.

Contraindications: See literature regarding fatal hypersensitivity reactions (which may include fever, rash, fatigue, nausea, vomiting, diarrhea, abdominal pain, or respiratory symptoms); discontinue as soon as suspected; do not restart, regardless of HLA-B*5701 status. Moderate or severe hepatic impairment.

Warnings/Precautions: Evaluate for presence of HLA-B*5701 allele prior to starting therapy or reinitiation; if positive, abacavir is not recommended; discontinue permanently if hypersensitivity cannot be ruled out. Decompensated liver disease or risk factors for liver disease. Suspend if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs. Cardiovascular disease. Smoking. Women, obesity, prolonged nucleoside exposure: increased risk of toxicity. Do not add as a single agent to a failing regimen. If stopped for reasons other than hypersensitivity, restart only if medical care can be readily accessed by patient or caregiver. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May antagonize methadone. May be potentiated by ethanol. Triple therapy (once daily regimen) with lamivudine + tenofovir: high rate of early viral non-response (see literature).

Adverse reactions: Nausea, vomiting, headache, malaise, fatigue, dreams/sleep disorders, diarrhea, fever, rash (may be severe, eg, Stevens-Johnson), ear/nose/throat infections, mild hyperglycemia, elevated triglycerides, pancreatitis; hypersensitivity reactions (may be fatal); lactic acidosis, severe hepatomegaly with steatosis, immune reconstitution syndrome, fat redistribution.

Note: Register pregnant patients exposed to abacavir by calling (800) 258-4263. Register patients who have had a hypersensitivity reaction to abacavir by calling (800) 270-0425.

How supplied: Tabs–60; Soln–240mL

ACYCLOVIR

R

ACYCLOVIR INJECTION (various)
Nucleoside analogue. Acyclovir (as sodium) 500mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; contains sodium 49mg/vial.

Indications: Genital herpes (severe initial episodes in immunocompetent patients). Herpes simplex (in neonates, and as initial and recurrent treatment in immunocompromised patients). Herpes simplex encephalitis. Varicella zoster (immunocompromised patients).

Adults: Give by IV infusion over 1 hour. Mucocutaneous herpes simplex

(immunocompromised): 5mg/kg every 8 hours for 7 days. Genital herpes: 5mg/kg every 8 hours for 5 days. Encephalitis: 10mg/kg every 8 hours for 10 days. Varicella zoster (immunocompromised): 10mg/kg every 8 hours for 7 days. All: max 20mg/kg every 8 hours. Obese: dose based on ideal body weight. Renal impairment: CrCl 25–50mL/min: give dose every 12 hours; CrCl 10–25mL/min: give dose every 24 hours; CrCl <10mL/min: reduce dose by 50% and give every 24 hours. Coincide a dose for after hemodialysis.

Children: Give by IV infusion over 1 hour. Neonatal (birth–3mos) herpes simplex: 10mg/kg every 8 hours for 10 days (doses of 15–20mg/kg every 8 hours have been used; see literature). Mucocutaneous herpes simplex (immunocompromised): 10mg/kg every 8 hours for 7 days. Encephalitis: 3mos–12yrs: 20mg/kg every 8 hours for 10 days. Varicella zoster: <12yrs (immunocompromised): 20mg/kg every 8 hours for 7 days. All: max 20mg/kg every 8 hours. Obese: dose based on ideal body weight. Renal impairment: CrCl 25–50mL/min: give dose every 12 hours; CrCl 10–25mL/min: give dose every 24 hours; CrCl <10mL/min: reduce dose by 50% and give dose every 24 hours. Coincide a dose for after hemodialysis.

Contraindications: Valacyclovir hypersensitivity.

Warnings/Precautions: Renal impairment: see literature. Maintain adequate hydration. Neurological or serious renal, hepatic, or electrolyte abnormalities, or significant hypoxia. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid nephrotoxic drugs. Potentiated by probenecid.

Adverse reactions: Inj site reactions, transient elevated BUN and serum creatinine, GI upset, pruritus, rash, CNS effects (esp. in elderly), elevated transaminases, hematologic abnormalities, renal failure, thrombotic thrombocytopenic purpura/hemolytic uremic syndrome in immunocompromised patients.

How supplied: Contact supplier.

ACYCLOVIR

R

ZOVIRAX CAPSULES GlaxoSmithKline
Nucleoside analogue. Acyclovir 200mg.

Also: Acyclovir

R

ZOVIRAX TABLETS
Acyclovir 400mg, 800mg.

Also: Acyclovir

R

ZOVIRAX SUSPENSION
Acyclovir 200mg/5mL; banana flavor.

Indications: Genital herpes. Herpes zoster. Varicella.

Adults: May give with food. Genital herpes: Initially 200mg every 4 hrs (5 times daily) for 10 days. Chronic: 400mg 2 times daily or 200mg 3–5 times daily for up to 12 months, then reevaluate. Intermittent: (at 1st sign of recurrence) 200mg every

4 hrs (5 times daily) for 5 days. Herpes zoster: 800mg every 4 hrs (5 times daily) for 7–10 days. Varicella (start at earliest sign/symptom): 800mg 4 times daily for 5 days. Renal impairment: reduce dose (see literature); give another dose after hemodialysis.

Children: <2yrs: not recommended. ≥2yrs: Varicella (start at earliest sign/symptom): 20mg/kg 4 times daily for 5 days; max 800mg/dose. >40kg: as adult. Others: see literature.

Contraindications: Valacyclovir hypersensitivity.

Warnings/Precautions: Renal impairment: see literature. Maintain adequate hydration. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid nephrotoxic drugs. Potentiated by probenecid.

Adverse reactions: Nausea, vomiting, headache, CNS disturbances (esp. elderly), diarrhea, vertigo, myalgia, rash, malaise, viral resistance, renal failure, thrombotic thrombocytopenic purpura/hemolytic uremic syndrome in immunocompromised patients.

How supplied: Caps, tabs–100; Susp–pt

ATAZANAVIR

R

REYATAZ Bristol-Myers Squibb
HIV-1 protease inhibitor. Atazanavir (as sulfate) 100mg, 150mg, 200mg, 300mg; caps.

Indications: HIV-1 infection, in combination with other antiretroviral agents.

Adults: See literature. Take with food. Treatment-naïve: atazanavir 300mg + ritonavir 100mg, both once daily; or atazanavir 400mg once daily if unable to tolerate ritonavir. Treatment-experienced: atazanavir 300mg + ritonavir 100mg; both once daily. Concomitant efavirenz (must also give ritonavir; not for treatment-experienced): atazanavir 400mg + ritonavir 100mg (both as a single daily dose) + efavirenz 600mg (on an empty stomach at bedtime). Concomitant tenofovir (must also give ritonavir): consider giving atazanavir 300mg + tenofovir 300mg + ritonavir 100mg; all as a single daily dose; see literature. Concomitant H₂-blockers or PPIs: see literature. ESRD with hemodialysis in treatment-naïve: atazanavir 300mg + ritonavir 100mg. Moderate hepatic impairment: 300mg once daily. Pregnancy (2nd or 3rd trimester) in treatment-experienced plus concomitant H₂-blocker or tenofovir: atazanavir 400mg + ritonavir 100mg, both once daily. All other pregnant patients: no dose adjustments needed. Postpartum period: no dose adjustments needed; monitor for adverse events during first 2 months after delivery.

Children: See literature. Take with food. <6yrs: not recommended. 6–18yrs: 15 to <20kg: atazanavir 150mg + ritonavir 100mg; 20 to <40kg: atazanavir 200mg + ritonavir 100mg; ≥40kg: atazanavir 300mg + ritonavir 100mg; all: single daily dose. Treatment-naïve: ≥13yrs and ≥40kg who are unable to tolerate ritonavir: atazanavir 400mg once daily. For patients ≥13yrs and ≥40kg receiving concomitant

tenofovir, H₂-blockers, or PPIs: give atazanavir with ritonavir.

Contraindications: Drugs metabolized by CYP3A or UGT1A1 that may cause serious effects if blood levels are elevated (eg, alfuzosin, rifampin, irinotecan, oral midazolam, triazolam, ergots, cisapride, St. John's wort, lovastatin, simvastatin, pimozide, indinavir, sildenafil [Revatio; when used to treat PAH]).

Warnings/Precautions: Cardiac conduction abnormalities. ESRD with hemodialysis in therapy-experienced or severe hepatic impairment: not recommended. Hepatic impairment. Hepatitis B and/or C or marked elevations in transaminases: monitor liver function tests before and during therapy. Consider alternative antivirals if jaundice, scleral icterus, or lactic acidosis occurs. Diabetes. Monitor for nephrolithiasis, hyperglycemia, fat redistribution, immune reconstitution syndrome, and hemophiliacs for spontaneous bleeding. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant nevirapine; other protease inhibitors (excluding ritonavir and saquinavir), salmeterol, or fluticasone (atazanavir + ritonavir): not recommended. Caution with drugs metabolized by UGT1A1 or CYP3A (eg, IV midazolam, calcium channel blockers, statins [eg, atorvastatin, rosuvastatin; use lowest dose necessary; max rosuvastatin dose is 10mg/day], immunosuppressants, PDE5 inhibitors: reduce doses of these to treat ED; max 25mg sildenafil in 48hrs; max 2.5mg vardenafil in 24hrs or 72hrs [atazanavir + ritonavir]; max 10mg tadalafil in 72hrs; tadalafil to treat PAH [see literature]), and CYP2C8 (eg, paclitaxel, repaglinide). Potentiated by CYP3A inhibitors, telaprevir. Antagonized by CYP3A inducers. Use cautiously and monitor diltiazem, antiarrhythmics, others that affect conduction (esp. if metabolized by CYP3A). Consider reducing diltiazem or clarithromycin dose by 50%; rifabutin dose by 75%. Variable effects on clarithromycin; consider other drugs. Plasma levels decreased by drugs that reduce gastric acidity (eg, H₂-blockers, antacids). Give proton pump inhibitors 12hrs before atazanavir + ritonavir; avoid in therapy-experienced. Give 2hrs before or 1hr after buffered or enteric coated didanosine. Antagonized by efavirenz, bosentan, tenofovir (see dose). Increased risk of lactic acidosis with nucleoside analogues. Potentiates saquinavir, trazodone, fluticasone, oral contraceptives, ketoconazole, itraconazole, buprenorphine (reduce dose), colchicine (esp. renal or hepatic impaired; do not use). Monitor warfarin, tricyclics, rifabutin, immunosuppressants.

Adverse reactions: GI upset, abdominal pain, jaundice, scleral icterus, rash (may be severe; discontinue if occurs), headache, insomnia, peripheral neuropathy, dizziness, myalgia, depression, fever, lab abnormalities, hyperglycemia, fat redistribution, immune reconstitution syndrome, hyperbilirubinemia, nephrolithiasis, 2nd or 3rd-degree AV block, QT

prolongation. Children: also cough, peripheral edema, extremity pain, nasal congestion, oropharyngeal pain, wheezing, rhinorrhea.

Note: Register pregnant patients exposed to atazanavir by calling (800) 258-4263. See ritonavir entry in this section for more information.

How supplied: 100mg, 150mg, 200mg-60; 300mg-30

BOCEPREVIR

R

VICTRELIS Merck

HCV NS3/4A protease inhibitor. Boceprevir 200mg; capsules.

Indications: Chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin in adult patients with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy including prior null responders, partial responders, and relapsers. Not for use as monotherapy.

Adults: ≥ 18 yrs: Take with food. 800mg three times daily. Start after 4 weeks therapy with peginterferon and ribavirin. Without cirrhosis: continue treatment as indicated by HCV-RNA levels at Weeks 8, 12, and 24 (see full labeling). With cirrhosis: continue for 44 weeks. Do not reduce dose. Discontinue if HCV-RNA levels indicate futility (see full labeling).

Children: < 18 yrs: not recommended.

Contraindications: Concomitant potent CYP3A4/5 inducers (eg, carbamazepine, phenobarbital, phenytoin, rifampin, St. John's Wort) or narrow therapeutic index CYP3A4/5 substrates (eg, alfuzosin, cisapride, ergot derivatives, lovastatin, simvastatin, drospirone, pimozone, sildenafil or tadalafil for PAH, triazolam, oral midazolam). Pregnant women and men whose partners are pregnant (note: ribavirin is Cat.X). Review peginterferon and ribavirin contraindications.

Warnings/Precautions: Female patients and partners must have (–) pregnancy test before therapy, use appropriate effective contraception, and undergo monthly pregnancy test. Monitor CBC w. differential, HCV-RNA. If $hgb < 10g/dL$: reduce or interrupt ribavirin; if $hgb < 8.5g/dL$: discontinue ribavirin; if ribavirin permanently discontinued, then peginterferon alfa and Victrelis must be discontinued. Co-infection with HBV or HIV. Decompensated cirrhosis. Organ transplant recipients. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See literature. Concomitant rifabutin, salmeterol, efavirenz, concomitant colchicine in renal or hepatic impairment: not recommended. Potentiates CYP3A4/5 substrates (eg, amiodarone, bepridil, propafenone, quinidine, flecainide, trazodone, desipramine, azole antifungals, clarithromycin). Antagonizes ethinyl estradiol. Antagonized by potent CYP3A4/5 inhibitors. Monitor warfarin, digoxin, dihydropyridine calcium channel blockers, bosentan, protease inhibitors, immunosuppressants,

opioids. Concomitant ketoconazole, itraconazole: max 200mg/day. Concomitant atorvastatin: max 40mg/day. Colchicine, PDE5 inhibitors for ED (eg, sildenafil, tadalafil, vardenafil), alprazolam, IV midazolam: reduce doses and monitor.

Corticosteroids: avoid, monitor if needed.

Adverse reactions: Fatigue, nausea, headache, dysgeusia, worsening anemia, neutropenia; hypersensitivity reactions (discontinue if occurs).

How supplied: Bottles (12 caps/bottle)-28

CIDOFOVIR

R

VISTIDE Gilead

Nucleotide analogue. Cidofovir 75mg/mL; for IV infusion after dilution; preservative-free.

Indications: Treatment of cytomegalovirus (CMV) retinitis in patients with AIDS.

Adults: Give by IV infusion over 1hr. Pretreat with oral probenecid (2g three hrs before starting cidofovir dose, and 1g two and eight hrs after cidofovir infusion has ended) and IV normal saline hydration (1L immediately before each dose of cidofovir; patients who can tolerate fluid load should receive a 2nd liter either during or after each dose of cidofovir). Induction: 5mg/kg once weekly for 2 consecutive weeks. Maintenance: 5mg/kg once every 2 weeks; reduce to 3mg/kg if serum creatinine increases 0.3–0.4mg/dL above baseline. Discontinue if serum creatinine increases ≥ 0.5 mg/dL above baseline or if $\geq 3+$ proteinuria develops.

Children: Not recommended.

Contraindications: Serum creatinine > 1.5 mg/dL or CrCl ≤ 55 mL/min, or urine protein ≥ 100 mg/dL. Severe probenecid or sulfa allergy. Within 7 days of discontinuing other nephrotoxic drugs (eg, amphotericin B, aminoglycosides, fosfarnet, IV pentamidine, NSAIDs, vancomycin). Not for intraocular injection.

Warnings/Precautions: Do not exceed recommended dose, frequency, or rate of administration (increased risk of nephrotoxicity). Women should use effective contraception during and one month after therapy. Men should use barrier contraception during and 3 months after therapy. Monitor serum creatinine, urine protein, WBC with differential before each dose; monitor intraocular pressure, visual acuity, ocular symptoms and for tinnitus. Handle and dispose of properly. Elderly. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: See Contraindications. Probenecid interferes with the metabolism or renal tubular secretion of many drugs (including didanosine, adjust dose).

Adverse reactions: Elevated serum creatinine, proteinuria, neutropenia, ocular hypotony, uveitis, iritis, metabolic acidosis, GI disturbances, fever, asthenia, rash, headache, alopecia, infection, chills, dyspnea; others: see literature.

How supplied: Single-use vials (5mL)-1

DARUNAVIR

PREZISTA Janssen Therapeutics
Protease inhibitor. Darunavir (as ethanolate) 75mg, 150mg, 400mg, 600mg, 800mg; tabs.

Also: Darunavir**PREZISTA ORAL SUSPENSION**

Darunavir (as ethanolate) 100mg/mL; strawberry-cream flavor.

Indications: Treatment of HIV infection in combination with ritonavir and with other antiretroviral agents.

Adults: Take with food. Use oral susp if unable to swallow tabs. ≥ 18 yrs: Treatment-naïve and treatment-experienced with no darunavir resistance associated substitutions: 800mg once daily with ritonavir 100mg once daily. Treatment-experienced with at least one darunavir resistance associated substitution: 600mg twice daily with ritonavir 100mg twice daily. Severe hepatic impairment: not recommended.

Children: < 3 yrs: not recommended. Take with food. Use oral susp if unable to swallow tabs. Treatment-naïve and treatment-experienced with no darunavir resistance associated substitutions: ≥ 3 yrs to < 18 yrs: ≥ 10 kg– < 11 kg: 350mg once daily with ritonavir 64mg once daily; ≥ 11 kg– < 12 kg: 385mg once daily with ritonavir 64mg once daily; ≥ 12 kg– < 13 kg: 420mg once daily with ritonavir 80mg once daily; ≥ 13 kg– < 14 kg: 455mg once daily with ritonavir 80mg once daily; ≥ 14 kg– < 15 kg: 490mg once daily with ritonavir 96mg once daily ≥ 15 – < 30 kg: 600mg (6mL of susp) once daily with ritonavir 100mg once daily; ≥ 30 kg– < 40 kg: 675mg (6.8mL of susp) once daily with ritonavir 100mg once daily; ≥ 40 kg: 800mg once daily with ritonavir 100mg once daily. Treatment-experienced with at least one darunavir resistance associated substitution: ≥ 3 yrs to < 18 yrs: ≥ 10 kg– < 11 kg: 200mg twice daily with ritonavir 32mg twice daily; ≥ 11 kg– < 12 kg: 220mg twice daily with ritonavir 32mg twice daily; ≥ 12 kg– < 13 kg: 240mg twice daily with ritonavir 40mg twice daily; ≥ 13 kg– < 14 kg: 260mg twice daily with ritonavir 40mg twice daily; ≥ 14 kg– < 15 kg: 280mg twice daily with ritonavir 48mg twice daily ≥ 15 – < 30 kg: 375mg (3.8mL of susp) twice daily with ritonavir 48 mg twice daily; ≥ 30 kg– < 40 kg: 450mg (4.6mL of susp) twice daily with ritonavir 60mg twice daily; ≥ 40 kg: 600mg twice daily with ritonavir 100mg twice daily. Severe hepatic impairment: not recommended.

Contraindications: Concomitant rifampin, alfuzosin, ergots, cisapride, St. John's wort, lovastatin, simvastatin, pimozide, oral midazolam, triazolam, sildenafil (Revatio; only when used to treat PAH).

Warnings/Precautions: Sulfonamide allergy. Hepatic impairment (eg, chronic hepatitis, cirrhosis, pre-treatment elevated transaminases); monitor liver enzymes; interrupt or discontinue therapy if liver dysfunction occurs or worsens. Severe renal impairment. Diabetes (may need insulin or oral hypoglycemics dose adjusted). Hemophilia: monitor

for spontaneous bleeding. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Voriconazole, salmeterol, boceprevir, telaprevir: not recommended. Avoid protease inhibitors other than those studied (lopinavir/ritonavir, saquinavir, indinavir, atazanavir), dexamethasone, fluticasone. Potentiates carbamazepine, risperidone, thioridazine, trazodone, desipramine, IV midazolam, rifabutin, digoxin, HMG-CoA reductase inhibitors (eg, pravastatin, atorvastatin, rosuvastatin; use lowest dose necessary; max atorvastatin dose is 20mg/day), sildenafil, vardenafil, tadalafil (reduce their doses). Potentiates, and is potentiated by, indinavir, ketoconazole, itraconazole. Increases bosentan (see literature), maraviroc, nevirapine, tenofovir, efavirenz, colchicine (dose adjustments: see literature) levels. Antagonizes sertraline, paroxetine, phenytoin, phenobarbital (monitor levels), ethinyl estradiol, norethindrone (use backup contraception). Caution with antimalarials (artemether, lumefantrine). Monitor carbamazepine, antiarrhythmics (eg, bepridil, systemic lidocaine, quinidine, amiodarone, flecainide, propafenone), calcium channel blockers, β -blockers, warfarin, digoxin, immunosuppressants (eg, tacrolimus, sirolimus, cyclosporine), buprenorphine, buprenorphine/naloxone, methadone (possible opiate withdrawal syndrome). Reduce concomitant clarithromycin dose in renal impairment. Separate dosing of didanosine. Others.

Adverse reactions: Diarrhea, nausea, vomiting, abdominal pain, headache; skin reactions (may be severe; discontinue if occurs), drug-induced hepatitis, new onset diabetes, hyperglycemia, fat redistribution, immune reconstitution syndrome, others.

Note: See ritonavir entry for more information. To register pregnant patients exposed to darunavir/ritonavir call (800) 258-4263.

How supplied: Tabs 75mg–480; 150mg–240; 400mg, 600mg–60, 800–30; Oral susp–200mL

DIDANOSINE

VIDEX EC Bristol-Myers Squibb Vir.

Nucleoside analogue (reverse transcriptase inhibitor). Didanosine 125mg, 200mg, 250mg, 400mg; e-c delayed-release caps.

Indications: HIV-1 infection.

Adults and Children: Take once daily on an empty stomach; swallow whole. < 20 kg: use oral soln. 20kg to < 25 kg: 200mg. 25kg to < 60 kg: 250mg. ≥ 60 kg: 400mg. Renal impairment (CrCl 30–59mL/min): < 60 kg: 125mg; ≥ 60 kg: 200mg. CrCl 10–29mL/min: 125mg. CrCl < 10 mL/min or dialysis: < 60 kg: use oral soln; ≥ 60 kg: 125mg.

Also: Didanosine**VIDEX PEDIATRIC POWDER FOR ORAL SOLUTION**

Didanosine 2g, 4g; pwd for oral soln after reconstitution and dilution.

Adults: Take on an empty stomach. < 60 kg: 125mg twice daily. ≥ 60 kg: 200mg twice daily. If once daily

dosing required: <60kg: 250mg, ≥60kg: 400mg. Renal impairment (CrCl 30–59mL/min): <60kg: 150mg once daily or 75mg twice daily; ≥60kg: 200mg once daily or 100mg twice daily; CrCl 10–29mL/min: <60kg: 100mg once daily; ≥60kg: 150mg once daily; CrCl <10mL/min or dialysis: <60kg: 75mg once daily; ≥60kg: 100mg once daily.

Children: See literature. Take on empty stomach. <2 weeks: not recommended. 2 weeks–8 months: 100mg/m² twice daily. ≥8 months: 120mg/m² twice daily. Renal impairment: consider reducing dose and/or increasing dosing interval.

Contraindications: Concomitant allopurinol or ribavirin.

Warnings/Precautions: Suspend if signs or symptoms of pancreatitis (discontinue if confirmed), lactic acidosis, or hepatotoxicity (eg, hepatomegaly or steatosis) occurs. Increased risk of pancreatitis (eg, alcohol abuse, advanced HIV disease, elderly, renal impairment); monitor. Women, obesity, or prolonged nucleoside exposure: increased risk of toxicity. Advanced HIV disease, history of neuropathy, or concomitant neurotoxic drugs: consider reducing dose or discontinuing if peripheral neuropathy occurs. Monitor for non-cirrhotic portal hypertension; discontinue if occurs. Hepatic dysfunction. Hyperuricemia. Do periodic retinal exam. Elderly. Pregnancy (Cat.B); monitor for lactic acidosis if used with stavudine. Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid with hydroxyurea and stavudine. Potentiated by ganciclovir, tenofovir (reduce dose of didanosine; monitor). Antagonized by methadone. For pediatric pwt: caution with magnesium- or aluminum-containing antacids. Separate dosing of delavirdine, indinavir, nelfinavir by 1 hour; give drugs affected by gastric pH (eg, ketoconazole, itraconazole) 2 hours prior. May antagonize quinolones, tetracyclines. Give at least 6 hours before or 2 hours after ciprofloxacin. See literature for dosing with concomitant tenofovir.

Adverse reactions: GI disturbances, headache, rash; elevated liver enzymes, amylase, and lipase; pancreatitis, lactic acidosis/hepatomegaly with steatosis, retinal changes, optic neuritis, peripheral neuropathy, hyperuricemia, fat redistribution, immune reconstitution syndrome, non-cirrhotic portal hypertension.

Note: Register pregnant patients exposed to didanosine by calling (800) 258-4263.

How supplied: EC caps–30; Pediatric pwt (bottles)–120mL, 240mL.

DOLUTEGRAVIR

TIVICAY ViiV Healthcare

HIV-1 integrase strand transfer inhibitor (INSTI).

Dolutegravir 50mg; tablets.

Indications: In combination with other antiretroviral agents for the treatment of HIV-1 infection.

Adults: ≥12 years and ≥40kg: treatment-naïve or treatment-experienced INSTI-naïve: 50mg once daily.

Treatment-naïve or treatment-experienced INSTI-naïve with concomitant potent UGT1A/CYP3A inducers (eg, efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, or rifampin): 50mg twice daily. INSTI-experienced with certain INSTI-associated resistance substitutions or clinically suspected INSTI resistance: 50mg twice daily.

Children: <12 years or <40kg, or INSTI-experienced with documented or clinically suspected resistance to other INSTIs (raltegravir, elvitegravir): not established.

Contraindications: Concomitant dofetilide.

Warnings/Precautions: Discontinue if hypersensitivity reactions develop. Increased risk for worsening/development of elevated transaminases in patients with hepatitis B or C; monitor LFTs prior to starting and during therapy. Severe hepatic impairment: not recommended. INSTI-experienced patients (with certain INSTI-associated resistance substitutions or clinically suspected INSTI resistance) with severe renal impairment: decrease in dolutegravir concentrations may result in loss of efficacy and development of resistance. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May be affected by drugs that induce or inhibit UGT1A1, UGT1A3, UGT1A9, BCRP, and P-gp enzymes or transporters. Avoid concomitant nevirapine, oxcarbazepine, phenytoin, phenobarbital, carbamazepine, St. John's wort. Avoid efavirenz unless coadministered with atazanavir/ritonavir, darunavir/ritonavir, or lopinavir/ritonavir. Concomitant efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, or rifampin: adjust dose to 50mg twice daily. Concomitant cation-containing antacids, laxatives, sucralfate, oral iron/calcium supplements, and buffered drugs: give dolutegravir 2 hours before or 6 hours after. Concomitant metformin; monitor closely and adjust metformin dose if necessary.

Adverse reactions: Insomnia, headache; immune reconstitution syndrome, lab abnormalities.

How supplied: Tabs–30

EFAVIRENZ

SUSTIVA Bristol-Myers Squibb Vir.
Non-nucleoside reverse transcriptase inhibitor.
Efavirenz 50mg, 200mg; caps.

Also: Efavirenz

SUSTIVA TABLETS

Efavirenz 600mg.

Indications: HIV-1 infection, in combination with other antiretroviral agents.

Adults and Children: Swallow whole; do not break tabs. If unable to swallow tabs or caps: may sprinkle capsule content and mix in 1–2tsp of soft food (eg, applesauce, grape jelly, yogurt) or 2tsp of room temperature infant formula; administer within 30mins of mixing. Give once daily on an empty stomach, preferably at bedtime. Consider pretreating with antihistamine (for children) or steroid to minimize rash. <3months: not recommended.

≥3months (3.5kg to <5kg):100mg; (5kg to <7.5kg): 150mg; (7.5kg to <15kg): 200mg; (15kg to <20kg): 250mg; (20kg to <25kg): 300mg; (25kg to <32.5kg): 350mg; (32.5kg to <40kg): 400mg; (≥40kg) and adults: 600mg. Concomitant voriconazole: increase voriconazole maintenance dose to 400mg every 12 hours and decrease efavirenz dose to 300mg once daily using capsule form. Concomitant rifampin (patient ≥50kg): increase efavirenz dose to 800mg once daily.

Contraindications: Concomitant bepridil, cisapride, ergots, midazolam, triazolam, pimozone, St. John's wort.

Warnings/Precautions: CNS or psychiatric disturbances. Hepatic impairment: moderate or severe: not recommended; mild: use caution. Monitor liver function before and during therapy in patients with underlying diseases (eg, hepatitis B or C coinfection, marked transaminase elevations, being treated with other hepatotoxic drugs). History of seizures. Monitor cholesterol and triglycerides before starting and periodically thereafter. Discontinue if severe rash (w. blistering, desquamation, mucosal involvement, or fever) occurs. Obtain (–) pregnancy test before starting; use adequate (barrier + hormonal) contraception during and for 12 weeks after discontinuation. Elderly. Pregnancy (Cat.D; avoid esp. during 1st trimester). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid concomitant other efavirenz-containing products (eg, Atripla unless needed for dose adjustment with rifampin), atazanavir (treatment-experienced), posaconazole, alcohol, psychoactive and/or other hepatotoxic drugs. Caution with drugs metabolized by, or that affect activity of, CYP2C9, CYP2C19, CYP3A4. Efavirenz levels decreased by carbamazepine, phenytoin, phenobarbital, rifampin (adjust dose), rifabutin. May decrease levels of indinavir, amprenavir, atazanavir, anticonvulsants, clarithromycin, calcium channel blockers (eg, diltiazem, felodipine, nifedipine, nifedipine, verapamil), itraconazole, ketoconazole, lopinavir (adjust dose: see literature), maraviroc, raltegravir, bupropion, methadone, rifabutin (increase dose: see literature), sertraline, simvastatin, atorvastatin, pravastatin, progestins (eg, norelgestromin, levonorgestrel), etonogestrel, immunosuppressants (eg, cyclosporine, sirolimus, tacrolimus). Efavirenz increases nelfinavir plasma levels. May affect or be affected by voriconazole (adjust dose). Levels of both drugs increased with ritonavir (monitor liver function and for adverse events). Levels of both drugs are decreased with telaprevir, or saquinavir (do not use as sole protease inhibitor). Closely monitor warfarin, anticonvulsants (esp. phenytoin, phenobarbital, carbamazepine), rifabutin, others. May cause false (–) cannabis screening test (CEDIA DAU multi-level THC assay).

Adverse reactions: CNS effects (eg, dizziness, headache, insomnia, impaired concentration, abnormal dreams), psychiatric effects (eg, severe

depression, suicidal ideation/attempt, aggression, paranoia, mania, delusions, psychosis), rash (may be severe; eg, Stevens-Johnson, erythema multiforme), nausea, vomiting, fatigue, fever, cough, dyspnea, immune reconstitution syndrome, redistribution of body fat; hepatotoxicity, dyslipidemia.

Note: Register pregnant patients exposed to efavirenz by calling (800) 258-4263.

How supplied: Caps 50mg–30; 200mg–90; Tabs 600mg–30

EFAVIRENZ + EMTRICITABINE + TENOFOVIR

ATRIPLA Bristol-Myers Squibb and Gilead
Non-nucleoside reverse transcriptase inhibitor + nucleoside analogue + nucleotide analogue.
Efavirenz 600mg, emtricitabine 200mg, tenofovir DF 300mg; tabs.

Indications: HIV-1 infection, use alone or in combination with other antiretroviral agents.

Adults: Take on empty stomach. ≥12yrs and ≥40kg: 1 tab once daily (preferably at bedtime). Concomitant rifampin (≥50kg): give additional 200mg/day of efavirenz.

Children: <12yrs: not recommended.

Note: See **Efavirenz, Emtricitabine, and Tenofovir** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions. Register pregnant patients exposed to Atripla by calling (800) 258-4263.

How supplied: Tabs–30

ELVITEGRAVIR + COBICISTAT + EMTRICITABINE + TENOFOVIR

STRIBILD Gilead
Integrase strand transfer inhibitor + pharmacokinetic enhancer + nucleos(t)ide analog HIV-1 reverse transcriptase inhibitors. Elvitegravir 150mg, cobicistat 150mg, emtricitabine 200mg, tenofovir disoproxil fumarate (DF) 300mg; tablets.

Indications: Treatment of HIV-1 infection in adults who are antiretroviral treatment-naïve.

Adults: 1 tablet once daily with food. Renal impairment (CrCl <70mL/min): do not initiate; if CrCl declines to <50mL/min during therapy discontinue. Severe hepatic impairment: not recommended.

Children: <18yrs: not established.

Contraindications: Concomitant afuzosin, rifampin, ergots, cisapride, St. John's wort, lovastatin, simvastatin, pimozone, sildenafil (when dosed for PAH), triazolam, oral midazolam.

Warnings/Precautions: Suspend therapy if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs. Not for treating chronic hepatitis B; test for HBV before starting therapy and closely monitor patients co-infected with HBV and HIV during and for several months after stopping treatment (discontinuing therapy may exacerbate HBV infection). Monitor creatinine clearance, urine glucose, urine

protein, serum phosphorus (for patients at risk for renal impairment). History of pathologic fracture or risk factors of osteoporosis or bone loss: consider monitoring bone mineral density (BMD). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid with concurrent or recent use of nephrotoxic agents. Do not administer with other antiretroviral agents. May be potentiated by CYP3A inhibitors, antagonized by CYP3A inducers. May potentiate drugs metabolized by CYP3A or CYP2D6, or are substrates of P-gp, BCRP, OATP1B1 or OATP1B3. May antagonize CYP2C9 substrates. Separate antacids by at least 2 hours. May potentiate antiarrhythmics, digoxin, clarithromycin (reduce dose by 50% if CrCl 50–60mL/min), telithromycin, carbamazepine, clonazepam, ethosuximide, SSRIs, TCAs, trazodone, ketoconazole (max 200mg/day), itraconazole (max 200mg/day), voriconazole, beta-blockers, calcium channel blockers, fluticasone (use alternative corticosteroid), atorvastatin, immunosuppressants, (monitor), neuroleptics, sedatives/hypnotics, PDE5 inhibitors (see literature for dose adjustments). Antagonized by carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifapentine, systemic dexamethasone. Concomitant colchicine (see literature); do not coadminister to patients with renal or hepatic impairment. Discontinue use of bosentan at least 36 hours prior to initiation of Stribild; after at least 10 days following initiation, resume bosentan. Concomitant salmeterol: not recommended; increased risk of cardiovascular events. Use alternative non-hormonal methods of contraception. Monitor INR.

Adverse reactions: Nausea, diarrhea; decreased BMD, fat redistribution, immune reconstitution syndrome.

How supplied: Tabs–30

EMTRICITABINE R

EMTRIVA Gilead

Nucleoside analogue (reverse transcriptase inhibitor). Emtricitabine 200mg; caps.

Indications: HIV-1 infection.

Adults: ≥ 18 yrs: 200mg once daily. Renal impairment (CrCl 30–49mL/min): 200mg every 48hrs; (CrCl 15–29mL/min): 200mg every 72hrs; (CrCl < 15 mL/min or dialysis): 200mg every 96hrs.

Children: < 3 months: not recommended. 3 months–17 yrs: ≤ 33 kg: use soln form. > 33 kg: 200mg once daily. Renal impairment: reduce dose or prolong dosing interval (see literature).

Also: Emtricitabine

EMTRIVA ORAL SOLUTION

Emtricitabine 10mg/mL; cotton candy flavor.

Adults: ≥ 18 yrs: 240mg (24mL) once daily. Renal impairment: (CrCl 30–49mL/min): 120mg (12mL) once daily; (CrCl 15–29mL/min): 80mg (8mL) once daily; (CrCl < 15 mL/min): 60mg (6mL) once daily.

Children: < 3 months: 3mg/kg once daily. 3 months–17 yrs: 6mg/kg [max 240mg (24mL)] once

daily. > 33 kg: may use cap form. Renal impairment: reduce dose or prolong dosing interval (see literature).

Warnings/Precautions: Suspend therapy if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs. Not for treating chronic hepatitis B; test for HBV before starting therapy and closely monitor patients co-infected with HBV and HIV during and for several months after stopping treatment (discontinuing therapy may exacerbate HBV infection). Women, obesity, or prolonged nucleoside exposure, other risk factors for hepatic dysfunction: increased risk of toxicity (eg, lactic acidosis). Renal impairment. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid concomitant drugs that contain emtricitabine or lamivudine.

Adverse reactions: Headache, GI upset, fatigue, dizziness, depression, insomnia, abnormal dreams, rash, abdominal pain, asthenia, increased cough, rhinitis; lactic acidosis, severe hepatomegaly with steatosis, fat redistribution, immune reconstitution syndrome, exacerbation of hepatitis B; also children: skin hyperpigmentation.

Note: Register pregnant patients exposed to emtricitabine by calling (800) 258-4263.

How supplied: Caps–30; Soln–170mL

EMTRICITABINE + TENOFOVIR R

TRUVADA Gilead

Nucleoside/nucleotide analogue (reverse transcriptase inhibitors). Emtricitabine 200mg, tenofovir disoproxil fumarate 300mg; tabs.

Indications: HIV-1 infection. Pre-exposure prophylaxis (PrEP) to reduce risk of sexually acquired HIV-1 in high-risk adults in combination with safer sex practices.

Adults: HIV-1 infection: ≥ 12 yrs (≥ 35 kg): 1 tab once daily. Renal impairment: CrCl 30–49mL/min: 1 tab every 48 hrs; CrCl < 30 mL/min, hemodialysis: not recommended. PrEP: Confirm negative HIV-1 test immediately prior to initiating, repeat at least every 3 months. 1 tab once daily. CrCl < 60 mL/min: do not use.

Children: < 12 yrs: not recommended.

Contraindications: PrEP in individuals with unknown or positive HIV-1 status.

Note: See **Emtricitabine** and **Tenofovir** monographs for Contraindications, Warnings/Precautions, Interactions, Adverse reactions. Register pregnant patients exposed to Truvada by calling (800) 258-4263.

How supplied: Tabs–30

EMTRICITABINE + TENOFOVIR + RILPIVIRINE R

COMPLERA Gilead

Nucleoside analogue reverse transcriptase inhibitors + non-nucleoside reverse transcriptase inhibitor. Emtricitabine 200mg, tenofovir disoproxil fumarate 300mg, rilpivirine 25mg; tabs.

Indications: HIV-1 infection.

Adults: Take with a meal. 1 tablet once daily. Renal impairment (CrCl <50mL/min): not recommended.

Children: <18yrs: not recommended.

Note: See **Emtricitabine**, **Tenofovir**, and **Rilpivirine** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions.

How supplied: Tabs-30

ETRAVIRINE

INTELENCE Janssen Therapeutics

Non-nucleoside reverse transcriptase inhibitor.

Etravirine 25mg+, 100mg, 200mg; tabs, (+) scored.

Indications: HIV-1 infection, in combination with other antiretrovirals, in treatment-experienced patients ≥ 6 yrs of age with evidence of viral replication and HIV-1 strains resistant to an NNRTI and other antiretrovirals.

Adults: Take after meals. May disperse tabs in water and drink. ≥ 18 yrs: 200mg twice daily.

Children: Take after meals. May disperse tabs in water and drink. <6yrs or <16kg: not established. ≥ 6 yrs: ≥ 16 kg- <20kg: 100mg twice daily. ≥ 20 kg- <25kg: 125mg twice daily. ≥ 25 kg- <30kg: 150mg twice daily. ≥ 30 kg: 200mg twice daily.

Warnings/Precautions: Severe hepatic impairment. Discontinue if severe rash, severe hypersensitivity, or liver transaminase elevations develop; monitor closely. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant tipranavir/ritonavir, fosamprenavir/ritonavir, atazanavir/ritonavir, Pls without ritonavir (eg, atazanavir, fosamprenavir, nelfinavir, indinavir), ritonavir (600mg twice daily), NNRTIs (eg, efavirenz, nevirapine, delavirdine): not recommended. Avoid rifampin, rifapentine, St. John's wort, carbamazepine, phenytoin, phenobarbital; rifabutin with darunavir/ritonavir, lopinavir/ritonavir or saquinavir/ritonavir. May affect, or be affected by, drugs that induce or inhibit, or that are substrates of, CYP3A4, CYP2C9, CYP2C19 (eg, azole antifungals, immunosuppressants); monitor. May antagonize antiarrhythmics (eg, amiodarone, bepridil, disopyramide, flecainide, lidocaine, mexiletine, propafenone, quinidine) (monitor), sildenafil, clopidogrel (consider alternatives), antimalarials (eg, artemether/lumefantrine). May potentiate warfarin, diazepam. May be antagonized by anticonvulsants, dexamethasone. Clarithromycin (consider azithromycin for treating MAC). Adjust statin dose (except pravastatin, rosuvastatin). Rifabutin (adjust dose with etravirine monotherapy). See full labeling.

Adverse reactions: Severe skin reactions (may be fatal, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme), hypersensitivity (eg, DRESS), peripheral neuropathy, diarrhea, fat redistribution, immune reconstitution syndrome, lab value changes (eg, lipids, blood glucose).

Note: Report pregnant patients exposed to etravirine by calling (800) 258-4263.

How supplied: Tabs 25mg, 100mg-120; 200mg-60

FAMCICLOVIR

FAMVIR Novartis

Nucleoside analogue. Famciclovir (prodrug of penciclovir) 125mg, 250mg, 500mg; tabs.

Indications: In immunocompetent adults: treatment of recurrent herpes labialis, treatment of recurrent episodes of genital herpes, chronic suppressive therapy of recurrent episodes of genital herpes, treatment of herpes zoster. In HIV-infected adults: treatment of recurrent episodes of orolabial or genital herpes. Limitations of use: not established for patients with 1st episode of genital herpes or ophthalmic zoster, immunocompromised patients other than for treatment of recurrent orolabial or genital herpes in HIV-infected patients, Black and African American patients with recurrent genital herpes.

Adults: ≥ 18 yrs: Herpes zoster: start as soon as herpes zoster is diagnosed (within 72hrs of onset of rash); treat for 7 days: 500mg every 8hrs. CrCl 40-59mL/min: 500mg every 12hrs; CrCl 20-39mL/min: 500mg every 24hrs; CrCl <20mL/min: 250mg every 24hrs; hemodialysis (HD): 250mg after each dialysis. Treatment of recurrent genital herpes: begin therapy at first sign or symptom (within 6hrs); 1000mg every 12hrs for 1 day; CrCl 40-59mL/min: 500mg every 12hrs for 1 day; CrCl 20-39mL/min: 500mg single dose; CrCl <20mL/min: 250mg single dose; HD: 250mg after dialysis. Suppression of recurrent genital herpes: 250mg every 12hrs (for up to 1yr). CrCl 20-39mL/min: 125mg every 12hrs; CrCl <20mL/min: 125mg every 24hrs; HD: 125mg after each dialysis. Recurrent herpes labialis: start at first sign or symptom of cold sore: treat with single dose: 1500mg. CrCl 40-59mL/min: 750mg; CrCl 20-39mL/min: 500mg; CrCl <20mL/min: 250mg; HD: 250mg following dialysis. Orolabial or genital herpes simplex in HIV patients: treat for 7 days: 500mg every 12hrs; CrCl 20-39mL/min: 500mg every 24hrs; CrCl <20mL/min: 250mg every 24hrs; HD: 250mg after each dialysis.

Children: <18yrs: not established.

Contraindications: Allergic to penciclovir cream.

Warnings/Precautions: Renal dysfunction.

Pregnancy (Cat.B). Nursing mothers.

Interactions: Probenecid, others eliminated by active tubular secretion may increase penciclovir concentrations. May be affected by drugs metabolized by aldehyde oxidase.

Adverse reactions: Headache, nausea, fatigue, paresthesia, pruritus.

Note: Register pregnant patients exposed to famciclovir by calling (888) 669-6682.

How supplied: Tabs 125mg, 250mg-30; 500mg-30, 50

FOSAMPRENAVIR

LEXIVA GlaxoSmithKline

HIV-1 protease inhibitor. Fosamprenavir (as calcium) 700mg; tabs; (prodrug of amprenavir).

Also: Fosamprenavir**LEXIVA ORAL SUSPENSION**Fosamprenavir (as calcium) 50mg/mL; grape-bubblegum-peppermint flavor; (prodrug of amprenavir). **Indications:** HIV-1 infection.**Adults:** Oral susp: take without food; if emesis occurs within 30 minutes after dosing, re-dose. Therapy-naïve: 1.4g twice daily; or fosamprenavir 1.4g + ritonavir 200mg once daily; or fosamprenavir 1.4g + ritonavir 100mg once daily; or fosamprenavir 700mg + ritonavir 100mg twice daily. Protease-inhibitor-experienced: fosamprenavir 700mg + ritonavir 100mg twice daily. Hepatic impairment: see full labeling for dose adjustments.**Children:** Protease inhibitor-naïve (<4wks) or Protease inhibitor-experienced (<6mos): not recommended. Oral susp: take with food; if emesis occurs within 30 minutes after dosing, re-dose. Protease inhibitor-naïve (≥4wks–18yrs) or Protease inhibitor-experienced (≥6mos): <11kg: fosamprenavir 45mg/kg + ritonavir 7mg/kg twice daily; 11–<15kg: fosamprenavir 30mg/kg + ritonavir 3mg/kg twice daily; 15–<20kg: fosamprenavir 23mg/kg + ritonavir 3mg/kg twice daily; ≥20kg: fosamprenavir 18mg/kg + ritonavir 3mg/kg twice daily. Alternatively, Protease inhibitor-naïve (≥2yrs): fosamprenavir 30mg/kg twice daily. For all: do not exceed the adult dosage (see full labeling). Other dosing considerations: see full labeling.**Contraindications:** Concomitant alfuzosin, cisapride, pimozide, ergots, midazolam, triazolam, St. John's wort, rifampin, lovastatin, simvastatin, delavirdine, sildenafil (Revatio; when used for treating PAH). Concomitant flecainide, or propafenone with ritonavir-boosted fosamprenavir.**Warnings/Precautions:** Sulfonamide allergy. Hepatic impairment: see full labeling. Do not exceed recommended dose. Discontinue if severe rash occurs. Monitor lipids, liver function, and for hyperglycemia, fat redistribution, immune reconstitution syndrome. Hemophilia: monitor for spontaneous bleeding. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** See Contraindications. Life-threatening arrhythmias possible with amiodarone, bepridil, lidocaine (systemic), quinidine. Concomitant salmeterol, telaprevir, boceprevir, or nevirapine without ritonavir: not recommended. Reduce rifabutin dose by at least ½ (or by 75% if with ritonavir) and monitor for neutropenia (do weekly CBCs). Potentiates sildenafil, tadalafil, vardenafil; reduce doses of these. May potentiate fluticasone (consider alternative therapy), trazodone (reduce trazodone dose). Monitor antiarrhythmics (eg, amiodarone), anticonvulsants (eg, phenytoin), H₂ blockers, immunosuppressants, tricyclics, warfarin, drugs that affect or are affected

R

by CYP3A4 (eg, azole antifungals, benzodiazepines, calcium channel blockers, NNRTIs, protease inhibitors, statins, steroids). May antagonize, or be antagonized by hormonal contraceptives (use non-hormonal methods), methadone, paroxetine. Concomitant bosentan, colchicine (adjust doses; see full labeling).

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Adverse reactions: Diarrhea, nausea, headache, rash (may be serious, eg, Stevens-Johnson), fatigue, hypertriglyceridemia, elevated liver enzymes, fat redistribution, immune reconstitution syndrome, vomiting (esp. children).**Note:** Register pregnant patients exposed to fosamprenavir by calling (800) 258-4263.**How supplied:** Tabs–60; Susp–225mL**GANCICLOVIR**

R

CYTOVENE IV Roche

Nucleoside analogue. Ganciclovir sodium 500mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; sodium content 46mg/vial.

Indications: Treatment of cytomegalovirus (CMV) retinitis in immunocompromised patients including patients with AIDS. Prevention of CMV disease in high-risk transplant recipients.**Adults:** Give by IV infusion over 1 hour. Induction for CMV retinitis: 5mg/kg every 12 hours for 14–21 days. Maintenance: 5mg/kg once daily for 7 days per week or 6mg/kg once daily for 5 days per week; if disease progression repeat induction therapy. Prevention of CMV: 5mg/kg every 12 hours for 7–14 days, then 5mg/kg once daily for 7 days per week or 6mg/kg once daily for 5 days per week. Renal impairment, hemodialysis: adjust or reduce dose; see literature.**Children: Not recommended.****Contraindications:** Acyclovir hypersensitivity.**Warnings/Precautions:** Monitor CBCs, platelets, ophthalmic, and renal function. Withhold dose if absolute neutrophil count <500cells/microliter or platelet count <25,000cells/microliter. Reduce dose or discontinue if blood dyscrasias occur. Pre-existing cytopenias or history of cytopenic reactions to other drugs, chemicals, or irradiation. Renal impairment. Maintain adequate hydration. Use effective contraception during (men and women) and for at least 90 days after treatment (men). Pregnancy (Cat.C: teratogenic, embryotoxic, carcinogenic, hypospermatogenesis in animals), nursing mothers: not recommended.**Interactions:** Zidovudine increases anemia/neutropenia risk. Caution with nephrotoxic drugs (eg, cyclosporine, amphotericin B). Monitor for toxicity with didanosine. May be potentiated by probenecid. Caution with drugs that inhibit replication of rapidly-dividing cells (eg, dapsone, pentamidine, antineoplastics). Avoid imipenem-cilastatin (seizures).**Adverse reactions:** Neutropenia, anemia, thrombocytopenia, elevated serum creatinine, retinal detachment, fever, GI upset, infections, elevated serum transaminases, inj site reactions, CNS effects, hypertension.**How supplied:** Vials (10mL)–25

INTERFERON ALFA-2B

R

INTRON A Merck

Interferon alfa-2b, recombinant; 10million, 18million, or 50million IU per vial; pwd; for inj after reconstitution/dilution; preservative-free.

Also: Interferon alfa-2b

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INTRON A SOLUTION

Interferon alfa-2b, recombinant; 10million IU, 18million IU, 25million IU; per vial; for inj; contains m-cresol.

Also: Interferon alfa-2b

R

INTRON A SOLUTION MULTIDOSE PENS

Interferon alfa-2b, recombinant; 18million IU, 30million IU, 60million IU; per pen; for SC inj; contains m-cresol.

Indications: Chronic hepatitis C. Chronic hepatitis B.

Adults: Use appropriate preparation and route: see literature. Use SC route if platelets $<50,000/\text{mm}^3$. Hepatitis C: 3million IU IM or SC three times weekly for 16 wks; if tolerated with normalization of ALT, continue to 18–24 months (72–96 wks). Hepatitis B: 5million IU daily or 10million IU IM or SC three times weekly for 16 wks; reduce dose by $\frac{1}{2}$ or interrupt dose if WBCs, granulocyte or platelet count decreases.

Children: $<1\text{yr}$: not recommended. Use appropriate preparation and route: see literature. $\geq 1\text{yr}$ of age for chronic hepatitis B: 3million IU/ m^2 SC three times weekly for 1 week, then increase to 6million IU/ m^2 (max 10million IU) three times weekly for a total of 16–24 weeks; reduce dose by $\frac{1}{2}$ or interrupt dose if WBCs, granulocytes or platelet counts decrease.

Contraindications: Hepatitis: decompensated liver disease. Autoimmune disorders.

Warnings/Precautions: May cause or exacerbate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, or infectious disorders: monitor closely, discontinue if they worsen. Severe psychiatric disorders (esp. depression). Cardiovascular or pulmonary disease. Severe myelosuppression. Uncontrolled thyroid abnormalities. Diabetes. Coagulation disorders. Maintain adequate hydration. Monitor blood, thyroid, visual and liver function before and during therapy; EKG in cardiovascular disease and cancer patients. Psoriasis. Renal dysfunction. Transplant recipients. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with myelosuppressives, and drugs that can exacerbate depression. May potentiate theophylline (may double its levels).

Adverse reactions: Flu-like symptoms (fever, headache, myalgia, fatigue); hepatic, hematologic, respiratory, skin, genitourinary system, CNS, cardiovascular, endocrine (esp thyroid), GI, or visual disorders; colitis, hypertriglyceridemia, pancreatitis, infections, injection site reactions; others (see literature).

How supplied: Pwd (w. diluent): 10million, 18million, 50million IU/vial-1; Soln (vials): 10million IU/vial-6 (kit w. supplies); Soln (multidose vials): 18million, 25million IU/vial-1; Soln (multidose pens, 6 doses/pen): 3million IU/0.2mL, 5million IU/0.2mL, 10million IU/0.2mL-1

LAMIVUDINE

R

EPIVIR GlaxoSmithKline

Nucleoside analogue (reverse transcriptase inhibitor). Lamivudine 150mg (+), 300mg; tabs; (+) scored.

Also: Lamivudine

R

EPIVIR ORAL SOLUTION

Lamivudine 10mg/mL; strawberry-banana flavor; contains sucrose 3g/15mL.

Indications: HIV infection.

Adults and Children: $\leq 3\text{months}$: not recommended.

3months–16years: 4mg/kg (max 150mg) twice daily; renal impairment: reduce dose or prolong dosing interval. $\geq 16\text{years}$, CrCl $\geq 50\text{mL/min}$: 300mg once daily or 150mg twice daily; CrCl 30–49mL/min: 150mg once daily; CrCl 15–29mL/min: 150mg for 1st dose then 100mg once daily; CrCl 5–14mL/min: 150mg for 1st dose then 50mg once daily; CrCl $<5\text{mL/min}$: 50mg for 1st dose then 25mg once daily.

Warnings/Precautions: Discontinue if pancreatitis (increased risk in pediatric patients) or lactic acidosis occurs. Suspend therapy if hepatotoxicity (eg, hepatomegaly, steatosis) occurs. Women, obesity, or prolonged nucleoside exposure: increased risk of toxicity (ie, lactic acidosis, steatosis). Hepatitis B (monitor for post-treatment exacerbation). Other liver disease risk factors. Diabetes (oral soln). Children with prior antiretroviral nucleoside exposure, history of pancreatitis or risk factors for pancreatitis. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant zalcitabine: not recommended. Avoid concomitant drugs that contain lamivudine or emtricitabine. Caution with drugs eliminated by active organic cationic secretion (eg, trimethoprim). Increased lamivudine absorption with TMP/SMX (clinical significance unknown). Triple therapy (once daily regimen) with abacavir + tenofovir or with didanosine + tenofovir: high rate of early viral non-response (see literature). Monitor for treatment-associated toxicities with interferon-alpha with or without ribavirin.

Adverse reactions: Adults: headache, malaise, fever, GI upset, neuropathy, dizziness, sleep or depressive disorders, rash, respiratory effects, musculoskeletal pain, lactic acidosis, severe hepatomegaly with steatosis, fat redistribution, neutropenia, abnormal liver function tests. Children: pancreatitis, paresthesias, peripheral neuropathy, fever, rash, respiratory effects, neutropenia, anemia, abnormal liver function tests.

Note: Register pregnant patients exposed to lamivudine by calling (800) 258-4263.

How supplied: Tabs 150mg-60; 300mg-30; Soln-240mL

LAMIVUDINE

R

EPIVIR-HBV GlaxoSmithKline

Nucleoside analogue (reverse transcriptase inhibitor). Lamivudine 100mg; tabs.

Also: Lamivudine

R

EPIVIR-HBV ORAL SOLUTION

Lamivudine 5mg/mL; strawberry-banana flavor.

Indications: Chronic hepatitis B associated with viral replication and active liver inflammation.

Adults: 100mg once daily. Renal impairment: CrCl 30–49mL/min: 100mg for 1st dose then 50mg once daily; CrCl 15–29mL/min: 100mg for 1st dose then 25mg once daily; CrCl 5–14mL/min: 35mg for 1st dose then 15mg once daily; CrCl <5mL/min: 35mg for 1st dose then 10mg once daily.

Children: <2years: not recommended. 2–17years: 3mg/kg (max 100mg) once daily. Renal impairment: consider dose reduction.

Contraindications: Concomitant zalcitabine.

Warnings/Precautions: Unrecognized or untreated HIV infection (do HIV testing and counseling before and periodically during treatment). Not for treatment of HIV and HBV co-infections (use doses appropriate for HIV). Discontinue if pancreatitis (increased risk in pediatric HIV patients) or lactic acidosis or hepatotoxicity occurs. Women, obesity, or prolonged nucleoside exposure: increased risk of toxicity (eg, lactic acidosis, steatosis). Risk of hepatitis B reactivation. Diabetes (oral soln). Monitor closely during and for several months after treatment. Reevaluate annually. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Caution with drugs eliminated by active organic cationic secretion (eg, trimethoprim). Increased lamivudine absorption with TMP/SMX; increased zidovudine levels with lamivudine (clinical significance unknown).

Adverse reactions: See literature. Rare: Lactic acidosis, severe hepatomegaly with steatosis, post-treatment exacerbation of hepatitis, pancreatitis, emergence of viral mutations.

Note: Register pregnant patients exposed to lamivudine by calling (800) 258-4263.

How supplied: Tabs–60; Soln–240mL

LAMIVUDINE + ZIDOVUDINE

R

COMBIVIR GlaxoSmithKline

Nucleoside analogues (reverse transcriptase inhibitors). Lamivudine 150mg, zidovudine 300mg; tabs.

Indications: HIV infection.

Adults: 1 tab twice daily. Hepatic or renal dysfunction (CrCl <50mL/min): not recommended.

Children: Not recommended.

Note: See **Lamivudine** and **Zidovudine** monographs for Contraindications, Warnings/Precautions, Interactions, and Adverse reactions. Register pregnant patients exposed to lamivudine by calling (800) 258-4263.

How supplied: Tabs–60

LOPINAVIR + RITONAVIR

R

KALETRA AbbVie

Protease inhibitor. Lopinavir, ritonavir; 100mg/25mg, 200mg/50mg; tabs.

Also: Lopinavir + Ritonavir

KALETRA ORAL SOLUTION

Lopinavir 80mg, ritonavir 20mg; per mL; cotton candy flavor; alcohol 42.4%.

Indications: HIV infection.

Adults: Swallow tabs whole; take oral soln with food. Lopinavir/ritonavir 400/100mg (two 200/50mg tabs or 5mL) twice daily or 800/200mg (four 200/50mg tabs or 10mL) once daily (in patients with less than 3 lopinavir resistance-associated substitutions). Once-daily administration not recommended if ≥3 lopinavir resistance-associated substitutions or if given in combination with carbamazepine, phenobarbital or phenytoin. Concomitant efavirenz, nevirapine, amprenavir or nelfinavir: 500/125mg (two 200/50mg tabs and one 100/25mg tab) or 533/133mg (6.5mL) twice daily.

Children: May use tabs if able to swallow whole and ≥15kg. Take oral soln with food. Postnatal age <14days or postmenstrual age of <42weeks: not recommended. 14days–6months: lopinavir/ritonavir 16/4mg/kg or 300/75mg/m² twice daily. Do not administer with efavirenz, nevirapine, amprenavir, or nelfinavir. ≥6months: lopinavir/ritonavir 230/57.5mg/m² twice daily or <15kg: 12/3mg/kg twice daily; ≥15–40kg: 10/2.5mg/kg twice daily; >40kg: max 400/100mg twice daily. Concomitant efavirenz, nevirapine, amprenavir, or nelfinavir: ≥6months: 300/75mg/m² twice daily or <15kg: 13/3.25mg/kg twice daily; ≥15–45kg: 11/2.75mg/kg twice daily; >45kg: max oral soln: 533/133mg twice daily; or max tabs: 500/125mg twice daily. See full labeling.

Contraindications: Drugs highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening reactions. Potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross-resistance (eg, alfuizosin, rifampin, St. John's wort, lovastatin, simvastatin, sildenafil (Revatio), cisapride, ergots, pimozone, orally administered midazolam, triazolam).

Warnings/Precautions: Suspend if pancreatitis occurs. History of, or risk factors for, pancreatitis (eg, elevated triglycerides). Hepatic impairment. Hepatitis. Diabetes. Monitor: lipids at baseline then periodically, ALT/AST in liver disease, for hyperglycemia or fat redistribution, hemophiliacs (for spontaneous bleed). Underlying structural heart disease. Pre-existing conduction system abnormalities. Ischemic heart disease. Cardiomyopathies. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Salmeterol, voriconazole: not recommended. Avoid oral soln with metronidazole, disulfiram. Potentiates statins metabolized by CYP3A; use atorvastatin with caution and at the lowest necessary doses; do not exceed rosvastatin 10mg daily. Potentiates sildenafil, vardenafil, tadalafil (reduce dose of these); avanafil, fluticasone (avoid). Potentiates fentanyl, parenteral midazolam; monitor. Potentiates anticancer agents (eg, vincristine, vinblastine, dasatinib, nilotinib); may

need dose adjustment (see full labeling). Potentiates colchicine; adjust dosing (see full labeling). Concomitant colchicine not recommended in renal or hepatic impairment. Potentiates bosentan. Increases levels of antiarrhythmics, dihydropyridine, calcium channel blockers, immunosuppressants (monitor); ketoconazole, itraconazole (avoid high doses); rifabutin (reduce rifabutin dose and monitor); clarithromycin (reduce clarithromycin dose in renal dysfunction), trazodone (reduce trazodone dose). Monitor other antiretrovirals, warfarin. Avoid concomitant rivaroxaban; increased bleeding risk. Decreases levels of atovaquone, methadone, bupropion, estrogen-containing oral contraceptives (use other or back-up contraception). Lopinavir levels decreased by anticonvulsants (eg, carbamazepine, phenobarbital, phenytoin), budesonide, dexamethasone, prednisone, efavirenz, nevirapine. Lopinavir levels may be increased by delavirdine, CYP3A inhibitors. May decrease boceprevir, lamotrigine, valproate, zidovudine or abacavir levels. Give didanosine 1 hour before or 2 hours after. See full labeling.

Adverse reactions: Diarrhea, GI upset, asthenia, headache, abdominal pain, rash, insomnia, pancreatitis, fat redistribution, hyperlipidemia, increased triglycerides, PR, QT prolongation, immune reconstitution syndrome.

How supplied: 100mg/25mg-60; 200mg/50mg-120; Soln-160mL (w. dose cup)

NELFINAVIR

VIRACEPT Agouron
HIV-1 protease inhibitor. Nelfinavir (as mesylate) 250mg, 625mg; tabs.

Also: Nelfinavir

VIRACEPT ORAL POWDER

Nelfinavir (as mesylate) 50mg/gram; contains phenylalanine.

Indications: HIV infection.

Adults and Children: Take with food. May dissolve tab and mix in small amount of water; powder may be mixed with a small amount of non-acidic food or beverage. <2yrs: not recommended. 2-13yrs: 45-55mg/kg twice daily or 25-35mg/kg 3 times daily; max 2.5g/day. >13yrs: 1.25g twice daily or 750mg 3 times daily. Reduce concomitant rifabutin dose by ½ and give nelfinavir 1.25g twice daily.

Contraindications: CYP3A substrates that may cause serious events if blood levels are elevated (eg, cisapride, pimozide, oral midazolam, triazolam, lovastatin, simvastatin, ergots, amiodarone, quinidine, alfuzosin, rifampin, St. John's wort, sildenafil [Revatio; when used to treat PAH]).

Warnings/Precautions: Hepatic impairment. Diabetes. Monitor for hyperglycemia, fat redistribution, or immune reconstitution syndrome, hemophiliacs for spontaneous bleeding. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Salmeterol: not recommended. Potentiates CYP3A substrates

(eg, dihydropyridine calcium channel blockers, cyclosporine, tacrolimus, sirolimus, rifabutin, rosuvastatin, atorvastatin [use lowest dose necessary; max atorvastatin dose is 40mg/day]), PDE5 inhibitors (adjust dose; see literature), phenytoin (monitor). Potentiates fluticasone (caution and consider alternatives w. long-term use), trazodone (use lower dose), bosentan, colchicine (adjust dose; see literature). Nelfinavir levels decreased by CYP3A inducers (eg, phenytoin, carbamazepine, phenobarbital) or CYP2C19 inducers. Nelfinavir levels increased by CYP3A or CYP2C19 inhibitors. Antagonizes methadone, oral contraceptives (use additional or alternative contraception). Indinavir, ritonavir, saquinavir increase nelfinavir levels. Concomitant azithromycin: monitor for azithromycin toxicity (eg, elevated liver enzymes). Administer didanosine 1hr before or 2hrs after nelfinavir. Monitor INR with warfarin. Others: see literature.

Adverse reactions: Diarrhea, nausea, flatulence, abdominal pain, rash, redistribution of body fat; diabetes, hyperglycemia, immune reconstitution syndrome.

Note: Register pregnant patients exposed to nelfinavir by calling (800) 258-4263.

How supplied: Tabs 250mg-300; 625mg-120; Oral Pwd-144g

NEVIRAPINE

VIRAMUNE Boehringer Ingelheim
Non-nucleoside reverse transcriptase inhibitor. Nevirapine 200mg; scored tabs.

Also: Nevirapine

VIRAMUNE ORAL SUSPENSION

Nevirapine (as hemihydrate) 50mg/5mL.

Indications: HIV-1 infection.

Adults: ≥16yrs: Initially 200mg once daily for 14 days. If no rash occurs, increase to 200mg twice daily. If mild-to-moderate rash occurs during the 14-day lead in period, do not give twice-daily regimen until rash has resolved; lead-in dosing regimen should not be continued beyond 28 days, consider alternative regimen. If severe rash or hepatic event occurs, discontinue permanently. Max 400mg/day. Retitrate if stopped for >7 days. Hemodialysis: give additional nevirapine 200mg dose after dialysis.

Children: <15days: not recommended. For oral susp: use dosing syringe or cup: ≥15days: Initially 150mg/m² once daily for 14 days; if no rash occurs increase to 150mg/m² twice daily. If mild-to-moderate rash occurs during the 14-day lead in period, do not give twice-daily regimen until rash has resolved; lead-in dosing regimen should not be continued beyond 28 days, consider alternative regimen. If severe rash or hepatic event occurs, discontinue permanently. Max 400mg/day. Retitrate if stopped for >7 days.

Also: Nevirapine

VIRAMUNE XR

Nevirapine 100mg, 400mg; ext-rel tabs.

Adults: Swallow whole. ≥18yrs: Initially Viramune 200mg once daily for 14 days, then Viramune XR

400mg once daily. If mild-to-moderate rash develops during the 14-day lead-in period, do not start Viramune XR until rash has resolved. Lead-in period not necessary if patient already on a regimen of immediate-release Viramune twice daily. Total duration of once daily lead-in period should not exceed 28 days; consider alternative regimen. If severe rash or hepatic event occurs, discontinue permanently. Retitrate if stopped for >7 days.

Children: <6yrs: not recommended. Swallow whole. ≥6–<18yrs: Initially 150mg/m² Viramune oral susp or immediate-release tabs once daily for 14 days; max 200mg/day, then Viramune XR dose based on BSA: 0.58–0.83m²: 200mg once daily; 0.84–1.16m²: 300mg once daily; ≥1.17m²: 400mg once daily. All: max 400mg/day. If mild-to-moderate rash develops during the 14-day lead-in period, do not start Viramune XR until rash has resolved. Lead-in period not necessary if patient already on a regimen of immediate-release Viramune twice daily. Total duration of once daily lead-in period should not exceed 28 days; consider alternative regimen. If severe rash or hepatic event occurs, discontinue permanently. Retitrate if stopped for >7 days.

Contraindications: Moderate-to-severe (Child-Pugh B or C) hepatic impairment. Use as part of occupational or non-occupational post-exposure prophylaxis regimens.

Warnings/Precautions: Women with CD4 counts >250cells/mm³ or men with CD4 counts >400cells/mm³ (increased risk of rash-associated hepatic events): usually not recommended (see literature). Monitor liver function (at baseline, during 1st 18 weeks, and throughout therapy). Suspend and discontinue permanently if signs/symptoms of hepatitis, elevated transaminases, severe rash, or rash with constitutional symptoms (eg, fever, blistering, oral lesions, conjunctivitis, swelling, muscle/joint aches or general malaise) occurs; do not restart after recovery. Co-infected with hepatitis B or C. Hepatitis fibrosis or cirrhosis; monitor. Renal dysfunction. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Potentiated by fluconazole (monitor). Antagonizes atazanavir, ketoconazole, oral contraceptives: not recommended (use nonhormonal contraception), clarithromycin (consider alternative). Antagonized by St. John's wort, rifampin: not recommended. Possible increased adverse reactions with concomitant efavirenz: not recommended. May antagonize methadone (monitor for withdrawal symptoms; increase methadone dose if needed), or drugs metabolized by CYP3A4 or CYP2B6. Monitor warfarin, rifabutin, other CYP450 substrates.

Adverse reactions: Potentially severe, life-threatening hepatotoxicity (eg, hepatic necrosis, cholestatic hepatitis) or skin reactions (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis); nausea, headache, abnormal liver function tests, fatigue, fever, vomiting, myalgia, abdominal pain,

fat redistribution, immune reconstitution syndrome. Children: also granulocytopenia.

Note: Register pregnant patients exposed to nevirapine by calling (800) 258-4263.

How supplied: Tabs–60; Susp–240mL; XR 100mg–90; 400mg–30

OSELTAMIVIR

R

TAMIFLU Roche

Neuraminidase inhibitor. Oseltamivir (as phosphate) 30mg, 45mg, 75mg; caps.

Also: Oseltamivir

R

TAMIFLU ORAL SUSPENSION

Oseltamivir (as phosphate) 6mg/mL; pld for reconstitution; tutti-frutti flavor.

Indications: Treatment of uncomplicated acute illness due to influenza infection in patients ≥2weeks of age who have been symptomatic for ≤2days. Prophylaxis of influenza in patients ≥1year of age.

Adults: Start within 2 days of symptom onset or exposure. Unable to swallow caps; use oral susp. If oral susp. unavailable; may open caps and mix with sweetened liquids (eg, regular or sugar-free chocolate syrup, corn syrup, caramel topping, or light brown sugar (dissolved in water)). If appropriate strength caps and oral susp. unavailable; have RPh compound an emergency supply of oral susp. from 75mg caps (see full labeling for preparation). ≥13yrs: Treatment: 75mg twice daily for 5 days; CrCl 10–30mL/min: 75mg once daily for 5 days. Prophylaxis: after close contact with infected individual: 75mg once daily for at least 10 days; during community outbreak: 75mg once daily for up to 6 weeks; CrCl 10–30mL/min: 75mg every other day or 30mg once daily.

Children: Start within 2 days of symptom onset. Unable to swallow caps; use oral susp. If oral susp. unavailable; may open caps and mix with sweetened liquids (eg, regular or sugar-free chocolate syrup, corn syrup, caramel topping, or light brown sugar (dissolved in water)). If appropriate strength caps and oral susp. unavailable; have RPh compound an emergency supply of oral susp. from 75mg caps (see full labeling for preparation). Treatment: <2weeks: not established. Treat for 5 days. ≥2weeks to <1yr: 3mg/kg twice daily. 1–12yrs: (≤15kg): 30mg twice daily; (15.1–23kg): 45mg twice daily; (23.1–40kg): 60mg twice daily; (≥40.1kg): 75mg twice daily. Prophylaxis: <1yr: not established. Treat for 10 days; during community outbreak: continue up to 6 weeks; 1–12yrs: (≤15kg): 30mg once daily; (15.1–23kg): 45mg once daily; (23.1–40kg): 60mg once daily; (≥40.1kg): 75mg once daily.

Warnings/Precautions: Not a substitute for influenza vaccination. Hepatic impairment. Chronic cardiac or respiratory disease. Immunocompromised. Monitor for signs of abnormal behavior (esp. in children). Pregnancy (Cat.C). Nursing mothers.

Interactions: Do not administer live attenuated influenza vaccine within 2 weeks prior or 48 hrs after treatment.

Adverse reactions: GI upset, bronchitis, headache, insomnia, vertigo, fatigue; serious skin/hypersensitivity reactions (discontinue if occur), possible neuropsychiatric events (eg, hallucinations, delirium, abnormal behavior).

How supplied: Caps-10; Susp-60mL (w. oral dispenser)

PALIVIZUMAB

R

SYNAGIS MedImmune

Antiviral monoclonal antibody (IgG1K). Palivizumab 50mg/vial, 100mg/vial; liq soln for IM inj; preservative-free.

Indications: Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high risk of RSV disease (eg, infants with bronchopulmonary dysplasia or born ≤ 35 wks gestational age), or children with hemodynamically significant congenital heart disease).

Adults: Not applicable.

Children: Give by IM injection into anterolateral thigh. 15mg/kg once per month before and during RSV season. Cardiopulmonary bypass: see literature. Divide doses >1 mL into 2 inj sites.

Warnings/Precautions: Have epinephrine (1:1000) inj available. Thrombocytopenia. Coagulation disorders. May interfere with RSV diagnostic tests (eg, antigen detection-based assays), viral culture assays. Pregnancy (Cat.C).

Adverse reactions: Anaphylaxis, hypersensitivity reactions, fever, rash.

How supplied: Single-use vials (soln)-1

PEGINTERFERON ALFA-2A

R

PEGASYS Roche

Peginterferon alfa-2a (polyethylene glycol/recombinant alfa interferon conjugate) 180mcg/mL (vials), 180mcg/0.5mL (prefilled syringe); soln for SC inj; contains benzyl alcohol.

Indications: Chronic hepatitis C (hep C), alone or with ribavirin (Copegus), in patients with compensated liver disease (including compensated cirrhosis) not previously treated with interferon alfa. HBeAg (+) or HBeAg (-) chronic hepatitis B (hep B), in patients with compensated liver disease and evidence of viral replication and liver inflammation.

Adults: ≥ 18 years: monotherapy for chronic hep C monoinfection, hep B monoinfection, or chronic hep C and HIV coinfection: 180mcg SC once weekly for 48 weeks. With ribavirin for hep C with or without HIV coinfection: see literature. ESRD on hemodialysis: 135mcg SC once weekly. Reevaluate if inadequate response after 24 weeks. Reduce dose and/or discontinue if ALT increases progressively, if bilirubin increases, or if neutropenia, thrombocytopenia, or depression occurs (see literature).

Children: <18 yrs: not recommended.

Contraindications: Autoimmune hepatitis. Hepatic decompensation (Child-Pugh B and C) in cirrhotic patients or cirrhotic CHC patients coinfecting with

HIV. Neonates. Infants. Combination with ribavirin contraindicated in pregnancy, men with pregnant partners, and in hemoglobinopathies.

Warnings/Precautions: May worsen neuropsychiatric, autoimmune, endocrine, ischemic, ophthalmic, pulmonary, or infectious disorders: monitor closely, discontinue if severe or persistently worsens. Cardiovascular or renal (CrCl <50 mL/min) disease. Severe myelosuppression. Discontinue if severe hypersensitivity reactions, colitis or pancreatitis develops. Monitor CBC, thyroid, visual, and hepatic function before and during therapy. Transplant recipients. CD4 cell count <100 cells/microliter. HBV or HCV co-infection. Elderly. Pregnancy (Cat.C); may have abortifacient effects. Nursing mothers: not recommended.

Interactions: May potentiate theophylline, methadone. Caution with NRTIs; monitor for toxicities.

Adverse reactions: Flu-like symptoms, psychiatric/CNS effects (depression, irritability, suicidal ideation, headache, insomnia), alopecia, GI upset, decreased CD4, CD8 counts; cardiovascular, hepatic, hematologic (eg, decreased WBCs, platelets), respiratory, thyroid, visual abnormalities, infections, anorexia, ALT elevations.

Note: See ribavirin entry in Antivirals section for more information.

How supplied: Vial single-use-1; Prefilled syringe-4 (w. supplies)

RALTEGRAVIR

R

ISENTRESS Merck

HIV-1 integrase strand transfer inhibitor. Raltegravir (as potassium) 25mg, 100mg $\pm$; chew tabs; scored (+); contain phenylalanine: 400mg; film-coated tabs.

Indications: HIV-1 infection, in combination with other antiretrovirals.

Adults: Film-coated tabs: swallow whole. 400mg twice daily. Avoid dosing before dialysis sessions. Concomitant rifampin: 800mg twice daily.

Children: <2 yrs: not recommended. 2- <6 yrs (and ≥ 10 kg): use chew tabs and base dose on weight. 6- <12 yrs: one 400mg film-coated tab twice daily or use chew tabs and base dose on weight; if 10- <14 kg: 75mg twice daily; 14- <20 kg: 100mg twice daily; 20- <28 kg: 150mg twice daily; 28- <40 kg: 200mg twice daily; ≥ 40 kg: 300mg twice daily. Chew tab max dose: 300mg twice daily. ≥ 12 yrs: one 400mg film-coated tab twice daily.

Warnings/Precautions: Chew tabs and film-coated tabs are not interchangeable. Severe hepatic impairment. Monitor liver aminotransferases, immune reconstitution syndrome (esp. during initial therapy), myopathy, and rhabdomyolysis. Discontinue if signs/symptoms of severe skin or hypersensitivity reactions develop. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Antagonized by rifampin, possibly other strong UGT1A1 inducers. May be potentiated by UGT1A1 inhibitors. Caution with other drugs that can cause myopathy (eg, statins).

Adverse reactions: Insomnia, headache, nausea, asthenia, fatigue, creatinine kinase elevations, myopathy, rhabdomyolysis; severe skin reactions (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), hypersensitivity, others (see literature).

Note: Register pregnant patients exposed to raltegravir by calling (800) 258-4263.

How supplied: Chew tabs, film-coated tabs—60

RIBAVIRIN

R

COPEGUS Roche

Nucleoside analogue. Ribavirin 200mg; tabs.

Indications: Chronic hepatitis C, in combination with peginterferon alfa-2a (Pegasys), in patients with compensated liver disease previously untreated with alpha interferon, including patients co-infected with HIV.

Adults: Take with food in 2 divided doses. ≥ 18 yrs: Genotype 1, 4: (< 75 kg): 1g/day for 48 weeks; (≥ 75 kg): 1.2g/day for 48 weeks. Genotype 2, 3: 800mg/day for 24 weeks. HIV patients: 800mg/day for 48 weeks. Reduce dose or discontinue if severe reactions or hematologic abnormalities occur. Cardiac disease: discontinue if cardiovascular status deteriorates; reduce dose or discontinue if hemoglobin levels decrease; see literature. Renal impairment ($\text{CrCl} < 50 \text{ mL/min}$): not recommended.

Children: ≤ 18 yrs: not recommended.

Contraindications: Autoimmune hepatitis. Significant or unstable cardiac disease, hemoglobinopathies (eg, thalassemia, sickle-cell anemia): not recommended. Renal dysfunction ($\text{CrCl} < 50 \text{ mL/min}$). Hepatic decompensation before or during therapy. Male partners of pregnant women. Pregnancy (Cat.X).

Warnings/Precautions: Women of childbearing potential: obtain negative pregnancy test immediately before starting therapy. Women of childbearing potential and men: use 2 forms of effective contraception during and for 6 months following treatment. Do baseline CBC (and at weeks 2 and 4 or more often if needed), white counts with differential, platelet counts, blood chemistry, thyroid, and monthly pregnancy tests (during and for 6 months after treatment). Suspend or discontinue if cardiovascular status deteriorates. Psychiatric disorders. Autoimmune disorders. Organ transplant. Pancreatitis. Decompensated hepatitis C. Nonresponders to interferon. Co-infection with hepatitis B virus. Maintain adequate hydration. Nursing mothers: not recommended.

Interactions: Avoid alcohol. May antagonize stavudine, zidovudine. Caution with NRTIs; monitor for toxicities. Concomitant didanosine: not recommended.

Adverse reactions: Anemia and other hematological disorders, flu-like symptoms, cardiac events, pulmonary events, psychiatric effects, dizziness, GI upset, weight loss, alopecia, rash, pruritus, diabetes, pancreatitis.

Note: Register pregnant women exposed to Copegus by calling (800) 593-2214 (see Contraindications).

How supplied: Tabs—168

RIBAVIRIN

R

REBETOL Merck

Nucleoside analogue. Ribavirin 200mg; caps.

Also: Ribavirin

R

REBETOL ORAL SOLUTION

Ribavirin 40mg/mL; liq; bubble-gum flavor.

Indications: Chronic hepatitis C: in combination with interferon alfa-2b (pegylated and nonpegylated), in patients ≥ 3 years of age with compensated liver disease.

Adults: Genotype 1: treat for 48 weeks (reevaluate after 24 weeks). Genotype 2/3: treat for 24 weeks. Swallow caps whole. Give consistently with regard to food. With Intron A: > 18 yrs (≤ 75 kg): 400mg in AM and 600mg in PM; > 75 kg: 600mg twice daily (AM & PM). With PEG-Intron: < 66 kg: 400mg twice daily (AM & PM); 66–80kg: 400mg in AM and 600mg in PM; 81–105kg: 600mg twice daily (AM & PM); > 105 kg: 600mg in AM and 800mg in PM. Dose adjustments: see full labeling.

Children: Genotype 1: treat for 48 weeks (reevaluate after 24 weeks). Genotype 2/3: treat for 24 weeks. Swallow caps whole. Give consistently with regard to food. < 3 yrs: not established. 3–18 yrs (< 47 kg): 15mg/kg per day in divided doses (AM & PM); use oral soln if < 47 kg or cannot swallow caps; 47–59kg: 400mg twice daily (AM & PM); 60–73kg: 400mg in AM and 600mg in PM; > 73 kg: 600mg twice daily (AM & PM). Dose adjustments: see full labeling.

Contraindications: Autoimmune hepatitis. Hemoglobinopathies (eg, thalassemia major, sickle-cell anemia): not recommended. Renal impairment ($\text{CrCl} < 50 \text{ mL/min}$). Male partners of pregnant women. Pregnancy (Cat.X). Concomitant didanosine.

Warnings/Precautions: Significant or unstable cardiac disease: not recommended. Women of childbearing potential: obtain negative pregnancy test immediately before starting therapy. Women of childbearing potential and men: use 2 forms of effective contraception during and for 6 months following treatment. Do baseline CBC (and at weeks 2 and 4 or more often if needed), WBCs with differential, platelets, blood chemistry, thyroid, and monthly pregnancy tests (during and for 6 months after treatment). Reduce dose or discontinue if severe reactions or hematologic abnormalities occur. Discontinue if cardiovascular status deteriorates. Psychiatric disorders: temporarily reduce dose if mild depression occurs; discontinue if severe depression or suicidal ideation/attempt occurs. Pulmonary disorders. Autoimmune disorders. Organ transplant. Pancreatitis (discontinue if occurs). Evaluate for ophthalmologic disorders. Decompensated hepatitis C. Nonresponders to interferon. Co-infection with hepatitis B virus or HIV infection. Maintain

adequate hydration. Elderly. Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid alcohol. May antagonize stavudine, zidovudine. Concomitant azathioprine; may induce severe pancytopenia and increase risk of myelotoxicity (monitor CBCs).

Adverse reactions: Anemia, other hematological disorders, flu-like symptoms, cardiac and pulmonary events (discontinue if occur), psychiatric effects, dizziness, GI upset, alopecia, rash, pruritus, diabetes, pancreatitis, dental and periodontal disorders.

How supplied: Caps-56, 70, 84; Soln-100mL

RIBAVIRIN

R

VIRAZOLE Valeant

Nucleoside analogue. Ribavirin 6g/vial; pwd for reconstitution and aerosol inhalation.

Indications: Severe lower respiratory infections due to respiratory syncytial virus in hospitalized infants and young children.

Adults: Not recommended.

Children: Begin treatment preferably within first 3 days of infection. 20mg/mL as starting solution in drug reservoir for continuous aerosol administration for 12–18 hours per day for 3–7 days.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: See literature. Monitor respiratory function, fluid status. Discontinue if pulmonary function deteriorates. Drug may precipitate in mechanical ventilator, causing dysfunction. Avoid unnecessary occupational exposure. Nursing mothers.

Interactions: Monitor digitalis.

Adverse reactions: Pulmonary function deterioration, bronchospasm, pulmonary edema, hypoventilation, bacterial pneumonia, pneumothorax, apnea, ventilator dependence, atelectasis, cardiac arrest, hypotension, reticulocytosis, hemolytic anemia, rash, conjunctivitis.

How supplied: Vials-1

RILPIVIRINE

R

EDURANT Janssen Therapeutics

Non-nucleoside reverse transcriptase inhibitor.

Rilpivirine 25mg; tablets.

Indications: In combination with other antiretroviral agents for HIV-1 infection in antiretroviral treatment-naïve adult patients with HIV-1 RNA $\leq 100,000$ copies/mL at start of therapy.

Adults: Take with a meal. 25mg once daily.

Children: <18yrs: not recommended.

Contraindications: Concomitant carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole, dexamethasone (more than single dose), St. John's wort.

Warnings/Precautions: May prolong QTc interval with supratherapeutic doses. Evaluate immediately if depressive symptoms develop. Monitor liver enzymes prior to initiation and during therapy in patients with underlying hepatitis B or C, or marked elevations in

transaminases; consider monitoring LFTs in patients with pre-existing hepatic dysfunction. Severe renal impairment or ESRD: monitor. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant NNRTIs: not recommended. Potentiated by CYP3A inhibitors.

Antagonized by CYP3A inducers (see Contraindications). May antagonize azole antifungals (monitor for breakthrough fungal infections), methadone (monitor). Separate antacids (by at least 2 hours before or at least 4 hours after) and H₂-receptor antagonists (by at least 12 hours before or 4 hours after rilpivirine); drugs that increase gastric pH may result in decreased plasma concentrations. Caution with drugs with a known risk for torsades de pointes.

Adverse reactions: Depression, insomnia, headache, rash; hepatotoxicity, fat redistribution, immune reconstitution syndrome (monitor).

How supplied: Tabs-30

RITONAVIR

R

NORVIR AbbVie

HIV protease inhibitor. Ritonavir 100mg; tabs, soft-gel caps (contains alcohol).

Also: Ritonavir

R

NORVIR ORAL SOLUTION

Ritonavir 80mg/mL; peppermint-caramel flavor; contains alcohol 43.2% (v/v), propylene glycol 26.57% (w/v).

Indications: HIV infection, in combination with other antiretroviral agents.

Adults: Swallow tabs whole. Take with meals. Oral soln: may be mixed with chocolate milk, Ensure, or Advera within 1 hour of dosing. Initially at least 300mg twice daily, increase every 2–3 days by 100mg twice daily to 600mg twice daily. Concomitant other PIs (eg, amprenavir, atazanavir, darunavir, fosamprenavir, saquinavir, tipranavir); reduce ritonavir dose. See literature.

Children: <1month: not recommended. Swallow tabs whole. Take with meals. Oral soln: may be mixed with chocolate milk, Ensure, or Advera within 1 hour of dosing. >1month: initially 250mg/m² twice daily, increase every 2–3 days by 50mg/m² twice daily to 350–400mg/m² twice daily; max 600mg twice daily. Consider alternative therapy if 400mg/m² twice daily is not tolerated.

Contraindications: Concomitant alfuzosin HCl, amiodarone, flecainide, quinidine, propafenone, voriconazole, ergots, oral midazolam, triazolam, pirozide, cisapride, St. John's Wort, lovastatin, simvastatin, sildenafil (Revatio; only when used to treat PAH).

Warnings/Precautions: Discontinue if pancreatitis occurs. Impaired hepatic function, liver enzyme abnormalities, hepatitis; consider monitoring ALT/AST, GGT at baseline and for first 3 months of therapy. Pre-existing conduction system disease, cardiomyopathy, ischemic heart or underlying structural heart disease. Monitor blood, CPK, uric

acid, triglycerides, cholesterol, and for hyperglycemia. Hemophilia. Diabetes. Elderly. Pregnancy (Cat.B). Oral soln for preterm neonates in immediate postnatal period not recommended unless benefits outweigh risks. Nursing mothers: not recommended.

Interactions: See Contraindications. Rifampin, high-dose or long-term meperidine: not recommended. Potentiates other protease inhibitors, PDE5 inhibitors, fentanyl (monitor), tramadol, propoxyphene, dasatinib, nilotinib, desipramine, colchicine, clarithromycin, bosentan (reduce doses; see literature); fluticasone and salmeterol (avoid). May be affected by, potentiate, or antagonize drugs that are metabolized by or induce CYP3A4, 2D6, 2C9, 3A, 1A2, 2C19, 2B6, or glucuronyl transferase, including: delavirdine, maraviroc, antiarrhythmics (eg, disopyramide, lidocaine, mexiletine), digoxin, anticoagulants, anticonvulsants, most antidepressants (eg, SSRIs, tricyclics, nefazodone, bupropion, trazodone), antiemetics (eg, dronabinol), antihypertensives (eg, calcium channel blockers, β -blockers), antiparasitics, corticosteroids, immunosuppressants, neuroleptics, sedative/hypnotics, CNS stimulants, statins, vinca alkaloids (eg, vincristine, vinblastine; consider withholding ritonavir); monitor these and others closely. Antagonizes theophylline, oral contraceptives, methadone. Avoid metronidazole, disulfiram; itraconazole or ketoconazole $>200\text{mg/day}$. Reduce rifabutin dose by at least $\frac{3}{4}$. See full labeling.

Adverse reactions: GI upset, abdominal pain, asthenia, headache, malaise, anorexia, paresthesias, dizziness, taste perversion, fever, hyperlipidemia, throat irritation, myalgia, somnolence, insomnia, sweating, vasodilation, pancreatitis, immune reconstitution syndrome, fat redistribution, anaphylaxis, rash (may be serious), PR interval prolongation; others.

Note: Register pregnant patients exposed to ritonavir by calling (800) 258-4263.

How supplied: Tabs-30; Caps-30, 120; Soln-8oz

SAQUINAVIR

INVIRASE CAPSULES Genentech

HIV protease inhibitor. Saquinavir (as mesylate) 200mg; hard gel caps.

Also: Saquinavir

INVIRASE TABLETS

Saquinavir (as mesylate) 500mg.

Indications: HIV infection (must use with zidovudine).

Adults: Take within 2 hours after a meal. $\geq 16\text{yrs}$: saquinavir 1g twice daily + zidovudine 100mg twice daily (taken at same time).

Children: $< 16\text{yrs}$: not recommended.

Contraindications: Congenital long QT syndrome. Refractory hypokalemia or hypomagnesemia. Complete AV block without implanted pacemakers, or those who are at high risk. Severe hepatic impairment. Use in combination with drugs that both increase saquinavir plasma concentrations and prolong the QT interval. Concomitant alfuzosin, amiodarone, bepridil,

disipride, dofetilide, ergots, flecainide, lidocaine, oral midazolam, pimozide, propafenone, quinidine, rifampin, sildenafil (Revatio; when used to treat PAH), lovastatin, simvastatin, trazodone, triazolam.

Warnings/Precautions: Not bioequivalent to soft gel form of saquinavir; do not interchange. Increased risk of cardiac conduction abnormalities in patients with ischemic heart or underlying structural heart disease, pre-existing conduction abnormalities, cardiomyopathies, CHF, bradyarrhythmias. Monitor ECG at baseline and during treatment. If QT interval $>450\text{msec}$, do not give ritonavir-boosted saquinavir. If QT interval $<450\text{msec}$, do on-treatment ECG after 3 to 4 days therapy; if QT interval $>480\text{msec}$ or prolongation over pre-treatment by $>20\text{msec}$, discontinue therapy. Correct and monitor electrolyte imbalances before and during therapy. Underlying hepatitis B or C, cirrhosis, chronic alcoholism. Hepatic impairment. Severe renal impairment. Hemophilia (monitor for spontaneous bleeding). Diabetes. Monitor clinical chemistry, triglycerides, and for hyperglycemia. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant tipranavir/ritonavir, fluticasone, salmeterol, St. John's wort, garlic capsules: not recommended. Limit dose of atorvastatin to 20mg daily. Plasma levels reduced by efavirenz, nevirapine, rifabutin, other CYP3A4 inducers (eg, carbamazepine, phenobarbital, phenytoin, dexamethasone). Plasma levels increased by clarithromycin (see literature), atazanavir, indinavir, lopinavir/ritonavir, ritonavir, delavirdine. Antagonizes methadone, oral contraceptives. Potentiates CYP3A4 substrates (eg, calcium channel blockers, warfarin, cyclosporine, tacrolimus, rapamycin, sildenafil, vardenafil, tadalafil), maraviroc, bosentan, colchicine, ketoconazole, itraconazole; monitor their effects; may need reduced doses. Cautious with digoxin, ibutilide, sotalol, tricyclics, benzodiazepines, neuroleptics (eg, clozapine, haloperidol, thioridazine), omeprazole, erythromycin, halofantrine, pentamidine, others (see literature).

Adverse reactions: GI disturbances, fatigue, abdominal pain, headache, paresthesia, weakness, lab abnormalities, depression, hyperglycemia, diabetes, hyperlipidemia, fat redistribution, immune reconstitution syndrome, hepatotoxicity, rash, pruritus; rare: 2nd or 3rd-degree AV block, QT prolongation, torsades de pointes.

Note: Register pregnant patients exposed to saquinavir by calling (800) 258-4263. See ritonavir entry in this section for more information.

How supplied: Caps-270; Tabs-120

TELAPREVIR

INCIVEK Vertex

Hepatitis C virus NS3/4A protease inhibitor.

Telaprevir 375mg; tabs.

Indications: Chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin in patients with compensated liver disease, including

cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based therapy, including prior null responders, partial responders, and relapsers. Not for use as monotherapy.

Adults: Take with food (not low fat). 750mg three times daily. Treat for 12 weeks (with peginterferon + ribavirin), then continue peginterferon + ribavirin according to HCV-RNA response at Weeks 4 and 12. Do not reduce dose or interrupt therapy. Discontinue if futile (see full labeling).

Children: ≤18yrs: not established.

Contraindications: Concomitant strong CYP3A inducers (eg, rifampin, St. John's wort), or narrow therapeutic index CYP3A substrates (eg, alfuzosin, cisapride, ergots, lovastatin, pimozide, simvastatin, sildenafil/tadalafil for PAH, triazolam, oral midazolam). Pregnant women, or partners. Review peginterferon and ribavirin contraindications.

Warnings/Precautions: Must have (–) pregnancy test before therapy, use 2 effective forms of contraception, and undergo monthly pregnancy test during treatment and for 6 months after. Risk of serious skin reactions (eg, Stevens-Johnson syndrome, DRESS, TEN); monitor. Moderate/severe hepatic impairment, decompensated liver disease: not recommended. Coinfection with HBV or HIV. Organ transplant recipients. Monitor hemoglobin and CBC with differential prior to and at weeks 2, 4, 8 and 12 during treatment. Monitor HCV-RNA at weeks 4 and 12, and clinical chemistry frequently. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid concomitant atorvastatin. Concomitant colchicine w/renal or hepatic impairment, voriconazole; lopinavir, fosamprenavir, darunavir (all w/ritonavir): not recommended. May be potentiated by macrolides, azole antifungals. May be antagonized by anticonvulsants, rifabutin, dexamethasone, HIV protease inhibitors, efavirenz. May potentiate antiarrhythmics, digoxin, macrolides, carbamazepine, trazodone, azole antifungals, colchicine, rifabutin, alprazolam, midazolam, calcium channel blockers, corticosteroids, bosentan, atazanavir, tenofovir, immunosuppressants, salmeterol, PDE5 inhibitors for ED (reduce dose). May antagonize escitalopram, zolpidem, efavirenz, ethinyl estradiol, methadone. Monitor warfarin.

Adverse reactions: Rash (if serious; discontinue therapy and treat, do not restart), pruritus, anemia, GI upset, anorectic effects, dysgeusia, fatigue, hyperbilirubinemia, hyperuricemia.

How supplied: Tabs–168 (7 blister strips × 6 tabs/blister strip × 4 weekly cartons)

TENOFOVIR

VIREAD Gilead

Nucleotide analogue (reverse transcriptase and polymerase inhibitor). Tenofovir disoproxil fumarate 150mg, 200mg, 250mg, 300mg; tabs.

Also: Tenofovir

VIREAD ORAL POWDER

Tenofovir disoproxil fumarate 40mg per 1g pwd.

Indications: HIV-1 infection. Chronic hepatitis B virus (HBV) in adults.

Adults: <35kg: not established. May use tabs or oral pwd (if unable to swallow). Mix oral pwd with 2–4oz of soft food not requiring chewing (eg, applesauce, baby food, yogurt). ≥12yrs (≥35kg): HIV or HBV: 300mg once daily. Renal impairment: CrCl 30–49mL/min: 300mg every 48hrs; CrCl 10–29mL/min: 300mg every 72–96hrs; hemodialysis: 300mg every 7 days or after a total of 12hrs of dialysis; CrCl <10mL/min: not recommended.

Children: <2yrs: not established. HIV: Mix oral pwd with 2–4oz of soft food not requiring chewing (eg, applesauce, baby food, yogurt). ≥2yrs: 8mg/kg once daily; max 300mg/day. ≥17kg: may use tablets if able to swallow. 17–<22kg: 150mg once daily. 22–<28kg: 200mg once daily. 28–<35kg: 250mg once daily. ≥35kg: 300mg once daily. See full labeling for additional dosing based on body wt.

Warnings/Precautions: Suspend if lactic acidosis or hepatotoxicity occurs. Calculate CrCl prior to initiating therapy. Monitor CrCl and serum phosphorus in patients at risk for renal impairment. Decompensated liver disease. Women, obesity, prolonged nucleoside exposure, other risk factors for hepatic dysfunction: increased risk of toxicity. Monitor hepatic function during and for several months after stopping anti-HBV treatment (discontinuing therapy may exacerbate HBV infection). HIV-1 and HBV coinfection: do HIV-1 antibody testing for HBV-infected patients, and test for presence of HBV in HIV-1 infected patients before starting therapy. History or risk of fractures, osteoporosis or bone loss: consider bone mineral density (BMD) assessment; Vit. D and calcium supplementation may be beneficial. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid concomitant drugs that contain tenofovir or adefovir dipivoxil. Potentiates didanosine toxicity (>60kg; reduce dose of didanosine); discontinue if toxicity develops. Monitor drugs that reduce renal function or compete for renal tubular secretion (eg, cidofovir, acyclovir, valacyclovir, ganciclovir, valganciclovir). Potentiated by lopinavir/ritonavir, atazanavir; monitor for toxicity. Concomitant atazanavir: must give with ritonavir. Caution with triple nucleoside-only regimens (high rate of early viral non-response); monitor and consider alternative therapy. See full labeling for dosing on concomitant didanosine or ritonavir.

Adverse reactions: Rash, diarrhea, headache, pain, depression, asthenia, nausea, insomnia, dizziness, pyrexia; lactic acidosis; severe hepatomegaly with steatosis, fat redistribution, immune reconstitution syndrome, worsening renal impairment, decreased BMD, severe acute

exacerbation of hepatitis, autoimmune disorders (eg, Graves' disease, polymyositis, Guillain-Barre).

Note: Register pregnant patients exposed to tenofovir DF by calling (800) 258-4263.

How supplied: Tabs-30

Oral pwd-60g (w. dosing scoop)

VALACYCLOVIR

R

VALTREX GlaxoSmithKline

Nucleoside analogue. Valacyclovir (as HCl) (prodrug of acyclovir) 500mg, 1g +; caplets; + scored.

Indications: Treatment of herpes zoster or herpes labialis. Treatment or suppression of genital herpes in immunocompetent patients. To reduce risk of heterosexual transmission of genital herpes from immunocompetent patients to susceptible partner. Suppression of recurrent genital herpes in HIV-infected patients. Treatment of chickenpox in immunocompetent children.

Adults: Begin at onset of signs/symptoms (within 48 hours for herpes zoster or initial episode of genital herpes). Coincide a dose for after hemodialysis. ≥ 18 yrs: Herpes zoster: 1g every 8 hours; CrCl 30-49mL/min: 1g every 12 hours; CrCl 10-29mL/min: 1g every 24 hours; CrCl < 10 mL/min: 500mg every 24 hours; all for 7 days. Initial episode of genital herpes: 1g every 12 hours; CrCl 10-29mL/min: 1g every 24 hours; CrCl < 10 mL/min: 500mg every 24 hours; all for 10 days. Treatment of recurrent genital herpes: 500mg every 12 hours; CrCl ≤ 29 mL/min: 500mg every 24 hours; both for 3 days. Suppression of recurrent genital herpes if immunocompetent (> 9 episodes/year; reevaluate annually): 1g every 24 hours; CrCl ≤ 29 mL/min: 500mg every 24 hours; (≤ 9 episodes/year): 500mg every 24 hours; CrCl ≤ 29 mL/min: 500mg every 48 hours; Reduction of genital herpes transmission risk (≤ 9 episodes/year): 500mg every 24 hours for source partner (and use safer sex practices); CrCl ≤ 29 mL/min: 500mg every 48 hours; Suppression of recurrent genital herpes if HIV-infected: 500mg every 12 hours; CrCl ≤ 29 mL/min: 500mg every 24 hours. ≥ 12 yrs: Herpes labialis (treat for 1 day): 2g every 12 hours; CrCl 30-49mL/min: 1g every 12 hours; CrCl 10-29mL/min: 500mg every 12 hours; CrCl < 10 mL/min: 500mg once.

Children: Herpes labialis: < 12 yrs: not recommended. Herpes zoster or genital herpes < 18 yrs: not recommended. Chickenpox: < 2 yrs or ≥ 18 yrs: not recommended. Begin at onset of signs/symptoms. 2-18 yrs: 20mg/kg three times daily for 5 days; max 1g three times daily. CrCl < 50 mL/min: not recommended.

Warnings/Precautions: Renal impairment. Maintain adequate hydration. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Renal or CNS toxicity with nephrotoxic drugs.

Adverse reactions: Headache, nausea, abdominal pain, dizziness, fatigue, rash, lab abnormalities

(CBC, AST, serum creatinine), CNS disturbances (esp. elderly). Thrombotic thrombocytopenic purpura/hemolytic uremic syndrome (in advanced HIV or transplant recipients on 8g/day).

How supplied: Caplets-30, 90

VALGANCICLOVIR

R

VALCYTE Roche

Nucleoside analogue. Valganciclovir (as HCl) (prodrug of ganciclovir) 450mg; tabs.

Indications: Treatment of AIDS-related cytomegalovirus (CMV) retinitis. Prevention of CMV disease in kidney, heart, or kidney-pancreas transplant adult patients at high risk. Prevention of CMV disease in kidney and heart transplant pediatric patients (4 months to 16 years old) at high risk.

Adults: Take with food. ≥ 16 yrs: Treatment: induction: 900mg twice daily for 21 days; maintenance: 900mg once daily. Prevention (heart or kidney-pancreas): 900mg once daily starting within 10 days of transplantation until 100 days post-op. Prevention (kidney): 900mg once daily starting within 10 days of transplantation until 200 days post-op. Renal impairment (CrCl < 60 mL/min): reduce dose; see literature. Hemodialysis (CrCl < 10 mL/min): not recommended (use ganciclovir).

Children: < 4 months: not recommended. Take with food. ≥ 4 months: Dose (mg) = $7 \times \text{BSA} \times \text{Creatinine Clearance}$ (if calculated Schwartz CrCl > 150 mL/min/1.73m², then use max value of 150 mL/min/1.73m² in equation). Round calculated dose to the nearest 25mg increment; max 900mg. If calculated dose within 10% of tablet strength, tablets may be used.

Also: Valganciclovir

R

VALCYTE FOR ORAL SOLUTION

Valganciclovir (as HCl) (prodrug of ganciclovir) 50mg/mL; pwd for reconstitution; tutti-frutti flavor.

Indications: Prevention of CMV disease in kidney and heart transplant pediatric patients (4 months to 16 years old) at high risk.

Adults: Use tablet form.

Children: < 4 months: not recommended. Take with food. ≥ 4 months: Dose (mg) = $7 \times \text{BSA} \times \text{Creatinine Clearance}$ (if calculated Schwartz CrCl > 150 mL/min/1.73m², then use max value of 150 mL/min/1.73m² in equation). Round calculated dose to the nearest 25mg increment; max 900mg.

Contraindications: Acyclovir or ganciclovir allergy.

Warnings/Precautions: Do not substitute on a mg-per-mg basis for ganciclovir. Avoid handling broken tabs. Withhold dose if absolute neutrophil count < 500 cells/microliter, platelet count $< 25,000$ /microliter, or hemoglobin < 8 g/dL. Reduce dose or discontinue if blood dyscrasias occur. Renal impairment. Cytopenia or cytopenic reactions to drugs, chemicals, irradiation. Monitor CBC with differential, platelets, ophthalmic, and renal function. Maintain adequate hydration. Use effective contraception during (men and women)

and for at least 90 days after treatment (men). Elderly. Pregnancy (Cat.C: teratogenic, embryotoxic, carcinogenic, aspermatogenesis in animals), nursing mothers: see literature.

Interactions: Zidovudine increases anemia/neutropenia risk. Probenecid increases levels. May potentiate mycophenolate mofetil (MMF) metabolites or be potentiated by MMF in patients with renal impairment (monitor). Caution with nephrotoxic or myelosuppressive drugs. Monitor for toxicity with didanosine.

Adverse reactions: GI upset, pyrexia, tremor, neutropenia, anemia, thrombocytopenia, graft rejection; children: also hypertension, upper respiratory tract infection, constipation, cough.

How supplied: Tabs-60; Soln-100mL (after constitution)

ZANAMIVIR

RELENZA GlaxoSmithKline

Neuraminidase inhibitor. Zanamivir 5mg/blister; dry pwd for oral inhalation; contains lactose.

Indications: Treatment of uncomplicated acute illness due to influenza A and B virus in patients ≥ 7 years of age who have been symptomatic for no more than two days. Prophylaxis of influenza in patients ≥ 5 years of age.

Adults and Children: Use supplied Diskhaler inhalation device. Complete course of treatment. Treatment: < 7 yrs: not recommended. ≥ 7 yrs: 2 inh (10mg total) twice daily (at least 2 hrs apart) on 1st day; then 2 inh (10mg total) twice daily at 12-hr intervals for the next 4 days (5 days total). Prophylaxis: < 5 yrs: not recommended. ≥ 5 yrs: 2 inh (10mg total) once daily. Household: use for 10 days. Community: use for 28 days.

Contraindications: Milk protein allergy.

Warnings/Precautions: Underlying airway disease (eg, asthma, COPD): not recommended; if used, patient must have a fast-acting bronchodilator available. Discontinue if bronchospasm or decline in respiratory function occurs or worsens. Monitor for signs of abnormal behavior (esp. in children). Pregnancy (Cat.C). Nursing mothers (unknown if drug excreted in milk).

Interactions: If an inhaled bronchodilator is scheduled for dosing at the same time, use the bronchodilator first. Caution with influenza virus vaccine live, intranasal (eg, FluMist); separate dosing by at least 48hrs before or 2 weeks after FluMist. May maintain normal influenza virus vaccine schedule.

Adverse reactions: GI upset, sinusitis, dizziness, headache, bronchitis, cough, nasal symptoms, respiratory function decline (eg, bronchospasm, dyspnea), allergic reactions (eg, oropharyngeal edema), possible neuropsychiatric events (eg, seizures, confusion, abnormal behavior).

How supplied: 4 blisters/Rotadisk-5 Rotadisks/box (w. 1 Diskhaler)

ZIDOVUDINE

RETROVIR TABLETS GlaxoSmithKline

Nucleoside analogue (reverse transcriptase inhibitor). Zidovudine 300mg.

Also: Zidovudine RETROVIR CAPSULES

Zidovudine 100mg.

Also: Zidovudine RETROVIR SYRUP

Zidovudine 50mg/5mL; strawberry flavor.

Indications: HIV infection. Prevention of maternal-fetal HIV transmission.

Adults: ≥ 18 yrs: 600mg daily in divided doses. End-stage renal disease on dialysis: 100mg every 6–8 hours. Vertical transmission, severe anemia and/or neutropenia: see literature.

Children: < 6 weeks and/or for vertical transmission: see literature. 6 weeks to < 18 yrs: (4 to < 9 kg): 24mg/kg/day (12mg/kg twice daily or 8mg/kg 3 times daily); (≥ 9 to < 30 kg): 18mg/kg/day (9mg/kg twice daily or 6mg/kg 3 times daily); (≥ 30 kg): 600mg/day (300mg twice daily or 200mg 3 times daily). Alternative dosing based on BSA: 480mg/m²/day (240mg/m² twice daily or 160mg/m² 3 times daily).

Also: Zidovudine RETROVIR IV

Zidovudine 10mg/mL; for IV infusion after dilution; preservative-free.

Adults: Give by IV infusion over 1 hour; use only until oral therapy can be given. 1mg/kg 5–6 times daily. End-stage renal disease on dialysis: 1mg/kg every 6–8 hours. Vertical transmission, severe anemia and/or neutropenia: see literature.

Children: Vertical transmission: see literature.

Warnings/Precautions: Suspend if lactic acidosis or hepatotoxicity (eg, hepatomegaly, steatosis) occurs. Monitor for hematologic toxicity; reduce dose or suspend if significant anemia and/or granulocytopenia occurs; transfuse if necessary. Renal or hepatic dysfunction: consider reducing dose. Bone marrow suppression. Risk of liver disease. Women, obesity, prolonged nucleoside exposure, or advanced HIV disease: increased risk of toxicity. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid stavudine, doxorubicin, ribavirin, other nucleoside analogues, other forms of zidovudine. Caution with other cytotoxic or myelosuppressive drugs (eg, ganciclovir, interferon-alpha, ribavirin). Fluconazole, atovaquone, lamivudine, probenecid, valproic acid, methadone increase zidovudine levels. Monitor phenytoin. May be antagonized by rifampin, ritonavir, nelfinavir. Monitor for treatment-associated toxicities with interferon-alpha with or without ribavirin.

Adverse reactions: Anemia, neutropenia, headache, malaise, GI disturbances, insomnia, pain, myopathy, neuropathy, myositis, thrombocytopenia,

lactic acidosis, steatosis, hepatomegaly, fat redistribution, immune reconstitution syndrome, pancreatitis, others. Children: also fever, cough.

Note: Register pregnant patients exposed to zidovudine by calling (800) 258-4263.

How supplied: Tabs-60; Caps-100; Syrup-240mL; IV (20mL/vial)-10

SECTION 10: MUSCULOSKELETAL DISORDERS 10A Arthritis/rheumatic disorders

ABATACEPT

R

ORENCIA Bristol-Myers Squibb

Selective costimulation modulator. Abatacept
250mg/vial; pld for IV infusion after reconstitution and dilution; 125mg/mL prefilled syringe; soln for SC inj; Both: preservative-free.

Indications: To reduce signs/symptoms, induce major clinical response, inhibit progression of structural damage, and improve physical function in patients with moderately-to-severely active rheumatoid arthritis; may be used alone or with DMARDs other than TNF antagonists. To reduce signs/symptoms of moderately-to-severely active polyarticular juvenile idiopathic arthritis in patients ≥ 6 years of age; may be used alone or with methotrexate.

Adults: IV regimen: give as IV infusion over 30 min at weeks 0, 2, and 4, then every 4 weeks thereafter. <60 kg: 500mg. 60-100kg: 750mg. >100 kg: 1g. SC regimen: following a single IV loading dose, give the first 125mg SC inj within a day, followed by 125mg SC inj once weekly. Patients who are unable to receive IV infusion, may begin weekly SC inj without an IV loading dose. Switching from IV to SC regimen: give the first SC dose instead of the next scheduled IV dose.

Children: Give as an IV infusion over 30 minutes at weeks 0, 2, and 4, then every 4 weeks thereafter. <6 ys: not recommended. 6-17ys: (<75 kg): 10mg/kg; (≥ 75 kg): use adult dose; max 1g.

Warnings/Precautions: Chronic or history of recurring infections. Conditions that predispose to infection. Test for tuberculosis, treat TB first. Monitor closely if new infection develops; discontinue if serious infection occurs. COPD (monitor). Immunosuppression. Juvenile arthritis: follow up on current immunizations before starting therapy. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant TNF antagonists, anakinra, live vaccines: not recommended (see literature).

Adverse reactions: Headache, upper respiratory tract infection, nasopharyngitis, nausea, infusion site reactions; infections (may be serious), malignancies (eg, lymphoma, lung cancer). Children: pyrexia, abdominal pain.

Note: Reconstitute with silicone-free disposable syringes only.

How supplied: Single-use vial-1 (w. silicone-free disposable syringe); Single-dose prefilled syringe-4

ADALIMUMAB

R

HUMIRA AbbVie

Tumor necrosis factor- α blocker. Adalimumab
20mg/0.4mL, 40mg/0.8mL; soln for SC inj; preservative-free.

Indications: To reduce signs/symptoms, induce major clinical response, inhibit progression of structural damage, and improve physical function in moderately-to-severely active rheumatoid arthritis (RA); may be used alone or with methotrexate (MTX) or DMARDs. To reduce signs/symptoms of moderately-to-severely active polyarticular juvenile idiopathic arthritis in patients ≥ 4 years of age; may be used alone or with MTX. To reduce signs/symptoms, inhibit progression of structural damage, and improve physical function in active psoriatic arthritis; may be used alone or with DMARDs. To reduce signs and symptoms of active ankylosing spondylitis.

Adults: Inject SC into thigh or abdomen; rotate inj sites; supervise 1st dose. ≥ 18 ys: 40mg every other week. May use with MTX, DMARDs, glucocorticoids, salicylates, NSAIDs, or analgesics. RA (without MTX): may increase frequency to once weekly.

Children: <4 ys or <15 kg: not recommended. Inject SC into thigh or abdomen; rotate inj sites; supervise 1st dose. 4-17ys: (15kg to <30 kg): 20mg every other week (20mg prefilled syringe should be used); (≥ 30 kg): 40mg every other week. May use with MTX, glucocorticoids, salicylates, NSAIDs, or analgesics.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Lymphoma and other malignancies. Active infections: do not initiate therapy. Chronic or history of recurring infections. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. CHF (monitor). Immunosuppression. Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs. CNS demyelinating disorders. Juvenile arthritis: follow up on current immunizations before starting therapy. Latex allergy. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant abatacept, anakinra, live vaccines, or other TNF blockers: not recommended. Immunosuppressants increase risk of infection.

Adverse reactions: Inj site reactions, infections (may be serious), headache, nausea, rash, abdominal pain; rare: malignancies (eg, lymphoma; esp children), blood dyscrasias, hypertension, neurological events, antibody formation, lupus-like syndrome.

How supplied: Single-dose prefilled syringe-2; Single-dose prefilled pen (40mg)-2

CELECOXIB

CELEBREX Pfizer
NSAID (COX-2 inhibitor). Celecoxib 50mg, 100mg, 200mg, 400mg; caps.

Indications: Osteoarthritis (OA). Rheumatoid arthritis (RA). Ankylosing spondylitis (AS). Juvenile rheumatoid arthritis (JRA).

Adults: ≥ 18 yrs: OA: 200mg once daily or 100mg twice daily. RA: 100–200mg twice daily. AS: 200mg in 1–2 divided doses; if no response after 6 weeks, 400mg once daily may be tried. < 50 kg: start at lowest recommended dose.

Children: < 2 yrs: not recommended. May sprinkle capsule contents into applesauce. JRA: ≥ 2 yrs (≥ 10 kg to ≤ 25 kg): 50mg twice daily; (> 25 kg): 100mg twice daily.

Contraindications: Sulfonamide or aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease or severe hepatic impairment: not recommended. Renal or liver dysfunction; reduce dose by 50% in moderate hepatic insufficiency (Child-Pugh class B). Discontinue if liver disease or systemic effects (eg, eosinophilia, rash) develops. History or risk of GI bleed/ulcer (monitor). Fluid retention. Heart failure. Hypertension. Asthma. Alcoholism. Dehydrated. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with drugs that inhibit CYP2C9 (eg, fluconazole) or are metabolized by CYP2D6. May antagonize, or increase risk of renal failure with ACEIs, diuretics. Increased risk of GI bleed with aspirin (except low-dose), corticosteroids, smoking, anticoagulants. May potentiate lithium. Monitor warfarin.

Adverse reactions: GI upset/pain, edema, pharyngitis, increase AST/ALT, GI ulcer/bleed; rare: intracranial bleed, liver failure; also children: headache, fever, cough. See literature re: risk of cardiovascular events.

How supplied: Caps 100mg, 200mg–100, 500; 50mg, 400mg–60

CYCLOSPORINE

NEORAL Novartis
DMARD (immunosuppressant). Cyclosporine (modified) 25mg, 100mg; caps; contains alcohol.

Also: Cyclosporine
NEORAL ORAL SOLUTION

Cyclosporine (modified) 100mg/mL; contains alcohol.

Indications: Severe, active rheumatoid arthritis unresponsive to methotrexate alone.

Adults: Give consistently with regard to meals and time of day. ≥ 18 yrs: 1.25mg/kg twice daily; may increase by 0.5–0.75mg/kg per day after 8 weeks and again after 12 weeks; max 4mg/kg per day (many patients on concomitant methotrexate can be treated with doses of 3mg/kg per day or less). Dilute soln in a glass of room temp orange or apple juice. Reduce dose by 25–50% if adverse events (eg, hypertension or serum creatinine increases $\geq 30\%$ above baseline) occur. Renal or severe hepatic impairment: consider reducing dose. Discontinue if adverse events are severe or persistent, or if no benefit by week 16.

Children: < 18 yrs: not established.

Contraindications: Renal impairment. Uncontrolled hypertension. Malignancies.

Warnings/Precautions: Be fully familiar with immunosuppressive therapy before prescribing. Not bioequivalent to all other forms of cyclosporine; do not interchange without physician supervision. Increased risk of infections, lymphomas and other malignancies (eg, skin). Avoid sun or UV light exposure. Monitor renal and hepatic function, BP, CBC, serum magnesium, potassium, uric acid, lipids (see full labeling for monitoring frequency). Reduce dose if hypertension occurs; do not attempt to manage medically. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid other nephrotoxic drugs (eg, ciprofloxacin, gentamicin, tobramycin, vancomycin, SMX/TMP, melphalan, amphotericin B, ketoconazole, cimetidine, ranitidine, tacrolimus, NSAIDs, colchicine), fibric acid derivatives. Cyclosporine levels increased by CYP3A inhibitors (eg, calcium channel blockers, amiodarone, azithromycin, azole antifungals, erythromycin, clarithromycin, quinupristin/dalfopristin, boceprevir, telaprevir, methylprednisolone, allopurinol, colchicine, bromocriptine, danazol, metoclopramide; probably indinavir, saquinavir, nelfinavir, ritonavir, imatinib, nefazodone, oral contraceptives). Avoid alcohol, grapefruit juice. Cyclosporine levels decreased by CYP3A inducers (eg, nafcillin, rifampin, carbamazepine, oxcarbazepine, bosentan, phenobarbital, phenytoin, octreotide, ticlopidine, St. John's wort), orlistat. Avoid potassium-sparing diuretics. Concomitant repaglinide: monitor blood glucose. Concomitant aliskiren: not recommended. Concomitant sirolimus: separate by 4 hours. May decrease effectiveness of vaccines; avoid live attenuated vaccines. May increase levels of digoxin (monitor), colchicine, prednisolone, statins (reduce dose), ambrisentan, and anthracycline antibiotics. Gingival hyperplasia with nifedipine (avoid). Convulsions with high-dose methylprednisolone.

Adverse reactions: Renal dysfunction, hypertension, headache, GI disturbances, hirsutism, hypertrichosis, leg cramps, pain, tremor, paresthesia, edema, dizziness, gum hyperplasia, liver dysfunction; increased risk of infections or malignancies,

progressive multifocal leukoencephalopathy, hyperkalemia, thrombotic microangiopathy, possible encephalopathy.

How supplied: Caps-30; Soln-50mL

DICLOFENAC POTASSIUM

CATAFLAM Novartis

NSAID (benzeneacetic acid deriv.). Diclofenac potassium 50mg; tabs.

Indications: Osteoarthritis. Rheumatoid arthritis. Ankylosing spondylitis.

Adults: Osteoarthritis: 50mg 2-3 times daily.

Rheumatoid arthritis: 50mg 3-4 times daily. Ankylosing spondylitis: 25mg 4 times daily, may add 25mg at bedtime.

Children: Not recommended.

Contraindications: Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. Peptic ulcer. GI bleeding. Monitor AST/ALT within 4 weeks and then periodically; also blood, hepatic, and renal function in chronic use. Edema. Cardiac failure. Hypertension. Hepatic porphyria. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Digoxin, methotrexate, cyclosporine, lithium toxicity. Antagonizes diuretics. May increase serum potassium level with K⁺-sparing diuretics. Avoid aspirin. Monitor oral anticoagulants, insulin and sulfonylureas. Increased risk of GI bleed with alcohol.

Adverse reactions: Peptic ulcer, GI bleeding, elevated AST/ALT, abdominal discomfort, constipation, diarrhea, indigestion, nausea, abdominal distention, headache, dizziness, fluid retention, rash (discontinue if occurs), pruritus, tinnitus. See literature re: risk of cardiovascular events.

How supplied: Tabs-100

DICLOFENAC SODIUM

VOLTAREN-XR Novartis

NSAID (benzeneacetic acid deriv.). Diclofenac sodium 100mg; ext-rel tabs.

Indications: Chronic therapy of osteoarthritis or rheumatoid arthritis.

Adults: Osteoarthritis: 100mg once daily. Rheumatoid arthritis: 100mg once daily; rarely 100mg twice daily may be used.

Children: Not recommended.

Also: Diclofenac sodium

DICLOFENAC SODIUM DELAYED-RELEASE TABLETS (various)

Diclofenac sodium 25mg, 50mg, 75mg; e-c tabs.

Indications: Acute or chronic therapy of osteoarthritis or rheumatoid arthritis. Ankylosing spondylitis.

Adults: Osteoarthritis: 50mg 2-3 times daily or 75mg twice daily. Rheumatoid arthritis: 50mg 3-4 times daily or 75mg twice daily. Ankylosing

spondylitis: 25mg 4 times daily, with an additional 25mg at bedtime if necessary.

Children: Not recommended.

Contraindications: Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. Peptic ulcers and GI bleeding. Check SGPT/SGOT within 4 weeks and then periodically. Edema. Cardiac failure. Hypertension. Bleeding disorders. Renal impairment. Hepatic porphyria. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Digoxin, methotrexate, cyclosporine, lithium toxicity. Hyper- and hypoglycemia with insulin and sulfonylureas. Reduced effect of diuretics. Increased serum potassium level with K⁺-sparing diuretics. Avoid aspirin. Monitor oral anticoagulants.

Adverse reactions: Peptic ulcers, GI bleeding, elevated SGPT or SGOT levels, anaphylactoid reactions, abdominal discomfort, constipation, diarrhea, indigestion, nausea, abdominal distention, headache, dizziness, fluid retention, rash (discontinue if occurs), pruritus, tinnitus. See literature re: risk of cardiovascular events.

How supplied: XR-100; Tabs-contact supplier

ETANERCEPT

ENBREL Amgen

Tumor necrosis factor (TNF) blocker. Etanercept 25mg; per vial (pwd for SC inj after reconstitution; preservative-free; diluent contains benzyl alcohol); 50mg/mL prefilled syringe (soln for SC inj; preservative free); 50mg/mL prefilled syringe SureClick autoinjector (soln for SC inj; preservative-free).

Indications: To reduce signs/symptoms, induce major clinical response, inhibit progression of structural damage, and improve physical function in patients with moderately to severely active rheumatoid arthritis; to reduce signs/symptoms, inhibit progression of structural damage of active arthritis, and improve physical function in patients with psoriatic arthritis; for both: may be used with or without methotrexate in patients who have not responded adequately to methotrexate alone. To reduce signs/symptoms of: ankylosing spondylitis, and of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA).

Adults: Use prefilled syringe. Inject 50mg SC once weekly into thigh, abdomen, or upper arm; rotate inj sites.

Children: Inject SC into thigh, abdomen, or upper arm; rotate inj sites. <2yrs: not recommended.

JIA: <63kg: 0.8mg/kg per week; max 50mg/week. ≥63kg: may use 50mg prefilled syringe or SureClick autoinjector.

Contraindications: Sepsis.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops]), or

other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections. Conditions that predispose to infection (eg, diabetes, immunosuppression). Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. Suspend if significant exposure to varicella occurs (consider varicella prophylaxis). Discontinue if lupus-like syndrome with antibody formation or serious hypersensitivity reaction occurs. CNS demyelinating disorders (eg, multiple sclerosis, myelitis, optic neuritis), seizures. Heart failure. Malignancies. Attempt to complete childhood immunizations first. Wegener's granulomatosis patients receiving immunosuppressive agents: not recommended. Moderate to severe alcoholic hepatitis. Latex allergy (syringe). Supervise 1st dose. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent cyclophosphamide, anakinra, abatacept, live vaccines, other TNF blockers: not recommended. Immunosuppressants increase risk of infection.

Adverse reactions: Inj site reactions, infections (eg, sepsis, osteomyelitis, cellulitis, pneumonia, pyelonephritis), antibody formation, respiratory disorders; worsening psoriasis; rare: CNS demyelinating disorders, pancytopenia, aplastic anemia, tuberculosis, malignancies (eg, lymphoma; esp. children), others. Children: also varicella, headache, GI disturbances.

How supplied: Multi-use vials—4 (w. supplies); Single-use prefilled syr (1mL)—4 (w. needles); Single-use prefilled SureClick autoinjector—4 (w. needles)

ETODOLAC

ETODOLAC CAPSULES (various)
NSAID (pyranocarboxylic acid deriv.). Etodolac 200mg, 300mg; caps.

Also: Etodolac

ETODOLAC TABLETS

Etodolac 400mg, 500mg.

Indications: Osteoarthritis. Rheumatoid arthritis.

Adults: Initially 600mg–1g/day in 2–3 divided doses; usual max 1g/day in divided doses; may increase to 1.2g/day when needed.

Children: Not recommended.

Also: Etodolac

ETODOLAC EXTENDED-RELEASE TABLETS

Etodolac 400mg, 500mg, 600mg; ext rel tabs.

Adults: 400mg–1g once daily; max 1.2g/day.

Children: Not recommended.

Contraindications: Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Discontinue if signs/symptoms of liver disease develop. History of upper

GI disease. Asthma. Renal or hepatic impairment. Advanced kidney disease: not recommended. Heart failure. Hypertension. Edema. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Dehydrated. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Antacids reduce serum levels. Avoid salicylates, phenylbutazone. Monitor anticoagulants, cyclosporine, lithium, digoxin, methotrexate. Renal toxicity may be potentiated with diuretics. May antagonize ACE inhibitors.

Adverse reactions: Dyspepsia, GI upset, edema, asthenia/malaise, dizziness, dysuria, urinary frequency, depression, nervousness, renal or hepatic toxicity, rash (discontinue if occurs), pruritus, chills/fever, GI bleed, peptic ulcer. See literature re: risk of cardiovascular events.

How supplied: Contact supplier.

GOLIMUMAB

SIMPONI Janssen Biotech

TNF blocker. Golimumab 50mg/0.5mL; soln for SC inj; preservative-free.

Indications: Moderately-to-severely active rheumatoid arthritis (RA), in combination with methotrexate (MTX). Active psoriatic arthritis (PsA), alone or with MTX. Active ankylosing spondylitis (AS).

Adults: 50mg SC once monthly. Rotate inj sites. Corticosteroids, non-biologic DMARDs, and/or NSAIDs may be continued during treatment.

Children: <18yrs: not established.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring or opportunistic infections. Conditions that predispose to infection.

Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, new or worsening CHF, hematological abnormality (eg, cytopenias), or serious hypersensitivity reaction develops. Malignancies. Prior history of dysplasia. CHF (monitor). Immunosuppression. CNS demyelinating disorders. Latex allergy. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent abatacept, anakinra, live vaccines, or other TNF blockers: not recommended. Immunosuppressants increase risk of infection. Monitor CYP450 substrates with narrow therapeutic index.

Adverse reactions: Inj site reactions, infections (may be serious), upper respiratory tract infection, nasopharyngitis, hypertension; rare: malignancies (eg, skin, lymphoma; monitor), blood dyscrasias, new

or worsening CHF, elevated liver enzymes, antibody formation, exacerbation or new onset of psoriasis.

How supplied: Single-dose SmartJect autoinjector-1; Single-dose prefilled syringe-1

HYDROXYCHLOROQUINE

Rx

PLAQUENIL Covis
DMARD (aminoquinoline). Hydroxychloroquine sulfate 200mg; tabs.

Indications: Refractory rheumatoid arthritis or lupus erythematosus.

Adults: Rheumatoid arthritis: initially 400–600mg daily with food or milk. Lupus: initially 400mg 1–2 times daily. Maintenance for both: 200–400mg daily.

Children: Not recommended.

Contraindications: Long-term use in children. Retinal or visual field changes.

Warnings/Precautions: Be fully familiar with this product's toxicity before use. Psoriasis. Porphyria. Hepatic dysfunction. Alcoholism. G6PD deficiency. Monitor ocular function, reflexes, and blood in chronic use. Discontinue if blood dyscrasias, visual symptoms or muscular weakness occur or if ineffective after 6 months in rheumatoid arthritis. Pregnancy: not recommended. Nursing mothers.

Interactions: Avoid other hepatotoxic or dermatotoxic drugs.

Adverse reactions: Irreversible retinopathy, blurred vision, corneal edema or deposits, visual field defects, irritability, neuromuscular dysfunction, hair bleaching, alopecia, pruritus, skin pigmentation, rash, blood dyscrasias, anorexia, nausea, weight loss.

How supplied: Tabs-100

IBUPROFEN

Rx

IBUPROFEN TABLETS (various)
NSAID (propionic acid deriv.). Ibuprofen 400mg, 600mg, 800mg.

Also: Ibuprofen

OTC

IBUPROFEN CHEWABLE TABLETS
Ibuprofen 50mg, 100mg; citrus flavor; contains phenylalanine.

Indications: Rheumatoid arthritis (RA). Osteoarthritis (OA). Juvenile arthritis (JA).

Adults: RA, OA: 400–800mg 3–4 times daily; max 3.2g/day.

Children: JA: 30–40mg/kg per day in 3–4 doses. May use 20mg/kg per day in 3–4 doses for milder disease.

Contraindications: Aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. History of upper GI disease. Active peptic ulcer. Impaired renal or hepatic function. Edema. Hypertension. Cardiac failure. Bleeding disorders. Diabetes. Monitor blood, hepatic, renal, and ocular function in chronic use. Discontinue if visual or liver dysfunction occurs. Dehydration. Elderly. Dehydrated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid aspirin. May increase bleeding with anticoagulants. Increases serum lithium levels. May increase toxicity of methotrexate. May decrease effect of furosemide, thiazide diuretics. Increased risk of GI bleed with alcohol.

Adverse reactions: Peptic ulcer or perforation, GI bleeding, vision disorders, nausea, epigastric pain, heartburn, dizziness, rash (discontinue if occurs), edema, renal papillary necrosis, jaundice, hepatitis. See literature re: risk of cardiovascular events.

How supplied: Contact supplier.

INDOMETHACIN

Rx

INDOMETHACIN (various)
NSAID (indole deriv.). Indomethacin 25mg, 50mg; caps.

Also: Indomethacin

Rx

INDOMETHACIN SUPPOSITORIES
Indomethacin 50mg; rectal supp.

Also: Indomethacin

Rx

INDOCIN SUSPENSION Iroko
Indomethacin 25mg/5mL; pineapple-coconut mint flavor; alcohol 1%.

Indications: Moderate to severe rheumatoid arthritis, osteoarthritis, ankylosing spondylitis. Acute painful shoulder. Gouty arthritis.

Adults: Give with food or antacids. Use lowest effective dose. Acute painful shoulder: 75–150mg/day in 3–4 divided doses until inflammation controlled (usually 7–14 days). Acute gouty arthritis: 50mg 3 times daily until pain tolerable; then rapidly reduce dose to discontinue. Other conditions: initially 25mg 2–3 times daily. Increase if needed at weekly intervals by 25–50mg daily; max 200mg daily.

Children: <14yrs: usually not recommended. If risk warranted, give with food or antacids; ≥2 yrs: 1–2mg/kg/day in divided doses; max 3–4mg/kg/day (or 150–200mg/day whichever less).

Also: Indomethacin

Rx

INDOMETHACIN ER
Indomethacin 75mg; ext-rel caps.

Indications: Moderate to severe rheumatoid arthritis, osteoarthritis, ankylosing spondylitis. Acute painful shoulder.

Adults: Give with food or antacids. Use lowest effective dose. Acute painful shoulder: 75–150mg/day (150mg dose: give as 75mg twice daily) until inflammation controlled (usually 7–14 days). Other conditions: initially 75mg once daily; may increase to 75mg twice daily if tolerated; max 150mg/day.

Children: <14yrs: not recommended.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery. Supp: history of proctitis or recent rectal bleeding.

Warnings/Precautions: Advanced renal disease: not recommended. History of GI lesions. Impaired renal or hepatic function. Heart failure. Hypertension. Edema. Sepsis. Volume depletion. Preexisting

asthma. Epilepsy. Depression. Parkinsonism. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use; monitor hepatic function in children. Discontinue if liver dysfunction occurs. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid salicylates, other NSAIDs, triamterene. Potentiated by diflunisal. Potentiates digoxin (monitor). Probenecid increases plasma levels. Increases serum lithium levels. Diuretics, β -blockers, ACE inhibitors (eg, captopril), angiotensin II antagonists (eg, losartan): reduced antihypertensive effect. Caution with cyclosporine, oral anticoagulants, methotrexate; monitor.

Adverse reactions: GI ulcers, bleeding or perforation, headache, nausea, dyspepsia, drowsiness, dizziness, edema, rash (discontinue if occurs), corneal deposits, retinopathy, hepatotoxicity, nephritis, nephrotic syndrome. See literature re: risk of cardiovascular events. Supp: rectal irritation, tenesmus.

How supplied: Caps, ER, supps—contact supplier. Susp—237mL

INFLIXIMAB

REMICADE Janssen Biotech
Tumor necrosis factor- α blocker. Infliximab
100mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free.

Indications: To reduce signs/symptoms, inhibit progression of structural damage, and improve physical function in psoriatic arthritis and with methotrexate in moderately to severely active rheumatoid arthritis (RA). To reduce signs/symptoms of active ankylosing spondylitis.

Adults: Give by IV infusion over at least 2 hours. RA: 3mg/kg at weeks 0, 2, 6, then every 8 weeks. May increase to 10mg/kg or give every 4 weeks. Ankylosing spondylitis: 5mg/kg at weeks 0, 2, 6, then every 6 weeks. Psoriatic arthritis: 5mg/kg at weeks 0, 2, 6, then every 8 weeks. All: max 5mg/kg in heart failure.

Children: Not recommended.

Contraindications: Moderate to severe heart failure (doses >5 mg/kg). Allergy to murine proteins.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial sepsis, viral, invasive fungal [treat empirically if develops], or other pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections or hematological abnormalities. Conditions that predispose to infection. Travel to, or residence in, areas with endemic TB or mycoses. Test/treat latent TB and HBV infection prior to initiating therapy. Monitor closely if new infection, active TB (even if initial latent test is negative), reactivation of HBV, or blood dyscrasias occurs; discontinue if serious or opportunistic infection, sepsis, HBV reactivation, or hematological abnormality develops. Discontinue if lupus-like syndrome with autoantibody formation,

severe hypersensitivity reactions, or jaundice with liver enzymes $\geq 5 \times$ ULN occurs. Pre-existing heart failure; closely monitor and discontinue if new or worsening symptoms occur. CNS demyelinating or seizure disorders; discontinue if significant CNS effects occur. Malignancies (eg, melanoma; perform periodic skin exams). Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concurrent anakinra, abatacept, tocilizumab, live vaccines, other TNF blockers or biological therapeutics: not recommended. Concomitant immunosuppressants (eg, corticosteroids, methotrexate) may increase risk of infection. May be potentiated by methotrexate. Concomitant CYP450 substrates with narrow therapeutic index (eg, warfarin, cyclosporine, theophylline): monitor and may need to adjust dose of these drugs. Caution with switching between DMARDs; overlapping may further increase the risk of infection.

Adverse reactions: Infection, infusion reactions (esp. after a period of no treatment), headache, abdominal pain, GI upset, fatigue, cough, fever, pain, dizziness, rash, pruritus, CHF, autoantibody formation; malignancies (eg, skin, lymphoma; esp children), optic neuritis, seizures, lupus-like syndrome, blood dyscrasias, hepatotoxicity.

How supplied: Single-use vials—1

LEFLUNOMIDE

ARAVA Sanofi Aventis
DMARD (pyrimidine synthesis inhibitor). Leflunomide
10mg, 20mg, 100mg; tabs.

Indications: Active rheumatoid arthritis to reduce signs/symptoms, inhibit structural damage, and improve physical function. May be used with aspirin, NSAIDs, and/or low-dose corticosteroids.

Adults: ≥ 18 rs: Loading dose: 100mg daily for three days; maintenance 20mg daily. If not well tolerated, may reduce to 10mg daily; monitor closely. If ALT elevations $>3 \times$ ULN, discontinue and determine if leflunomide-induced; if positive, give cholestyramine and activated charcoal as needed. Max 20mg/day.

Children: <18 rs: not recommended.

Contraindications: Women of childbearing potential who are not using reliable contraception. Pregnancy (Cat.X).

Warnings/Precautions: Pre-existing hepatic disease or ALT $>2 \times$ ULN: not recommended. Monitor liver function (esp. ALT) and blood (WBCs, platelets, HCT) at baseline, then monthly for 1st six months; then every 6–8 weeks. Obtain (–) pregnancy test before starting therapy; use reliable contraception. All women of childbearing potential and men wishing to father a child should use cholestyramine or activated charcoal to eliminate drug after therapy (see protocol in labeling). Test and treat, if positive for latent TB infection prior to starting therapy. Obtain platelets, WBC, hemoglobin, hematocrit at baseline and

monthly for 6 months following initiation and every 6–8 weeks thereafter. Renal impairment. Monitor BP. Severe immunodeficiency, bone marrow dysplasia, severe uncontrolled infections, nursing mothers: not recommended.

Interactions: Concomitant methotrexate, other immunosuppressants: monitor for hepatic or hematologic toxicity monthly. May increase levels of diclofenac, ibuprofen, tolbutamide. Caution with rifampin, and with other hepatotoxic drugs. Concomitant live vaccines: not recommended; consider leflunomide long half-life before giving live vaccines after stopping therapy.

Adverse reactions: Diarrhea, elevated liver enzymes, alopecia, rash, respiratory infections, hypertension, headache, GI upset; rare: hepatotoxicity (may be fatal), interstitial lung disease, immunosuppression (possible sepsis), bone marrow suppression, Stevens-Johnson syndrome, toxic epidermal necrolysis, peripheral neuropathy: stop therapy and perform drug elimination procedure.

How supplied: Tabs 10mg, 20mg–30; 100mg–blister pack (1 × 3)

MELOXICAM

MOBIC Boehringer Ingelheim
NSAID (oxicam deriv.). Meloxicam 7.5mg, 15mg; tabs.

Also: Meloxicam

MOBIC ORAL SUSPENSION

Meloxicam 7.5mg/5mL; raspberry flavor.

Indications: Osteoarthritis. Rheumatoid arthritis. Juvenile rheumatoid arthritis.

Adults: ≥18yrs: 7.5mg once daily; max 15mg once daily. Hemodialysis: max 7.5mg/day.

Children: <2yrs: not recommended. JRA: ≥2yrs: 0.125mg/kg (max 7.5mg) once daily.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: NSAIDs may increase risk of serious cardiovascular thrombotic events, MI, stroke; may be fatal. Monitor for GI ulcer/bleed (risk is increased if history of GI bleed or ulcer, extended or high-dose NSAID therapy, smokers, alcoholics, or if patient is otherwise at high risk). Severe renal disease (CrCl ≤20mL/min): not recommended. Women with difficulties conceiving or undergoing investigation of infertility: not recommended. Discontinue if liver dysfunction develops. Monitor hemoglobin or hematocrit if signs of anemia occur. Bleeding disorders. Renal or hepatic dysfunction. Dehydration. Fluid retention. Heart failure. Hypertension. Asthma. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C; Cat.D starting 30 weeks gestation). Nursing mothers: not recommended.

Interactions: Concomitant Kayexalate with Mobic oral suspension (sorbitol): not recommended; intestinal necrosis possible. Increased risk of GI bleed with aspirin, oral corticosteroids, anticoagulants. May antagonize or increase risk of renal failure with ACE inhibitors, diuretics. Monitor

warfarin (may increase INR). May potentiate lithium. May enhance toxicity of methotrexate, cyclosporine; use caution.

Adverse reactions: GI upset, anemia, headache, rash (discontinue if occurs), dizziness, edema, pruritus, GI ulcer/bleed, upper respiratory tract infections, elevated liver enzymes. Children: abdominal pain, pyrexia.

How supplied: Tabs–100; Susp–100mL

METHOTREXATE

RHEUMATREX Stada

DMARD (folic acid antagonist). Methotrexate sodium 2.5mg; unit-of-use weekly dose pack; scored tabs.

Indications: Severe recalcitrant rheumatoid arthritis or polyarticular-course juvenile rheumatoid arthritis.

Adults: Initially 7.5mg once per week as a single dose, or a course of three 2.5mg doses at 12-hour intervals once per week; max 20mg/week. May give test dose first.

Children: <2yrs: not recommended, ≥2yrs: initially 10mg/m² once weekly; max 20mg/m² per week.

Contraindications: Immunodeficiency. Blood dyscrasias. Alcoholism. Chronic liver disease. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Be fully familiar with this drug's toxicity before use. Discontinue if malignant lymphomas occur. Obtain baseline and monitor CBCs with differential, platelet counts, chest X-ray, and hepatic, renal and pulmonary function. During therapy monitor hematology monthly, renal and hepatic function every 1–2 months, more often if increasing dose or predisposed to toxicity (eg, dehydration). Discontinue immediately if blood counts drop significantly. Rule out pregnancy in women of childbearing potential; use effective contraception during therapy and for at least 1 ovulatory cycle afterwards for women and for at least 3 months afterwards for men. Interrupt therapy if vomiting, diarrhea, stomatitis, or pulmonary symptoms occur. Hepatic or renal impairment. Obesity. Diabetes. Peptic ulcer. Ulcerative colitis. Infection. Dehydration. Folate deficiency. Ascites, pleural effusions: evacuate fluid, monitor for toxicity and reduce dose or discontinue if needed. Elderly (use low doses and monitor closely). Debilitated.

Interactions: Avoid other hepatotoxic drugs, live virus vaccines. Caution with nephrotoxic agents. Toxicity increased by NSAIDs, salicylates, phenytoin, sulfonyleureas, sulfonamides, probenecid, penicillins (monitor), tetracyclines, chloramphenicol, non-absorbable broad spectrum antibiotics, folic acid antagonists. Impaired response to immunization. May potentiate theophylline. Antagonized by folic acid. Radiotherapy increases risk of soft tissue necrosis, osteonecrosis. Recall reactions after UV radiation.

Adverse reactions: Elevated liver enzymes, nausea, vomiting, stomatitis, thrombocytopenia, rash, pruritus, dermatitis, diarrhea, alopecia, leukopenia, pancytopenia, dizziness, hepatotoxicity, bone marrow

suppression, GI toxicity, fibrosis, cirrhosis, tumor lysis syndrome, fatal skin reactions, opportunistic infections, cough, chest lesions.

How supplied: Tabs 2.5mg (4-card dose pack)–5mg/week, 7.5mg/week, 10mg/week, 12.5mg/week, 15mg/week

NABUMETONE

NABUMETONE (various)
NSAID (*naphthylalkanone*). Nabumetone 500mg, 750mg; tabs.

Indications: Rheumatoid arthritis. Osteoarthritis.

Adults: Initially 1g once daily; max 2g/day in 1 or 2 divided doses. Renal insufficiency (CrCl 30–49mL/min): initial max 750mg once daily, may increase to 1.5g/day; (CrCl <30mL/min): initial max 500mg once daily, may increase to 1g/day.

Children: Not recommended.

Contraindications: Aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. History of upper GI disease or other ulcer risk. Cardiovascular disease. Renal or severe hepatic impairment. Fluid retention. Heart failure. Hypertension. Asthma. Monitor BP, renal and hepatic function. Discontinue if hepatic dysfunction or skin rash occurs. Monitor hemoglobin or hematocrit if signs of anemia occur. Avoid sun, UV light. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Renal toxicity potentiated with diuretics. May potentiate lithium. May antagonize ACE inhibitors. Monitor oral anticoagulants (eg, warfarin). Caution with methotrexate.

Adverse reactions: GI bleeding or upset, edema, photosensitivity, dry mouth, dizziness, headache, fatigue, sweating, insomnia, nervousness, somnolence, rash (discontinue if occurs), pruritus, tinnitus. See literature re: risk of cardiovascular events.

How supplied: Contact supplier

NAPROXEN

NAPROSYN Roche
NSAID (*arylacetic acid deriv.*). Naproxen 250mg, 375mg, 500mg; tabs.

Also: Naproxen

NAPROSYN SUSPENSION

Naproxen 125mg/5mL; pineapple-orange flavor.

Indications: Rheumatoid arthritis. Osteoarthritis. Ankylosing spondylitis. Juvenile rheumatoid arthritis (JRA). Tendinitis. Bursitis. Acute gout.

Adults: Arthritis, spondylitis: 250–500mg twice daily; max 1.5g/day (up to 6 months). Tendinitis, bursitis: 500mg once, then 500mg twice daily or 250mg every 6–8 hrs; max (first day) 1.25g, then max 1g/day. Acute gout: 750mg once, then 250mg every 8 hrs.

Children: <2yrs: not recommended. ≥2yrs: JRA: 5mg/kg twice daily. Other uses: Doses of 2.5–5mg/kg/dose, max 15mg/kg/day have been used.

Also: Naproxen

EC-NAPROSYN

Naproxen 375mg, 500mg; e-c tabs.

Indications: Rheumatoid arthritis. Osteoarthritis. Ankylosing spondylitis. JRA.

Adults: Swallow whole. 375–500mg twice daily.

Children: <2yrs: not recommended. ≥2yrs: use susp form.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation). Advanced renal disease: not recommended. Active peptic ulcer. History of GI or inflammatory bowel disease. Impaired renal or hepatic function. Hypovolemia. Heart failure. Salt depletion. Edema. Hypertension. Preexisting asthma. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid concomitant aspirin. May potentiate protein-bound drugs (eg, hydantoins, sulfonamides, sulfonylureas). Monitor oral anticoagulants. Increased risk of GI bleeding with oral corticosteroids, SSRIs, smoking, alcohol. May antagonize diuretics, β-blockers, ACEIs, ARBs or other antihypertensives. Increased renal toxicity with ACEIs or ARBs. Methotrexate excretion reduced. Increases serum lithium levels. Probenecid increases plasma levels and delays elimination. Concomitant H₂ blockers, sucralfate, intensive antacid therapy: use immediate-release forms of naproxen. Cholestyramine may delay absorption.

Adverse reactions: GI bleeding, peptic ulcer, constipation, heartburn, abdominal pain, nausea, headache, dizziness, drowsiness, pruritus, rash (discontinue if occurs), tinnitus, edema, nephritis, nephrotic syndrome, jaundice, hepatitis. See full labeling re: risk of cardiovascular or GI events.

How supplied: Tabs–100; Susp–pt; EC–100

NAPROXEN SODIUM

ANAPROX Roche
NSAID (*arylacetic acid deriv.*). Naproxen sodium 275mg; tabs.

Also: Naproxen sodium

ANAPROX DS

Naproxen sodium 550mg; tabs.

Indications: Rheumatoid arthritis. Osteoarthritis. Ankylosing spondylitis. Juvenile rheumatoid arthritis (JRA). Tendinitis. Bursitis. Acute gout.

Adults: Arthritis, spondylitis: 275mg or 550mg twice daily. Tendinitis, bursitis: Initially 550mg, then 550mg every 12 hrs or 275mg every 6–8 hrs; max 1.375g (first day), then max 1.1g/day. Acute gout: 825mg once then 275mg every 8 hrs.

Children: <2yrs: not recommended. ≥2yrs: use susp form of naproxen.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation). Advanced renal disease: not recommended. Active peptic ulcer. History of GI or inflammatory bowel disease. Impaired renal or hepatic function. Hypovolemia. Heart failure. Salt depletion. Edema. Hypertension. Preexisting asthma. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid concomitant aspirin. May potentiate protein-bound drugs (eg, hydantoins, sulfonamides, sulfonylureas). Monitor oral anticoagulants. Increased risk of GI bleeding with oral corticosteroids, SSRIs, smoking, alcohol. May antagonize diuretics, β -blockers, ACEIs, ARBs, or other antihypertensives. Increased renal toxicity with ACEIs or ARBs. Methotrexate excretion reduced. Increases serum lithium levels. Probenecid increases plasma levels and delays elimination. Concomitant H_2 blockers, sucralfate, intensive antacid therapy: use immediate-release forms of naproxen. Cholestyramine may delay absorption.

Adverse reactions: GI bleeding, peptic ulcer, constipation, heartburn, abdominal pain, nausea, headache, dizziness, drowsiness, pruritus, rash (discontinue if occurs), tinnitus, edema, nephritis, nephrotic syndrome, jaundice, hepatitis. See full labeling re: risk of cardiovascular or GI events.

How supplied: Tabs 275mg-100; 550mg-100

OXAPROZIN

DAYPRO Pfizer

NSAID (propionic acid deriv.). Oxaprozin 600mg; scored caplets.

Indications: Rheumatoid arthritis (RA).

Osteoarthritis (OA). Juvenile rheumatoid arthritis (JRA).

Adults: RA (≥ 16 years) or OA: 1.2g once daily; max 1.8g or 26mg/kg daily, whichever is less, in divided doses. Low body weight, milder disease, or on dialysis: initially 600 mg once daily; max 1.2g daily.

Children: < 6 years: not recommended. JRA: 6-16 years (22-31 kg): 600mg once daily; (32-54 kg): 900mg once daily; (≥ 55 kg): 1.2g once daily.

Contraindications: Aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. Renal or hepatic dysfunction. Discontinue if renal or hepatic disease develops. History of GI bleed/ulcer. Bleeding disorders. Monitor CBC, hepatic, and renal function in chronic use; and for GI bleed/ulcer. Heart failure. Hypertension. Asthma. Alcoholism. Dehydrated. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates methotrexate, lithium, protein bound drugs. Increased risk of GI bleed with

aspirin, corticosteroids, smoking, anticoagulants. May antagonize, or increase risk of renal failure with ACEIs, diuretics. Monitor oral anticoagulants, antihypertensives.

Adverse reactions: GI upset, CNS effects, tinnitus, blurred vision, dysuria, edema, photosensitivity, GI ulcer/bleed, blood dyscrasias, renal or hepatic dysfunction, rash (discontinue if occurs). See literature re: risk of cardiovascular events.

How supplied: Caplets-100, 500

PIROXICAM

FELDENE Pfizer

NSAID (oxicam). Piroxicam 10mg, 20mg; caps.

Indications: Osteoarthritis. Rheumatoid arthritis.

Adults: 20mg daily. May give in 2 divided doses.

Children: Not recommended.

Contraindications: Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. History of upper GI disease.

Impaired renal or hepatic function. Cardiac failure. Bleeding disorders. Hypertension. Monitor blood, hepatic, renal, and ocular function in chronic use. Discontinue if liver dysfunction occurs. Elderly.

Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May potentiate lithium (monitor for toxicity), methotrexate, oral anticoagulants, other highly-protein bound drugs. Diuretics increase risk of renal disorders. Aspirin reduces serum levels.

Adverse reactions: Peptic ulcer, GI bleeding or perforation, peripheral edema, anemia, serum sickness, nephritis, nephrotic syndrome, jaundice, hepatitis, rash (discontinue if occurs). See literature re: risk of cardiovascular events.

How supplied: 10mg-100

20mg-100, 500

RITUXIMAB

RITUXAN Genentech

B-lymphocyte-restricted differentiation antigen [CD20] inhibitor. Rituximab 10mg/mL; soln for IV infusion; preservative-free.

Indications: In combination with methotrexate (MTX): to reduce signs/symptoms and inhibit progression of structural damage in moderately-to-severely active rheumatoid arthritis patients who have had an inadequate response to one or more TNF antagonist therapies.

Adults: Give glucocorticoids 30 minutes prior to each infusion. In combination with MTX: give two 1000mg IV infusions separated by 2 weeks. Subsequent courses should be given every 24 weeks or based on response, but not sooner than every 16 weeks.

Children: Not recommended.

Warnings/Precautions: Severe, active infections: not recommended. Discontinue if severe infusion or mucocutaneous reactions occur (eg, hypoxia, pulmonary infiltrates, acute respiratory distress

syndrome, MI, ventricular fibrillation, cardiogenic shock, Stevens-Johnson syndrome, toxic epidermal necrolysis). Tumor lysis syndrome (esp. with high tumor burden); monitor for renal toxicity, fluid balance, electrolyte abnormalities (correct if occurs). Monitor for new-onset neurologic manifestations; discontinue if progressive multifocal leukoencephalopathy (PML) develops. Pre-existing cardiovascular disease; monitor during and after treatment. Hepatitis B reactivation with fulminant hepatitis may occur; monitor for signs of active HBV infection, discontinue if occurs. Monitor CBCs, platelet counts at 2-4 month intervals during treatment, then periodically. Concomitant biologic agents and DMARDs except MTX: monitor for infections. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Live virus vaccines: not recommended. Renal toxicity with cisplatin.

Adverse reactions: Fever, chills, rigors, nausea, pruritus, angioedema, asthenia, hypotension, headache, bronchospasm, throat irritation, rhinitis, urticaria, rash, vomiting, myalgia, dizziness, hypertension, cough, flushing, chest tightness; myelosuppression (eg, lymphopenia, neutropenia, leukopenia, anemia, thrombocytopenia), infusion reactions (may be fatal), mucocutaneous reactions (may be fatal), progressive multifocal leukoencephalopathy, viral infections (discontinue if serious), tumor lysis syndrome, renal toxicity, bowel obstruction/perforation, hepatitis B reactivation with fulminant hepatitis, cardiac arrhythmias (discontinue if serious).

How supplied: Single-use vial (10mL, 50mL)-1

SODIUM HYALURONATE

R

EUFLEXXA Ferring

Hyaluronan. Sodium hyaluronate 10mg/mL; soln for intra-articular inj.

Indications: Osteoarthritis of the knee in patients who have failed nonpharmacologic therapy and analgesics (eg, acetaminophen).

Adults: Prior to treatment: remove joint effusion (use separate syringe), if present. Inject 2mL (full syringe contents) intra-articularly in each affected knee weekly for 3 weeks. Use separate syringes for each knee.

Children: Not recommended.

Contraindications: Knee joint infection or skin disease at inj site.

Warnings/Precautions: Repeated treatment cycles: not established. Avoid intravascular injection. Avoid strenuous activity within 48hrs after injection. Pregnancy. Nursing mothers.

Interactions: Avoid disinfectants with quaternary ammonium salts. Concomitant other intra-articular injectables: not recommended.

Adverse reactions: Arthralgia, increase blood pressure, inj site pain, local reactions, transient knee inflammation.

How supplied: Single-use prefilled syringes (2mL)-1

SODIUM HYALURONATE

R

HYALGAN Sanofi Aventis

Hyaluronan. Sodium hyaluronate 20mg/2mL; soln for intra-articular inj.

Indications: Osteoarthritis of the knee in patients who have failed nonpharmacologic therapy and analgesics (eg, acetaminophen).

Adults: Prior to treatment: remove joint effusion (use separate syringe), if present; and give local anesthetic (eg, lidocaine) by SC inj. Inject 2mL intra-articularly in each affected knee weekly for 5 weeks. Use separate syringes for each knee.

Children: Not recommended.

Contraindications: Infection or skin disease at inj site.

Warnings/Precautions: Treatment cycles <3 injections: not recommended. Avian protein, feather, egg allergy. Avoid strenuous activity within 48hrs after injection. Pregnancy. Nursing mothers.

Interactions: Avoid disinfectants with quaternary ammonium salts. Concomitant other intra-articular injectables: not recommended.

Adverse reactions: Inj site pain, local reactions, transient knee inflammation.

How supplied: Single-use vials-1

Single-use prefilled syringes-1

TOFACITINIB

R

XELJANZ Pfizer

Janus kinase (JAK) inhibitor. Tofacitinib 5mg tabs.

Indications: Treatment of adults with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate (MTX); may be used as monotherapy or in combination with MTX or other nonbiologic disease-modifying anti-rheumatic drugs (DMARDs). Do not use in combination with biologic DMARDs or potent immunosuppressants (eg, azathioprine, cyclosporine).

Adults: 5mg twice daily. Moderate-to-severe renal impairment or moderate hepatic impairment; concomitant potent CYP3A4 inhibitors, or drugs that result in both moderate CYP3A4 and potent CYP2C19 inhibition: 5mg once daily. Dose adjustments: see full labeling.

Children: Not established.

Warnings/Precautions: Increased risk of serious or fatal infections (eg, TB, bacterial, viral, invasive fungal, or other opportunistic pathogens). Active infections: do not initiate therapy. Chronic or history of recurring infections. Travel to, or residence in, areas with endemic TB or mycoses. Conditions that predispose to infection. Test/treat latent TB infection prior to initiating therapy. Monitor closely if new infection, or active TB (even if initial latent test is negative) occurs; interrupt treatment if serious or opportunistic infection, or sepsis develops. Known malignancy. History of GI perforations. Monitor lymphocytes, neutrophils, hemoglobin at baseline and during treatment; do not initiate therapy if lymphocytes <500cells/mm³, ANC

<1000cells/mm³, or hemoglobin <9g/dL. Severe hepatic impairment: not recommended. Routinely monitor liver enzymes; interrupt therapy if drug-induced liver injury suspected. Monitor lipids 4–8 weeks following initiation. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant live vaccines: not recommended. Potentiated by potent CYP3A4 inhibitors (eg, ketoconazole), or drugs that result in both moderate CYP3A4 and potent CYP2C19 (eg, fluconazole) inhibition. Antagonized by potent CYP3A4 inducers (eg, rifampin). Concomitant immunosuppressants (eg, azathioprine, tacrolimus, cyclosporine) or corticosteroids may increase risk of infections.

Adverse reactions: Upper respiratory tract infections, headache, diarrhea, nasopharyngitis; serious or opportunistic infections, TB, malignancies (eg, lymphoma).

How supplied: Tabs–28, 60, 180

10B Bone disorders

ALENDRONATE

FOSAMAX Merck

Bisphosphonate. Alendronate (as sodium) 5mg, 10mg, 35mg, 40mg, 70mg; tabs.

Also: Alendronate FOSAMAX ORAL SOLUTION

Alendronate (as sodium) 70mg/75mL; raspberry flavor; contain parabens.

Indications: Treatment and prevention of postmenopausal osteoporosis. Treatment of osteoporosis in men. Treatment of glucocorticoid-induced osteoporosis. Paget's disease of bone. Limitations of use: optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3–5yrs.

Also: Alendronate FOSAMAX PLUS D

Bisphosphonate + Vit. D₃. Alendronate (as sodium) 70mg + cholecalciferol (Vit. D₃) 2800 IU, alendronate (as sodium) 70mg + cholecalciferol (Vit. D₃) 5600 IU; tabs.

Indications: Treatment of postmenopausal osteoporosis. Treatment of osteoporosis in men. Limitations of use: alone should not be used to treat vitamin D deficiency. Optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3–5yrs.

Adults: Swallow whole. Take in the AM with plain (not mineral) water only, at least 30mins before the first food, drink, or medication of the day (6–8oz water after tabs or 2oz after oral solution); do not lie down for at least 30mins and until after the first food of the day. Osteoporosis treatment in men or postmenopausal women: 10mg tab once daily or 70mg once weekly or one 70mg/2800 IU or 70mg/5600 IU tab once weekly. Osteoporosis prevention in postmenopausal women: 5mg tab

once daily or 35mg tab once weekly. Glucocorticoid-induced: 5mg tab once daily; glucocorticoid-induced in postmenopausal women not on estrogen: 10mg tab once daily. Paget's: 40mg once daily for 6 months; may retreat after a 6-month post-treatment evaluation period (based on serum alkaline phosphatase).

Children: Not applicable.

Contraindications: Esophageal abnormalities which delay esophageal emptying (eg, stricture, achalasia). Inability to stand or sit upright for at least 30mins. Aspiration risk (oral solution). Hypocalcemia.

Warnings/Precautions: Active upper GI disease; discontinue and reevaluate if signs/symptoms of esophageal reaction occur. Severe renal insufficiency (CrCl <35mL/min): not recommended. Correct preexisting hypocalcemia, other mineral (eg, Vit. D deficiency) or bone disturbances before starting. Monitor for hypocalcemia during therapy. Ensure adequate Vit. D and calcium intake. Risk of osteonecrosis of the jaw; consider discontinuing therapy during invasive dental procedures (eg, tooth extraction, implants, surgery). History of bisphosphonate exposure: evaluate for atypical fractures if thigh/groin pain develops; consider withholding therapy until risk/benefit assessment. Reevaluate periodically. Glucocorticoid-induced osteoporosis: prior to treatment, check patients' gonadal hormonal status and consider appropriate replacement; if concomitant glucocorticoids, monitor BMD before starting and repeat after 6–12 months. Pregnancy (Cat.C). Nursing mothers.

Interactions: Calcium supplements, antacids, other multivalent cations reduce absorption (separate dosing by at least 30min). Increased GI distress with aspirin and alendronate >10mg/day; caution with NSAIDs, other GI irritants. Anticonvulsants, cimetidine, thiazides, olestra, mineral oils, orlistat, bile acid sequestrants may antagonize Vit. D₃.

Adverse reactions: Abdominal pain, acid regurgitation, constipation, diarrhea, dyspepsia, nausea, musculoskeletal pain (may be severe), headache; esophagitis, esophageal ulcer, stricture, or erosion, melena, jaw osteonecrosis, atypical femur fractures; rarely: gastric or duodenal ulcer.

How supplied: Tabs 5mg–30, 100; 10mg–30, 100, 1000; 35mg, 70mg–4; 40mg–30; Soln–4 × 75mL; Plus D–4

CALCITONIN-SALMON

MIACALCIN Novartis

Hormone. Calcitonin-salmon 200Units/spray; nasal spray.

Indications: Postmenopausal osteoporosis.

Adults: 1 spray (200Units) in alternating nostrils daily.

Children: Not applicable.

Also: Calcitonin-salmon MIACALCIN INJECTION

Calcitonin-salmon 200Units/mL; SC or IM inj.

Indications: Paget's disease of bone. Hypercalcemia. Postmenopausal osteoporosis.

Adults: Paget's: 100Units SC or IM daily. Hypercalcemia: initially 4Units/kg SC or IM every 12hrs, may increase after 1–2 days to 8Units/kg every 12hrs, and then after 2 more days to max 8Units/kg every 6hrs. Postmenopausal osteoporosis: 100Units SC or IM every other day.

Children: Not recommended.

Warnings/Precautions: For nasal spray: do periodic nasal exams; discontinue if severe ulceration occurs. For inj: monitor for hypocalcemic tetany initially and urine sediments in chronic use; serum alkaline phosphatase and hydroxyproline in Paget's. Postmenopausal osteoporosis: supplement diet with calcium (1–1.5g/day) and Vit.D (400 IU/day); reevaluate periodically. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: May antagonize lithium. Nasal spray: may be antagonized by prior diphosphonate therapy in patients with Paget's disease.

Adverse reactions: Nasal spray: rhinitis and other nasal/respiratory symptoms, back pain, GI upset. Inj: GI upset, local inflammation, flushing, rash, antibody formation. Both: hypersensitivity reactions, anaphylaxis.

How supplied: Nasal spray (3.7mL)–1 (30 doses); Inj (2mL) vial–1

DENOSUMAB

R

PROLIA Amgen

Osteoclast inhibitor (RANKL inhibitor). Denosumab 60mg/mL; soln for SC injection; preservative-free.

Indications: In postmenopausal women with osteoporosis: at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other therapy; to reduce incidence of vertebral, nonvertebral, and hip fractures. To increase bone mass in men with osteoporosis at high risk for fracture. To increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer; to reduce incidence of vertebral fractures. To increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

Adults: Should be administered by a healthcare professional. 60mg SC once every 6 months; inject into upper arm, upper thigh, or abdomen.

Children: Not established.

Contraindications: Hypocalcemia. Pregnancy (Cat.X).

Warnings/Precautions: Correct hypocalcemia before starting; ensure adequate daily calcium (≥ 1000 mg) and Vit. D (≥ 400 IU) intake, esp. in renal impairment (CrCl < 30 mL/min). Monitor calcium, phosphorus, magnesium levels in susceptible patients (hypoparathyroidism, thyroid or parathyroid surgery, malabsorption, excision of small intestine, severe renal impairment, on dialysis). Monitor for infections, jaw osteonecrosis, bone oversuppression. Do baseline oral exam and preventive dentistry if risks for jaw osteonecrosis exist (eg, tooth extraction,

dental implants, oral surgery, poor oral hygiene, periodontal disease and/or other pre-existing dental disease, ill-fitting dentures, cancer, anemia, coagulopathy, infection). Maintain good oral hygiene. Evaluate for atypical fractures if thigh/groin pain develops; consider withholding therapy until risk/benefit assessment. Immunosuppressed. Latex allergy (prefilled syringe). Nursing mothers: avoid (may impair mammary glands/lactation).

Interactions: Concomitant other denosumab-containing products (eg, Xgeva): not recommended. Concomitant immunosuppressants (increased infection risk). Corticosteroids, chemotherapy (increased jaw osteonecrosis risk).

Adverse reactions: Pain (back, lower extremities or musculoskeletal), arthralgia, hypercholesterolemia, cystitis; infections (may be serious; eg, cellulitis, UTI, otic, abdominal), dermatitis, rash, eczema, osteonecrosis of jaw, atypical femur fractures, suppression of bone turnover, exacerbation of hypocalcemia, pancreatitis.

How supplied: Single-use vial (1mL)–1; Single-dose prefilled syr (1mL)–1

IBANDRONATE

R

BONIVA Roche

Bisphosphonate. Ibandronate (as monosodium monohydrate) 150mg; tabs.

Indications: Prevention and treatment of postmenopausal osteoporosis. Limitations of use: optimal duration of use has not been determined. For patients at low-risk for fracture: consider drug discontinuation after 3–5yrs.

Adults: Swallow whole. Take in the AM with plain (not mineral) water (6–8oz), at least 60mins before the first food, drink, or medication of the day; do not lie down for at least 60mins after. 150mg once monthly (take on the same day each month). Do not take two 150mg tablets within the same week.

Children: Not established.

Also: Ibandronate

R

BONIVA INJECTION

Ibandronate (as monosodium monohydrate) 3mg/3mL; soln for IV inj.

Indications: Treatment of postmenopausal osteoporosis. Limitations of use: optimal duration of use has not been determined. For patients at low-risk for fracture: consider drug discontinuation after 3–5yrs.

Adults: Must be given by healthcare professional. Give as IV bolus inj over 15–30secs. 3mg every 3 months; if dose is missed, give as soon as possible, then every 3 months from the date of last inj.

Children: Not established.

Contraindications: Hypocalcemia. Tabs:

Esophagus abnormalities which delay esophageal emptying (eg, stricture, achalasia). Inability to stand or sit upright for at least 60mins.

Warnings/Precautions: Active upper GI disease; discontinue and reevaluate if signs/symptoms of esophageal reaction occur. Severe renal impairment

(CrCl <30mL/min): not recommended. Correct preexisting hypocalcemia, other mineral or bone disturbances before starting. Risk of osteonecrosis of the jaw; consider discontinuing therapy during invasive dental procedures (eg, tooth extraction, implants, surgery). History of bisphosphonate exposure: evaluate for atypical fractures if thigh/groin pain develops; consider withholding therapy until risk/benefit assessment. Ensure adequate Vit. D and calcium intake. Reevaluate periodically. Inj: check renal function before each dose. Pregnancy (Cat.C). Nursing mothers.

Interactions: Calcium, aluminum, magnesium, other divalent cations reduce absorption (separate dosing). Caution with aspirin, NSAIDs, other GI irritants. May interfere with bone-imaging agents. Concomitant nephrotoxic agents; monitor for renal toxicity.

Adverse reactions: Back pain, dyspepsia, musculoskeletal pain (may be severe), diarrhea, headache, myalgia; dysphagia, esophagitis, esophageal or gastric ulcer, jaw osteonecrosis; atypical femur fractures. Inj: inj site reactions, flu-like syndrome, anaphylaxis.

How supplied: Tabs 150mg-3; Prefilled syringe (5mL)-1 (w. supplies)

RALOXIFENE

R

EVISTA Lilly

Selective estrogen receptor modulator (SERM). Raloxifene HCl 60mg; tabs.

Indications: Prevention and treatment of osteoporosis in postmenopausal women.

Adults: 60mg once daily.

Children: Not recommended.

Contraindications: Active or history of venous thromboembolic events. Nursing mothers. Pregnancy (Cat.X). Women who may become pregnant.

Warnings/Precautions: Not for use in premenopausal women. Concomitant systemic estrogen therapy: not recommended. Discontinue 72 hours before, and during prolonged immobilization; resume when fully ambulatory. Coronary heart disease or risk of coronary event (increased risk of death due to stroke). Hepatic dysfunction. Moderate to severe renal impairment.

Interactions: May antagonize warfarin; monitor. Avoid concomitant cholestyramine, other anion exchange resins. Caution with other highly protein-bound drugs (eg, diazepam, diazoxide, lidocaine).

Adverse reactions: Hot flashes, leg cramps, peripheral edema, flu syndrome, arthralgia, sweating; rare: venous thromboembolic events.

How supplied: Tabs-30, 100, 2000

RISEDRONATE

R

ACTONEL Warner Chilcott

Bisphosphonate. Risedronate (as sodium) 5mg, 30mg, 35mg, 75mg, 150mg; tabs.

Indications: Prevention and treatment of postmenopausal osteoporosis and glucocorticoid-

induced osteoporosis (men & women). Treatment to increase bone mass in men with osteoporosis. Treatment of Paget's disease of bone. Limitations of use: optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3-5yrs.

Adults: Swallow whole; take in the AM with a full glass (6-8oz) plain (not mineral) water at least 30min before other food or drink; take in upright position; do not lie down for at least 30min afterwards.

Postmenopausal: 5mg once daily or 35mg once weekly or one 75mg tab taken on 2 consecutive days per month or one 150mg tab once monthly. Glucocorticoid-induced: 5mg once daily. Osteoporosis in men: 35mg once weekly. Paget's: 30mg once daily for 2 months; may retreat after a 2-month post-treatment evaluation period.

Children: Not applicable.

Contraindications: Esophagus abnormalities which delay esophageal emptying (eg, stricture, achalasia). Inability to stand or sit upright for at least 30min. Hypocalcemia.

Warnings/Precautions: Active upper GI disease; discontinue and reevaluate if signs/symptoms of esophageal reaction occur. Severe renal impairment (CrCl <30mL/min): not recommended. Correct

preexisting hypocalcemia, other mineral or bone disturbances before starting. Risk of osteonecrosis of the jaw; consider discontinuing therapy during invasive dental procedures (eg, tooth extraction, implants, surgery). History of bisphosphonate exposure: evaluate for atypical fractures if thigh/groin pain develops; consider withholding therapy until risk/benefit assessment. Obtain and correct sex steroid hormonal status before initiating therapy in glucocorticoid-induced osteoporosis. Ensure adequate Vit. D and calcium intake. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Calcium, aluminum, magnesium, other divalent cations reduce absorption (separate dosing). Caution with other GI irritants. May interfere with bone-imaging agents.

Adverse reactions: Back pain, arthralgia, abdominal pain, dyspepsia, constipation, others; atypical femur fractures; rarely: dysphagia, esophagitis, gastric ulcer, jaw osteonecrosis; hypersensitivity.

How supplied: Tabs 5mg, 30mg-30; 35mg-4, 12; 75mg-2; 150mg-1, 3

TERIPARATIDE

R

FORTEO Lilly

Hormone (human parathyroid hormone, recombinant). Teriparatide (recombinant) 250mcg/mL; soln for SC inj; contains m-cresol.

Indications: Postmenopausal osteoporosis in women who are at high risk for fracture. To increase bone mass in men with primary or hypogonadal osteoporosis who are at high risk for fracture.

Treatment of men and women with osteoporosis associated with sustained glucocorticoid therapy at high risk for fracture (see literature).

Adults: 20mcg SC once daily into thigh or abdominal wall; may treat for up to 2 years.

Children: Not recommended.

Warnings/Precautions: Increased baseline risk for osteosarcoma (eg, Paget's disease of bone, unexplained increased alkaline phosphatase, open epiphyses, prior skeletal radiation therapy), bone metastases, history of skeletal malignancies, metabolic bone disease, hypercalcemia or risk thereof (eg, hyperparathyroidism): not recommended. Urolithiasis. Hypercalciuria. Hepatic, renal, or cardiac disease. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with digoxin (teriparatide-induced hypercalcemia increases risk of toxicity).

Adverse reactions: Arthralgia, pain, nausea; transient orthostatic hypotension, hypercalcemia, hyperuricemia, inj site reactions.

How supplied: Multidose Pen (2.4mL)–1

ZOLEDRONIC ACID

R

RECLAST Novartis

Bisphosphonate. Zoledronic acid 5mg/100mL bottle; soln for IV infusion.

Indications: Treatment: postmenopausal osteoporosis; to reduce the incidence of new clinical fractures in patients at high risk of fractures (those with recent low-trauma hip fracture). Prevention of osteoporosis in postmenopausal women. To increase bone mass in men with osteoporosis. Paget's disease of bone (men and women). Treatment and prevention: glucocorticoid-induced osteoporosis in men and women expected to be on glucocorticoids for at least 12 months (see literature).

Adults: Give by IV infusion over at least 15 minutes. CrCl $\geq$ 35mL/min: Osteoporosis treatment: 5mg once a year. Osteoporosis prevention: 5mg once every 2 years. Glucocorticoid-induced: 5mg once a year. For all: supplement with calcium and Vit. D, when needed. Paget's disease: a single dose of 5mg; supplement with calcium 1500mg daily in divided doses and Vit. D 800 IU daily esp. during 2 wks post-treatment.

Children: Not recommended.

Contraindications: Hypocalcemia. CrCl $<$ 35mL/min and evidence of acute renal impairment.

Warnings/Precautions: Increased risk of renal impairment: pre-existing renal compromise, advanced age, concomitant nephrotoxic drugs or diuretics, or severe dehydration. Chronic renal impairment. Monitor creatinine clearance before each dose and in at-risk patients. Correct preexisting hypocalcemia, other mineral or bone disturbances before starting. Ensure adequate hydration, Vit.D and calcium intake. History of bisphosphonate exposure: evaluate for atypical fractures if thigh/groin pain develops; consider withholding therapy until risk/benefit

assessment. Aspirin-sensitive asthma. Avoid dental surgery (do preventative dental work before therapy). Reevaluate periodically. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid concomitant other forms of zoledronic acid (eg, Zometa). Additive hypocalcemic effect with aminoglycosides, loop diuretics. Caution with other nephrotoxic drugs (eg, NSAIDs).

Adverse reactions: Pyrexia, musculoskeletal pain (may be severe), headache, arthralgia, pain in extremity, GI upset, flu-like illness, hypertension, hypocalcemia; acute renal failure, atypical femur fractures; rare: osteonecrosis of the jaw.

How supplied: Bottle–1

10C Gout

ALLOPURINOL

R

ZYLOPRIM Promethues

Xanthine oxidase inhibitor. Allopurinol 100mg, 300mg; scored tabs.

Indications: Gout.

Adults: Take with food. Initially 100mg daily. Maintain prophylactic therapy initially. Increase by 100mg daily increments at weekly intervals; max 800mg/day and 300mg/dose. Usual range: mild: 200–300mg daily; severe: 400–600mg daily.

Children: Not recommended.

Warnings/Precautions: Discontinue if rash occurs. Renal or hepatic dysfunction. Monitor blood, renal, and hepatic tests for first few months of therapy. Maintain neutral or alkaline urine and increase urine output to $\geq$ 2 liters daily. Pregnancy (Cat.C). Nursing mothers.

Interactions: Increase in azathioprine and mercaptopurine toxicity. May potentiate oral anticoagulants, chlorpropamide, cyclosporine. Uricosurics reduce drug effect. Increased rash with ampicillin, amoxicillin. Monitor renal function with thiazides.

Adverse reactions: Rash, GI disorders, acute gout, ecchymosis, fever, headache, hepatic necrosis, drowsiness, neuritis, arthralgia, necrotizing angitis, blood dyscrasias, bone marrow depression, toxic skin reactions (eg, Stevens-Johnson syndrome), renal failure.

How supplied: 100mg–100; 300mg–100, 500

COLCHICINE

R

COLCRYS URL Pharma

Antiinflammatory (alkaloid). Colchicine 0.6mg; tabs.

Indications: Prophylaxis and treatment of acute gout flares. Familial Mediterranean fever (FMF).

Adults: Gout prophylaxis: $>$ 16yrs: 0.6mg once or twice daily; max 1.2mg/day. Gout treatment: 1.2mg at first sign of gout flare, then 0.6mg 1 hour later; max 1.8mg over a 1 hour period; may be given during prophylaxis at max 1.2mg at first sign of flare, then 0.6mg 1 hour later, wait 12 hours, then resume prophylactic dose. FMF: Usual range: 1.2mg–2.4mg

daily; may give in 1–2 divided doses. May increase/decrease dose (depending on tolerability) in increments of 0.3mg/day to max daily dose. For all: concomitant CYP3A4 and/or P-glycoprotein inhibitors, severe renal or hepatic impairment: reduce dose (see literature).

Children: FMF: <4yrs: not recommended. Give as a single or divided dose twice daily. 4–6yrs: 0.3mg–1.8mg daily; 6–12yrs: 0.9mg–1.8mg daily. May increase/decrease dose (depending on tolerability) in increments of 0.3mg/day to max daily dose. Concomitant CYP3A4 and/or P-glycoprotein inhibitors, severe renal or hepatic impairment: reduce dose (see literature).

Contraindications: Renal or hepatic impairment with concomitant strong CYP3A4 or P-glycoprotein inhibitors (life-threatening toxicity possible).

Warnings/Precautions: Monitor for toxicity; if present, consider temporary interruption or discontinuation. Renal or hepatic impairment. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Potentiated by concomitant CYP3A4 inhibitors (eg, atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, amprenavir, aprepitant, diltiazem, erythromycin, fluconazole, fosamprenavir, verapamil, grapefruit juice) and/or P-glycoprotein inhibitors (eg, cyclosporine, ranolazine). Concomitant statins, gemfibrozil, fibrates, digoxin may potentiate myopathy and rhabdomyolysis.

Adverse reactions: GI upset, abdominal pain, pharyngolaryngeal pain; blood dyscrasias (myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, aplastic anemia), neuromuscular toxicity, rhabdomyolysis, overdose (may be fatal).

How supplied: Tabs–30, 60, 100, 250, 500, 1000

FEBUGOSTAT

ULORIC Takeda

Xanthine oxidase inhibitor. Febuxostat 40mg, 80mg; tabs.

Indications: Chronic management of hyperuricemia in patients with gout.

Adults: ≥18yrs: initially 40mg once daily; if serum uric acid is not <6mg/dL after 2 weeks, may increase to 80mg once daily. Gout flare prophylaxis, with an NSAID or colchicine, upon initiation of therapy and for up to 6 months, is recommended.

Children: <18yrs: not established.

Contraindications: Concomitant azathioprine, mercaptopurine.

Warnings/Precautions: Not recommended for treating asymptomatic hyperuricemia. Cardiovascular events: monitor for signs and symptoms of MI and stroke. Severe renal impairment or ESRD on dialysis. Severe hepatic impairment. Obtain liver test panel at baseline. Measure liver tests promptly if liver injury suspected; interrupt therapy and investigate cause;

if ALT>3×ULN with serum total bilirubin >2×ULN without alternative etiologies, do not restart; for lesser elevations, use with caution. Obtain target serum uric acid levels <6mg/dL after 2 weeks of initiating therapy. Secondary hyperuricemia (eg, Lesch-Nyhan syndrome, malignant disease, or in organ transplant recipients): not recommended. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Potentiates xanthine oxidase substrate drugs (theophylline).

Adverse reactions: Liver function abnormalities, nausea, arthralgia, rash, gout flares.

How supplied: Tabs 40mg–30, 90, 500; 80mg–30, 100, 1000

PEGLOTICASE

KRYSTEXXA Savient

PEGylated uric acid specific enzyme. Pegloticase 8mg/mL (as uricase protein) in phosphate buffered saline; for IV infusion after dilution.

Indications: Chronic gout in adult patients refractory to conventional therapy.

Adults: Discontinue oral urate-lowering agents before starting; do not institute while on pegloticase therapy. Premedicate with antihistamines and corticosteroids. Give by IV infusion over at least 2 hours. ≥18yrs: 8mg once every 2 weeks. Slow rate, or stop and restart at lower rate, if infusion reaction occurs; observe at least 1 hour post-infusion.

Children: <18yrs: not recommended.

Contraindications: G6PD deficiency.

Warnings/Precautions: Not for treating asymptomatic hyperuricemia. Screen patients at risk for G6PD deficiency (African or Mediterranean descent). Administer in healthcare setting by clinician prepared to manage infusion reactions and anaphylaxis. Monitor closely for anaphylaxis/infusion reactions, esp. in patients receiving retreatment after a drug-free interval >4 weeks. CHF. Monitor serum uric acid levels before each infusion; consider discontinuing when levels >6mg/dL, particularly with 2 consecutive levels >6mg/dL (increased risk of anaphylaxis and infusion reactions). Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Gout flares (prophylax with NSAIDs or colchicine), infusion reactions, GI upset, confusion, ecchymosis, nasopharyngitis, constipation, chest pain, anaphylaxis, CHF exacerbation, antibody formation.

How supplied: Single-use vial–1

PROBENECID

PROBENECID (various)

Uricosuric. Probenecid 500mg; scored tabs.

Indications: Hyperuricemia associated with gout and gouty arthritis.

Adults: 250mg twice daily for 1 week, then 500mg twice daily thereafter. Renal impairment, dose adjustments: see literature.

Children: Not recommended.

Contraindications: Acute gouty attack. Blood dyscrasias. Uric acid kidney stones. Children <2 yrs of age. Concomitant salicylates (antagonizes uricosuric effect).

Warnings/Precautions: History of peptic ulcer. Renal insufficiency. G6PD deficiency. Maintain adequate hydration. Alkalization of urine may be required. Pregnancy.

Interactions: Affects renal clearance of many drugs (esp. penicillins). Potentiates methotrexate (monitor and reduce methotrexate dose). May potentiate thiopental, ketamine, NSAIDs, oral sulfonyleureas, acetaminophen, lorazepam, rifampin, other sulfonamides. Pyrazinamide antagonizes uricosuric effect. May cause falsely high readings of theophylline levels.

Adverse reactions: Headache, dizziness, GI upset, urinary frequency, sore gums, uric acid kidney stones, dermatitis, fever, hematuria, renal colic, blood dyscrasias, hemolytic anemia; rare: severe allergic reactions, anaphylaxis.

How supplied: Contact supplier.

10D Muscle spasms

BACLOFEN

BACLOFEN (various)
Muscle relaxant (central). Baclofen 10mg, 20mg; scored tabs.

Indications: Spasticity associated with MS and spinal cord injury or disease.

Adults: 5mg 3 times daily. Increase in increments of 5mg 3 times daily every 3 days if needed; max 80mg daily. Use lowest dose possible.

Children: Not recommended.

Warnings/Precautions: Impaired renal function. Beneficial spasticity. Stroke. Epilepsy. Avoid abrupt cessation. Pregnancy. Nursing mothers.

Interactions: Alcohol and other CNS depressants potentiated.

Adverse reactions: Transient drowsiness, confusion, dizziness, weakness, fatigue, headache, hypotension, nausea, increased urinary frequency; seizures and hallucinations on abrupt withdrawal.

How supplied: Tabs—contact supplier

CYCLOBENZAPRINE

CYCLOBENZAPRINE HCl TABLETS (various)
Muscle relaxant (central). Cyclobenzaprine HCl 5mg, 10mg; tabs.

Indications: Relief of acute muscle spasm, as adjunct to rest and physical therapy.

Adults: ≥15yrs: initially 5mg 3 times daily, may increase to 10mg 3 times daily; max 2–3 weeks. Elderly or mild hepatic impairment: initially 5mg and then titrate slowly upward.

Children: <15yrs: not established.

Contraindications: Acute post-MI. Arrhythmias, heart block, other conduction disturbances. CHF. Hyperthyroidism. During or within 14 days of MAOIs.

Warnings/Precautions: Moderate-to-severe hepatic impairment: not recommended. Urinary retention. Glaucoma. Increased intraocular pressure. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: See Contraindications. Hypertensive crisis with MAOIs. Increased risk of serotonin syndrome with other serotonergic drugs (eg, SSRIs, SNRIs, tricyclic antidepressants, tramadol, bupropion, meperidine, verapamil, or MAOIs); monitor closely. Potentiates anticholinergics, alcohol, other CNS depressants. May antagonize guanethidine, clonidine. Tramadol increases seizure risk.

Adverse reactions: Drowsiness, dry mouth, dizziness, fatigue, headache, GI upset, asthenia, irritability, nervousness, blurred vision, confusion, arrhythmias, tachycardia, hypotension.

How supplied: Contact supplier.

DIAZEPAM

VALIUM Roche
Benzodiazepine. Diazepam 2mg, 5mg, 10mg; scored tabs.

Indications: Skeletal muscle spasm.

Adults: 2–10mg 3–4 times daily. Elderly, debilitated: initially 2–2.5mg 1–2 times daily; increase gradually.

Children: <6months: not recommended. ≥6months: initially 1–2.5mg 3–4 times daily; increase gradually.

Also: Diazepam

DIAZEPAM INJECTION

Diazepam 5mg/mL; contains propylene glycol 40%, ethyl and benzyl alcohol.

Adults: Initially 5–10mg slow IV (5mg/min) or IM. May repeat after 3–4 hours. Tetanus: may need larger dose. Do not use small vein.

Children: Max 0.25mg/kg over 3 minutes; if no response after 3rd dose consider adjunctive therapy. Tetanus: age <30 days: not recommended. 30 days–5yrs: 1–2mg IM or slow IV. >5yrs: 5–10mg IM or slow IV. Both: may repeat after 3–4 hours. Do not use small vein.

Contraindications: Acute narrow-angle glaucoma.

Warnings/Precautions: Not for use in untreated open-angle glaucoma. Inj not for use in shock, coma, acute alcohol intoxication, or obstetrical conditions. Discontinue if paradoxical reaction occurs. Drug or alcohol abuse. Depression. Suicidal tendencies. Renal or liver dysfunction. Avoid abrupt cessation. May increase tonic-clonic seizures. Reevaluate periodically. Monitor blood counts, liver function. Elderly. Debilitated. Psychosis, pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants (consider reducing opioid doses by at least ½). Increased serum levels with cimetidine. Potentiated by sertraline. Inj: hypotension, muscle weakness with narcotics, barbiturates, alcohol.

Adverse reactions: CNS depression, ataxia, memory impairment, paradoxical excitement,

salivation changes, neutropenia, jaundice. Inj: apnea, cardiac arrest, venous thrombosis, phlebitis, status epilepticus (when treating petit mal).

How supplied: Tabs 2mg-100; Tabs 5mg, 10mg-100, 500; Vials (10mL)-contact supplier

METAXALONE

R

SKELAXIN King

Muscle relaxant (central). Metaxalone 800mg; scored tabs.

Indications: Acute, painful musculoskeletal conditions.

Adults: 800mg 3-4 times daily.

Children: ≤12yrs: not recommended.

Contraindications: Anemias. Significant renal or hepatic dysfunction.

Warnings/Precautions: Renal or hepatic impairment (monitor). Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Alcohol, other CNS depressants potentiated. May cause false (+) Benedict's test.

Adverse reactions: Drowsiness, dizziness, headache, nervousness, GI upset, rash, jaundice, hemolytic anemia, leukopenia; rare: anaphylactoid reactions.

How supplied: Tabs-100, 500

METHOCARBAMOL

R

ROBAXIN Actient

Muscle relaxant (central). Methocarbamol 500mg; tabs.

Indications: Painful musculoskeletal conditions.

Adults: ≥16yrs: initially 1.5g 4 times daily for 2-3 days; if severe, may give up to 8g/day. Maintenance: 1g 4 times daily.

Children: <16yrs: not recommended.

Also: Methocarbamol

ROBAXIN-750

Methocarbamol 750mg; tabs.

Adults: ≥16yrs: initially 1.5g 4 times daily for 2-3 days; if severe, may give up to 8g/day. Maintenance: 750mg every 4 hours or 1.5g 3 times daily.

Children: <16yrs: not recommended.

Warnings/Precautions: Pregnancy (Cat.C).

Nursing mothers.

Interactions: Alcohol and other CNS depressants potentiated. May antagonize pyridostigmine.

Adverse reactions: Drowsiness, dizziness, GI upset, blurred vision, headache.

How supplied: Tabs 500mg-100; 750mg-100, 500

ORPHENADRINE

R

ORPHENADRINE CITRATE EXTENDED-RELEASE TABLETS (various)

Anticholinergic muscle relaxant (central).

Orphenadrine citrate 100mg; sust-rel tabs.

Indications: Painful musculoskeletal conditions.

Adults: 100mg twice daily (AM and PM).

Children: Not recommended.

Also: Orphenadrine

NORFLEX INJECTION Medicis

Orphenadrine citrate 60mg; per 2mL; contains sulfites.

Adults: 60mg IM or IV every 12 hrs.

Children: Not recommended.

Contraindications: Glaucoma. Acalasia. GU or GI obstruction. Myasthenia gravis.

Warnings/Precautions: Coronary disease, insufficiency, or arrhythmias. Asthma (inj). Monitor blood, urine, and liver in long-term use. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates anticholinergics, alcohol, other CNS depressants, MAOIs, antidepressants.

Tremors, mental confusion with propoxyphene. Antagonizes steroids, barbiturates, phenylbutazone.

Adverse reactions: Tachycardia, transient dizziness or syncope, other anticholinergic effects (eg, weakness, increased intraocular pressure, urinary retention, blurred vision, dry mouth), GI upset.

How supplied: Tabs-contact supplier; Amps (2mL)-6

TIZANIDINE

R

ZANAFLEX TABLETS Acorda

α₂-adrenergic agonist. Tizanidine HCl 4mg (quadrisection score); tabs.

Also: Tizanidine

ZANAFLEX CAPSULES

Tizanidine HCl 2mg, 4mg, 6mg; caps.

Indications: Muscle spasticity (due to its short duration of action reserve for when relief is most important).

Adults: Initially: usually 4mg, may increase by 2-4mg as needed every 6-8 hrs to a max of 3 doses in 24hrs; max 12mg/dose and 36mg/day. Renal impairment (CrCl <25mL/min): reduce dose. May sprinkle contents of capsules on applesauce (may affect absorption). Tabs and caps not bioequivalent under fed conditions. See literature.

Children: Not recommended.

Contraindications: Concomitant fluvoxamine, ciprofloxacin.

Warnings/Precautions: Hepatic dysfunction.

Monitor ophthalmic and liver function

(aminotransferases at baseline, 1, 3, 6 months,

then periodically) and for orthostatic hypotension.

Renal dysfunction. Cardiovascular disease. Avoid abrupt cessation. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid other α₂-agonists (eg, clonidine). Hypotension possible with other antihypertensives. Avoid concomitant use with other CYP1A2 inhibitors (eg, amiodarone, mexiletine, propafenone, verapamil, cimetidine, famotidine, other fluorquinolones, oral contraceptives, acyclovir, ticlopidine, zileuton); if clinically necessary, use caution. May potentiate CNS depression with alcohol, baclofen, benzodiazepines, other CNS depressants.

Adverse reactions: Dry mouth, somnolence, asthenia, dizziness, UTI, constipation, liver injury or elevated liver enzymes, vomiting, speech disorder, blurred vision, dyskinesia, nervousness, pharyngitis, hypotension, bradycardia, hallucinations/psychosis.
How supplied: Tabs, caps—150

SECTION 11: NEUROLOGIC DISORDERS

11A Alzheimer's dementia

DONEPEZIL

ARICEPT Eisai

Reversible acetylcholinesterase inhibitor (piperidine deriv). Donepezil HCl 5mg, 10mg, 23mg; tabs.

Also: Donepezil

ARICEPT ODT

Donepezil HCl 5mg, 10mg; orally-disintegrating tablets.

Indications: Alzheimer's dementia.

Adults: Tabs: Swallow whole with water. ODT: dissolve on tongue, then drink water. Mild-moderate: Initially 5mg daily at bedtime, may increase to 10mg daily after 4–6 weeks; usual dose: 5mg or 10mg once daily. Moderate-severe: initially 10mg daily at bedtime, may increase to 23mg daily after 3 months; usual dose: 10mg or 23mg once daily.

Children: Not applicable.

Warnings/Precautions: Cardiac conduction conditions. Peptic ulcer. Monitor for GI bleeding. Seizures. Asthma or COPD. GI or GU obstruction. Body weight <55kg. Pregnancy (Cat.C). Nursing mothers.

Interactions: Drugs that affect CYP2D6 and CYP3A4 may affect rate of elimination. Antagonizes anticholinergics. May potentiate succinylcholine-type muscle relaxants, other cholinesterase inhibitors, cholinergic agonists (eg, bethanechol). Concomitant NSAIDs may increase risk of GI bleed.

Adverse reactions: GI upset, insomnia, muscle cramps, fatigue, anorexia, weight loss (esp. using 23mg/day dose).

How supplied: Tabs 5mg, 10mg–30, 90, 1000; 23mg–30, 90; ODT–30

GALANTAMINE

RAZADYNE Janssen

Reversible acetylcholinesterase inhibitor (benzazepine deriv). Galantamine (as HBr) 4mg, 8mg, 12mg; tabs.

Also: Galantamine

RAZADYNE ORAL SOLUTION

Galantamine (as HBr) 4mg/mL.

Indications: Mild to moderate Alzheimer's dementia.

Adults: Give with AM & PM meals. Initially 4mg twice daily; if well-tolerated may increase by 4mg twice daily at intervals of ≥ 4 weeks; max 12mg twice daily (24mg/day). Re-titrate if interrupted for more than

several days. Moderate hepatic or renal impairment: usual max 16mg/day.

Children: Not established.

Also: Galantamine

RAZADYNE ER

Galantamine (as HBr) 8mg, 16mg, 24mg; ext-rel caps.

Adults: Give with AM meal. Initially 8mg/day; if well-tolerated may increase by 8mg/day at intervals of ≥ 4 weeks; max 24mg/day. Re-titrate if interrupted for more than several days. Moderate hepatic or renal impairment: usual max 16mg/day.

Children: Not established.

Warnings/Precautions: Conduction disorders (eg, AV block). History of ulcer disease. Bladder outflow obstruction. Asthma. COPD. Seizures. Monitor for active or occult GI bleed, respiratory or neurological effects, and patient's weight. Maintain adequate hydration. Severe hepatic or renal impairment (CrCl <9 mL/min): not recommended. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates neuromuscular blockers (eg, succinylcholine), cholinesterase inhibitors, cholinergic agonists (eg, bethanechol). Antagonizes anticholinergics. Caution with drugs that slow heart rate. May be potentiated by ketoconazole, cimetidine, paroxetine, fluoxetine, erythromycin, possibly others that affect CYP2D6 or CYP3A4. Monitor for GI bleed with NSAIDs.

Adverse reactions: Nausea, vomiting, diarrhea, dizziness, headache, anorexia, weight loss, syncope, bradycardia.

Note: This product was formerly named Reminyl.

How supplied: Tabs–60; Soln–100mL (w. cal. pipette); ER caps–30

MEMANTINE

NAMENDA Forest

N-methyl-D-aspartate (NMDA) receptor antagonist.

Memantine HCl 5mg, 10mg; tabs.

Also: Memantine

NAMENDA ORAL SOLUTION

Memantine HCl 2mg/mL; sugar-and alcohol-free; peppermint flavor.

Indications: Moderate-to-severe dementia of the Alzheimer's type.

Adults: Initially 5mg once daily; titrate at intervals of at least 1 week to 5mg twice daily, then to 5mg and 10mg as separate doses, then to 10mg twice daily (prescribe Titration Pak for 1st 4 weeks). Severe renal impairment (CrCl 5–29mL/min): titrate to max 5mg twice daily.

Children: Not established.

Also: Memantine

NAMENDA XR

Memantine HCl 7mg, 14mg, 21mg, 28mg; ext-rel caps.

Adults: Do not divide doses. Swallow whole or may open caps and sprinkle on applesauce, then consume entire contents. Initially 7mg once daily; titrate at intervals of at least 1 week in increments of 7mg

to target dose of 28mg once daily. Max 28mg once daily. Severe renal impairment (CrCl 5–29mL/min): titrate to target dose of 14mg/day. Switching from immediate-release tabs: give XR caps the day after last dose of immediate-release tabs; see full labeling.

Children: Not established.

Warnings/Precautions: Severe hepatic impairment. Alkalinized urine (eg, renal tubular acidosis, severe UTI) increases memantine serum levels. Seizure disorder. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with other NMDA antagonists (eg, amantadine, ketamine, dextromethorphan, fentanyl). May affect or be affected by renally-excreted drugs (eg, triamterene, HCTZ, cimetidine, nicotine, ranitidine, quinidine). Plasma levels may be increased by urinary alkalinizers.

Adverse reactions: Headache, dizziness, diarrhea, constipation, hypertension, pain, somnolence, hallucination, urinary disorders, dyspnea.

How supplied: Tabs–60; Titration Pak (28 × 5mg + 21 × 10mg)–1; Oral soln–360mL; XR caps 7mg, 21mg–30; 14mg, 28mg–30, 90; XR Titration Pak (7 × 7mg + 7 × 14mg + 7 × 21mg + 7 × 28mg)–1

RIVASTIGMINE

EXELON Novartis

Reversible acetylcholinesterase inhibitor (carbamate deriv). Rivastigmine (as tartrate) 1.5mg, 3mg, 4.5mg, 6mg; caps.

Also: Rivastigmine

EXELON ORAL SOLUTION

Rivastigmine (as tartrate) 2mg/mL.

Indications: Mild to moderate dementia of the Alzheimer's type.

Adults: Take with food in the AM and PM. Soln: may give directly from syringe or mix with water, fruit juice, or soda. Caps and soln may be interchanged at equal doses. Initially 1.5mg twice daily; if well-tolerated, may increase by 1.5mg twice daily at intervals of at least 2 weeks. Usual range: 6–12mg/day; max 12mg/day. If dose is not tolerated, suspend for several doses and restart at same or next lower dose. If stopped for more than several days restart at 1.5mg twice daily and retitrate.

Children: Not applicable.

Also: Rivastigmine

EXELON PATCH

Rivastigmine 4.6mg/24hrs, 9.5mg/24hrs, 13.3mg/24hrs; transdermal system.

Indications: Treatment of dementia of the Alzheimer's type.

Adults: Apply to clean, dry, hairless intact skin. Rotate application site (allow 14 days before reapplying to same site). Initially apply one 4.6mg/24hrs patch once daily; if tolerated, may increase to 9.5mg/24hrs patch after 4 weeks at previous dose; can further be increased to max 13.3mg/24hrs dose. Mild-to-moderate: usually

9.5mg/24hrs or 13.3mg/24hrs once daily. Severe: usually 13.3mg/24hrs once daily. If dosing interrupted for > 3 days, restart with 4.6mg/24hrs patch and titrate again. Mild-to-moderate hepatic impairment: initial and max dose 4.6mg/24hrs patch. Low body wt. (<50kg): monitor for toxicities and consider reducing maintenance dose to 4.6mg/24hr patch. Switching from capsules or oral solution: see full labeling.

Children: Not applicable.

Contraindications: Patches: previous history of application site reactions suggestive of allergic contact dermatitis.

Warnings/Precautions: Monitor for nausea, vomiting, anorexia, weight loss, GI bleed. Sick sinus syndrome, other supraventricular conduction disturbances. Seizures. History or risk of ulcers. Urinary obstruction. Asthma. COPD. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Antagonizes anticholinergics. May potentiate succinylcholine-type muscle relaxants, other cholinesterase inhibitors, cholinergic agonists. Monitor for GI bleed with NSAIDs.

Adverse reactions: GI upset, dyspepsia, abdominal pain, dizziness, anorexia, weight loss, headache, fatigue, insomnia, asthenia, malaise, tremor, syncope, hyperhidrosis, cholinergic effects; also, patches: application site reactions, allergic contact dermatitis (consider switching to oral form).

How supplied: Caps–60, 500; Soln–120mL (ie. dosing syringe); Patches–30

11B Multiple sclerosis

DALFAMPRIDINE

AMPYRA Acorda

Potassium channel blocker. Dalfampridine 10mg; ext-rel tabs.

Indications: To improve walking in patients with multiple sclerosis (demonstrated by an increase in walking speed).

Adults: Swallow whole. ≥18yrs: 10mg every 12 hours.

Children: <18yrs: not recommended.

Contraindications: History of seizures. Moderate to severe renal impairment (CrCl ≤50mL/min). Concomitant other forms of 4-aminopyridine.

Warnings/Precautions: Mild renal impairment (CrCl 51–80mL/min) (increased seizure risk). Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Adverse reactions: UTI, insomnia, dizziness, headache, GI upset, asthenia, back pain, balance disorder, MS relapse, paresthesia, nasopharyngitis, constipation, throat pain; seizures (possible at higher doses).

Note: AMPYRA will be distributed exclusively through specialty pharmacies. For more information, call AMPYRA Patient Support Services at (888) 881-1918.

How supplied: Tabs–60

DIMETHYL FUMARATE**TECFIDERA** Biogen Idec

Dimethyl fumarate 120mg, 240mg; delayed-release caps.

Indications: Treatment of patients with relapsing forms of multiple sclerosis.**Adults:** Swallow whole. Take with or without food. Initially 120mg twice daily for 7 days, then increase to 240mg twice daily.**Children:** Not established.**Warnings/Precautions:** Obtain CBCs (within 6 months) prior to initiation to identify pre-existing lymphopenia; test annually, and as clinically indicated. Serious infection; consider withholding until resolved. Pre-existing low lymphocyte counts (not studied). Administration with food may reduce incidence of flushing. Pregnancy (Category C). Nursing mothers.**Adverse reactions:** Flushing, abdominal pain, diarrhea, nausea, vomiting, pruritus, rash; lymphopenia.**How supplied:** Starter Pack (30-day)-1 (120mg × 14 + 240mg × 46); Delayed-rel caps 120mg-14; 240mg-60

R

arrest, CHF, recurrent syncope, untreated sleep apnea, AV block, sino-atrial block), QT prolongation risk (eg, hypokalemia, hypomagnesemia, congenital long-QT syndrome); monitor ECG overnight after first dose. Monitor BP during treatment. Active acute or chronic infection: do not start treatment until infection resolved. Obtain recent CBC before starting treatment. Consider suspending therapy if serious infection develops; monitor for infections during treatment and for 2 months after discontinuation. Test for antibodies to varicella zoster virus; consider immunization before starting fingolimod. Immunosuppressed. Diabetes, history of uveitis; increased risk of macular edema. Monitor visual acuity and for visual disturbances. Do ophthalmic exam at baseline, and at 3-4 months after starting therapy. Recent LFTs (eg, within 6 months) should be available; monitor; discontinue if liver injury occurs. Respiratory dysfunction; obtain spirometry and DLCO when needed. Renal or severe hepatic impairment. Pregnancy (Cat.C) (use effective contraception during and for 2 months after discontinuation), nursing mothers: not recommended.

Interactions: Concomitant QT prolonging drugs (eg, citalopram, chlorpromazine, haloperidol, methadone, erythromycin): risk of torsades de pointes; monitor. Potentiated by ketoconazole; monitor if receiving systemic therapy. Concomitant β -blockers, digoxin, diltiazem, verapamil may be associated with severe bradycardia or heart block. Avoid live virus vaccines during treatment and for 2 months after discontinuing fingolimod; may have suboptimal response. Antineoplastic, immunosuppressant or immunomodulating therapies may increase risk of immunosuppression; use caution when switching from long-acting therapies with immune effects (eg, natalizumab, mitoxantrone).

Adverse reactions: Headache, influenza, diarrhea, back pain, increased liver transaminases, cough, hypertension; transient decreased heart rate and AV conduction, increased infection risk, macular edema, decreased pulmonary function.

How supplied: Caps-7, 28**FINGOLIMOD****GILENYA** Novartis

Sphingosine 1-phosphate receptor modulator.

Fingolimod (as HCl) 0.5mg; caps.

Indications: For relapsing forms of multiple sclerosis (MS); to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability.**Adults:** ≥ 18 yrs: 0.5mg once daily. First dose monitoring for bradycardia: see Warnings/Precautions. Re-initiation of therapy: within first 2 weeks, first dose procedures are recommended after interruption of 1 day or more, during week 3 and 4, first dose procedures are recommended after interruption of more than 7 days.**Children:** < 18 yrs: not recommended.**Contraindications:** Recent (within the last 6 months) occurrence of: MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless paced. Baseline QTc interval ≥ 500 ms. Treatment with a Class Ia or Class III antiarrhythmic drug.

Warnings/Precautions: Risk of bradyarrhythmia; observe all patients for bradycardia for at least 6 hours after first dose with hourly pulse and BP measurement. Obtain ECG prior to dosing and at the end of observation period. If heart rate (HR) < 45 bpm, or new onset 2nd degree or higher AV block; monitor until resolution, those at the lowest post-dose HR should be monitored until HR increases. Symptomatic bradycardia: begin continuous ECG monitoring until resolved; if pharmacological intervention necessary, continue ECG monitoring overnight, and first dose monitoring procedures should be repeated for second dose. Pre-existing cardiac conditions (eg, ischemic heart disease, history of MI or cardiac

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GLATIRAMER**COPAXONE** Teva CNS

Immunomodulator. Glatiramer acetate 20mg/mL; soln for SC inj; contains mannitol; preservative-free.

Indications: To reduce the frequency of relapses in patients with relapsing-remitting multiple sclerosis, including those who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis.**Adults:** Supervise first dose. Rotate inj sites. ≥ 18 yrs: 20mg SC daily.**Children:** < 18 yrs: not recommended.**Warnings/Precautions:** Pregnancy (Cat.B). Nursing mothers.**Adverse reactions:** Inj site and post-inj reactions, vasodilatation, rash, dyspnea, chest pain, asthenia,

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infection, pain, nausea, arthralgia, anxiety, hypertonia; rare: lipatrophy, skin necrosis, modified immune response.

How supplied: Single-use prefilled syringes—30

INTERFERON BETA-1A

R

AVONEX Biogen Idec

Interferon beta-1a 30mcg per prefilled syringe (albumin-free liq) or per vial [pwd for reconstitution (preservative-free, contains albumin)]; or per prefilled autoinjector (albumin-free liq); for IM inj.

Indications: Treatment of relapsing forms of multiple sclerosis to slow the accumulation of physical disability and decrease the frequency of clinical exacerbations in patients with first clinical episode and MRI consistent with MS.

Adults: Rotate inj sites. ≥ 18 yrs: 30mcg IM once weekly. May titrate dose to reduce severity of flu-like symptoms; dosed once weekly, IM: Week 1: 7.5mcg. Week 2: 15mcg. Week 3: 22.5mcg. Week 4: 30mcg. May use concurrent analgesics/antipyretics on treatment days.

Children: < 18 yrs: not recommended.

Warnings/Precautions: Depression. Suicidal ideation. Seizure disorders. Myelosuppression. Cardiac disease. Monitor hemoglobin, CBC, differential, platelets, blood chemistries, liver and thyroid function, and for autoimmune disorders. Pregnancy (Cat.C), may be abortifacient; consider discontinuing drug. Nursing mothers: not recommended.

Interactions: Avoid alcohol. Monitor with myelosuppressants or hepatotoxic drugs.

Adverse reactions: Flu-like symptoms, asthenia, anemia, headache, GI upset, depression, blood dyscrasias, seizures; rare: hepatic injury.

Note: Register pregnant patients exposed to Avonex by calling (800) 456-2255.

How supplied: Single-use prefilled syringes (0.5mL) dose pack-1 (4 syringes, supplies); Single-use vial dose pack-1 (4 vials, diluent, supplies); Single-use prefilled autoinjector (0.5mL) dose pack-1 (4 autoinjectors, supplies)

INTERFERON BETA-1B

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EXTAVIA Novartis

Immunomodulator. Interferon beta-1b 0.3mg/vial; pwd for SC inj after reconstitution; contains albumin (human), mannitol.

Indications: To reduce frequency of clinical exacerbations in relapsing multiple sclerosis.

Adults: ≥ 18 yrs: initially 0.0625mg SC every other day; increase by 25% every 2 weeks to target dose of 0.25mg SC every other day.

Children: < 18 yrs: not recommended.

Warnings/Precautions: Depression. Suicidal ideation. Monitor CBC, differential, platelets, chemistries, liver function (at 1, 3, and 6 months then periodically). Thyroid disorders. Elderly. Pregnancy (Cat.C; may be abortifacient). Nursing mothers: not recommended.

Adverse reactions: Lymphopenia, neutropenia, leukopenia, lymphadenopathy, headache, insomnia, incoordination, hypertension, dyspnea, abdominal pain, increased liver enzymes, rash, skin disorder, hypertonia, myalgia, urinary urgency, metrorrhagia, impotence, asthenia, flu-like symptoms, pain, peripheral edema, chest pain, malaise, injection site reactions/necrosis (suspend therapy if multiple lesions occur); anaphylaxis.

How supplied: Single-use vials—15 (w. prefilled diluent syringe, supplies)

NATALIZUMAB

R

TYMSABRI Biogen Idec

Immunomodulator (integrin receptor antagonist).

Natalizumab 300mg/15mL; soln; for IV infusion after dilution; preservative-free.

Indications: To reduce the frequency of clinical exacerbations and delay accumulation of physical disability in relapsing forms of multiple sclerosis (MS).

Adults: ≥ 18 yrs: Give by IV infusion over 1 hour; monitor during and for 1 hour post-infusion. 300mg every 4 weeks.

Children: < 18 yrs: not recommended.

Contraindications: Progressive multifocal leukoencephalopathy (PML).

Warnings/Precautions: Renal or hepatic insufficiency. Monitor for signs and symptoms of PML; discontinue if occurs. Test patients for anti-JVC antibody status prior to or during treatment if status unknown; patients with negative status should be retested periodically. Increased risk of PML with longer treatment duration, prior treatment with immunosuppressant, and/or presence of anti-JVC antibodies. Reevaluate periodically (at 3months and 6months post-infusion, then every 6months thereafter). Immunosuppression. Vaccinations. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant other immunosuppressants: not recommended.

Adverse reactions: Headache, fatigue, arthralgia, infections, allergic reactions (discontinue if occurs; do not restart), hepatotoxicity (monitor and discontinue if occurs), depression, cholelithiasis, urticaria, inj site reactions; antibody formation (if persistent, may substantially reduce efficacy); changes in blood cell counts.

Note: This product is only available through the TOUCH prescribing program. For more information call (800) 456-2255.

How supplied: Single-use vial (300mg)—1

TERIFLUNOMIDE

R

AUBAGIO Genzyme

Pyrimidine synthesis inhibitor. Teriflunomide 7mg, 14mg; tablets.

Indications: Relapsing forms of multiple sclerosis (MS).

Adults: 7mg or 14mg once daily.

Children: Not established.

Contraindications: Severe hepatic impairment. Pregnancy (Cat.X), women of childbearing potential not using reliable contraception. Co-administration with leflunomide.

Warnings/Precautions: Perform accelerated elimination procedure (see literature) after drug discontinuance. Severe liver injury may be possible; obtain transaminase and bilirubin levels within 6 months before starting, monitor ALT at least monthly for 6 months after starting. Discontinue if drug-induced liver injury suspected; monitor liver tests weekly until normalized. Pre-existing liver disease: increased risk of developing elevated serum transaminases. Obtain CBCs within 6 months prior to starting. Severe immunodeficiency, bone marrow disease, or severe, uncontrolled infections: not recommended. Screen for latent TB; do not start therapy until infection resolved. Monitor BP before starting and periodically. Diabetes, >60 years: increased risk of peripheral neuropathy. Monitor for new onset or worsening pulmonary symptoms, discontinue if interstitial lung disease suspected. Male patients: undergo elimination procedure before fathering child. Nursing mothers: not recommended.

Interactions: See Contraindications. Live vaccines: not recommended. Risk of liver injury with hepatotoxic drugs. Risk of peripheral neuropathy with neurotoxic drugs. Potentiates drugs metabolized by CYP2C8 (eg, repaglinide, paclitaxel, pioglitazone, rosiglitazone), oral contraceptives. Antagonizes drugs metabolized by CYP1A2 (eg, duloxetine, alosetron, theophylline, tizanidine). Monitor INR. Concomitant immunosuppressives, immunomodulators: not evaluated.

Adverse reactions: ALT increased, alopecia, diarrhea, influenza, nausea, paresthesia; bone marrow suppression, immunosuppression potential, infection (consider suspending therapy), peripheral neuropathy; hyperkalemia, acute renal failure (check K⁺ levels); possible severe skin reactions (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis; discontinue if occurs), respiratory effects.

How supplied: Tabs-5, 28

11C Parkinsonism

BENZTROPINE

BENZTROPINE (various)

Anticholinergic. Benztropine mesylate 0.5mg, 1mg, 2mg; scored tabs.

Also: Benztropine

COGENTIN INJECTION Lundbeck

Benztropine mesylate 1mg/mL; soln for IM or IV inj.

Indications: Adjunct in Parkinsonism, drug-induced extrapyramidal disorders.

Adults: Parkinsonism: initially 0.5-1mg at bedtime. May increase by 0.5mg at 5-6 day intervals; max 6mg daily. Extrapyramidal disorders: 1-4mg 1-2 times daily. Acute dystonic reactions: 1-2mg IM or IV.

Children: See Contraindications. Use cautiously in older children.

Contraindications: Children <3yrs old.

Warnings/Precautions: Tardive dyskinesia: not recommended. Narrow-angle glaucoma. Tachycardia. Psychosis. Prostatic hypertrophy. GI or GU obstruction. Chronically ill. Alcoholics. CNS disease. Exposure to extreme heat. Elderly. Pregnancy.

Interactions: Paralytic ileus, hyperthermia, heat stroke with phenothiazines, tricyclic antidepressants. Antagonizes psychotropics.

Adverse reactions: Anticholinergic and antihistaminic effects, weakness, confusion, anhidrosis, excitement, GI upset, depression, lethargy, heat stroke, dysuria, toxic psychosis, rash.

How supplied: Tabs-contact supplier; Amps-(5 × 2mL)

CARBIDOPA + LEVODOPA

SINEMET CR Merck

Dopa-decarboxylase inhibitor + dopamine precursor.

Carbidopa, levodopa; 25-100, 50-200; sust-rel tabs.

Indications: Parkinsonism.

Adults: ≥18yrs: Do not crush or chew. Patients not receiving levodopa: initially one Sinemet CR 50-200 tab twice daily, at intervals of at least 6 hrs. Others: see literature. Allow 3 days between dosage adjustments. If given at intervals <4 hrs and/or divided doses not equal: give smaller doses at end of day. May add immediate-release Sinemet 25-100 or 10-100 in advanced disease.

Children: <18yrs: not recommended.

Also: Carbidopa + Levodopa

SINEMET

Carbidopa, levodopa; 10-100, 25-100, 25-250; tabs.

Adults: ≥18yrs: Initially one Sinemet 25-100 tab 3 times daily or one Sinemet 10-100 tab 3-4 times daily; increase every 1-2 days up to 2 tabs (of either 25-100 or 10-100 tabs) 4 times daily. If more levodopa is needed, initially one Sinemet 25-250 tab 3-4 times daily; max 8 tabs daily.

Children: <18yrs: not recommended.

Contraindications: During or within 14 days of nonselective MAOIs (eg, phenelzine). Narrow-angle glaucoma. Undiagnosed skin lesions. History of melanoma.

Warnings/Precautions: Severe cardiovascular or pulmonary disease. Asthma. Renal, hepatic, or endocrine disorders. History of peptic ulcer or MI with residual arrhythmias. Suicidal tendencies. Psychosis. Orthostatic hypotension. Chronic wide-angle glaucoma. Discontinue levodopa at least 12 hrs before starting Sinemet or Sinemet CR. Sinemet CR not bioequivalent to Sinemet; see literature when switching forms. Monitor renal and liver function, intraocular pressure, blood counts. May stain body fluids. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Orthostatic hypotension with selegiline, antihypertensives. Antagonized by phenothiazines, butyrophenones,

risperidone, phenytoin, papaverine. Hypertension, dyskinesia with tricyclic antidepressants. May be antagonized by iron, high protein diets. May cause false (+) urinary ketone test or false (-) urinary glucose (glucose oxidase) test.

Adverse reactions: Dyskinesia, GI upset, hallucinations, confusion, psychological disturbances, depression, dizziness, headache, dream abnormalities, dystonia, cardiac arrhythmias, hypotension, dyspnea, on-off phenomenon, back pain, blepharospasm (may indicate excess dosage), hypertension, anticholinergic effects, anorexia, insomnia, leukopenia, renal and liver function disorders, seizures, neuroleptic malignant syndrome.

How supplied: CR-100, 500; Tabs-100

ENTACAPONE

COMTAN Novartis

COMT inhibitor. Entacapone 200mg; tabs.

Indications: Adjunct to levodopa/carbidopa in patients with idiopathic Parkinson's disease and end-of-dose wearing off.

Adults: 200mg with each dose of levodopa/carbidopa, up to 8 times daily.

Children: Not applicable.

Warnings/Precautions: Dyskinesias. Hepatic impairment. Biliary obstruction. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers.

Interactions: Nonselective MAOIs: not recommended. Consider reducing levodopa dose. Potentiates CNS depression with alcohol, other CNS depressants. Chelates iron. Cardiac effects with drugs metabolized by COMT (eg, epinephrine, isoproterenol, dopamine, dobutamine, methyl dopa, amorphine, bitolterol). Caution with drugs that interfere with biliary excretion, glucuronidation, intestinal beta-glucuronidase (eg, probenecid, cholestyramine, erythromycin, rifampicin, ampicillin, chloramphenicol).

Adverse reactions: Dyskinesia, nausea, urine discoloration, hyperkinesia, diarrhea, GI disturbances, back pain, dyspnea, somnolence, anxiety, sweating, purpura, asthenia, taste perversion; rarely: orthostatic hypotension, syncope, hallucinations, rhabdomyolysis, hyperpyrexia and confusion upon withdrawal.

How supplied: Tabs-10, 100, 500

PRAMIPEXOLE

MIRAPEX Boehringer Ingelheim

Dopamine agonist (non-ergot). Pramipexole dihydrochloride 0.125mg, 0.25mg+, 0.5mg+, 0.75mg, 1mg+, 1.5mg+; tabs; + scored.

Indications: Idiopathic Parkinson's disease.

Adults: May take with food. Gradually increase from initial dose at intervals of 5-7 days. Initially 0.125mg three times daily; max 1.5mg three times daily. Renal impairment: CrCl 30-50mL/min: initially 0.125mg twice daily; max 0.75mg three times daily. CrCl 15-<30mL/min: initially 0.125mg once daily; max

1.5mg once daily. CrCl <15mL/min, hemodialysis: not recommended.

Children: Not established.

Also: Pramipexole

MIRAPEX ER

Pramipexole dihydrochloride extended-release 0.375mg, 0.75mg, 1.5mg, 2.25mg, 3mg, 3.75mg, 4.5mg; tabs.

Adults: Swallow whole. May take with food. Initially 0.375mg once daily; may increase gradually at intervals of 5-7 days, first to 0.75mg/day, then by 0.75mg increments up to max 4.5mg/day. Reevaluate response at intervals of ≥5 days after each dose increment. Switching overnight from immediate-release pramipexole: give same daily dose; monitor and adjust dose as needed. Renal impairment: CrCl 30-50mL/min: initially give every other day; reevaluate before increasing to daily dosing after 1 week and before titrating by 0.375mg increments up to 2.25mg/day. CrCl <30mL/min, hemodialysis: not recommended.

Children: Not established.

Warnings/Precautions: See full labeling. Consider discontinuing if excessive daytime sleepiness or if sudden onset of sleep during daily activities occurs. Monitor for drowsiness or sleepiness, orthostatic hypotension, or compulsive behaviors. Renal disease. Sleep disorders. Dyskinesia. Avoid abrupt cessation (withdraw over 1 week). Elderly may have higher risk of hallucinations. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Consider reducing concomitant levodopa dose. Pramipexole levels increased by cimetidine, possibly other renally-excreted basic drugs (eg, ranitidine, diltiazem, triamterene, verapamil, quinidine, quinine). Caution with alcohol, other CNS depressants. May be antagonized by dopamine antagonists (eg, neuroleptics, metoclopramide).

Adverse reactions: Early disease: somnolence (including sudden sleep onset), nausea, constipation, dizziness, fatigue, hallucinations, dry mouth, muscle spasms, peripheral edema, insomnia, asthenia, accidental injury, dyspepsia, others. Late disease: dyskinesia, nausea, constipation, hallucinations, headache, anorexia, postural hypotension, extrapyramidal syndrome, insomnia, dizziness, accidental injury, dream abnormalities, confusion, asthenia, somnolence (including sudden sleep onset), dystonia, abnormal gait, hypertonia, dry mouth, amnesia, urinary frequency, leg cramps, others.

How supplied: Tabs-90; ER tabs 0.375mg, 0.75mg, 1.5mg-7, 30; 2.25mg, 3mg, 3.75mg, 4.5mg-30

RASAGILINE

AZILECT Teva CNS

MAO-B inhibitor. Rasagiline 0.5mg, 1mg; tabs.

Indications: Idiopathic Parkinson's disease, as initial monotherapy and as adjunct to levodopa.

Adults: Monotherapy: 1mg once daily. Adjunctive therapy: initially 0.5mg once daily; may increase to

1mg once daily (consider reducing levodopa dose if side effects increase). Mild hepatic impairment (Child-Pugh score 5–6) or concomitant CYP1A2 inhibitors: 0.5mg once daily.

Children: Not recommended.

Contraindications: During or within 2 weeks of meperidine, tramadol, propoxyphene, methadone, MAOIs. Concomitant dextromethorphan, St. John's wort, cyclobenzaprine.

Warnings/Precautions: Avoid tyramine-rich foods (see literature). Mild hepatic impairment: reduce dose; moderate to severe hepatic impairment (Child-Pugh score ≥ 7): not recommended. Monitor for melanoma. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Possible hypertensive crisis with excess dietary tyramine (see literature). Potentiated by CYP1A2 inhibitors (eg, ciprofloxacin). Severe CNS toxicity (hyperpyrexia, death) with triazolopyridines, tricyclics, tetracyclics, SSRIs, SNRIs, and MAOIs (both nonselective and type B selective); allow at least 14 days after discontinuing rasagiline before starting triazolopyridines, tricyclics, tetracyclics, SSRIs, or SNRIs; allow 5 weeks after discontinuing fluoxetine before starting rasagiline. Caution with sympathomimetics (eg, nasal, oral, ophthalmic decongestants or cold remedies).

Adverse reactions: As monotherapy: flu syndrome, arthralgia, depression, dyspepsia. With levodopa: also dyskinesia, accidental injury, weight loss, postural hypotension, GI upset, anorexia, abdominal pain, constipation, dry mouth, rash, abnormal dreams, fall.

How supplied: Tabs–30

RIVASTIGMINE

R

EXELON Novartis

Reversible acetylcholinesterase inhibitor (carbamate deriv). Rivastigmine (as tartrate) 1.5mg, 3mg, 4.5mg, 6mg; caps.

Also: Rivastigmine

R

EXELON ORAL SOLUTION

Rivastigmine (as tartrate) 2mg/mL.

Also: Rivastigmine

R

EXELON PATCH

Rivastigmine 4.6mg/24hrs, 9.5mg/24hrs, 13.3mg/24hrs; transdermal system.

Indications: Mild to moderate dementia associated with Parkinson's disease.

Adults: Take with food in the AM and PM. May mix soln with water, fruit juice, or soda. Caps and soln may be interchanged at equal doses. Initially 1.5mg twice daily; if tolerated, may increase by 1.5mg twice daily at intervals of at least 4 weeks. Usual range: 3–12mg/day; max 12mg/day. If dose is not tolerated, suspend for several doses and restart at same or next lower dose. If stopped for more than several days restart at 1.5mg twice daily and retitrate. Patch: Apply to clean, dry, hairless intact skin. Rotate application site (allow 14 days before reapplying to same site). Initially apply one 4.6mg/24hrs patch

once daily; if tolerated, may increase to 9.5mg/24hrs patch after 4 weeks at previous dose; can further be increased to max 13.3mg/24hrs dose. If dosing interrupted for >3 days, restart with 4.6mg/24hrs patch and titrate again. Mild-to-moderate hepatic impairment: initial and max dose 4.6mg/24hrs patch. Low body wt. (<50 kg): monitor for toxicities and consider reducing maintenance dose to 4.6mg/24hr patch. Switching from capsules or oral solution: see full labeling.

Children: Not applicable.

Contraindications: Patches: previous history of application site reactions suggestive of allergic contact dermatitis.

Warnings/Precautions: Monitor for nausea, vomiting, anorexia, weight loss, GI bleed. Sick sinus syndrome, other supraventricular conduction disturbances. Seizures. History or risk of ulcers. Urinary obstruction. Asthma. COPD. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Antagonizes anticholinergics. May potentiate succinylcholine-type muscle relaxants, other cholinesterase inhibitors, cholinergic agonists. Monitor for GI bleed with NSAIDs.

Adverse reactions: GI upset, dyspepsia, abdominal pain, dizziness, anorexia, weight loss, headache, fatigue, insomnia, asthenia, malaise, tremor, syncope, hyperhidrosis, cholinergic effects; also, patches: application site reactions, allergic contact dermatitis (consider switching to oral form).

How supplied: Caps–60, 500; Soln–120mL (w. dosing syringe); Patches–30

ROPINIROLE

R

REQUIP GlaxoSmithKline

Dopamine agonist (non-ergot). Ropinirole (as HCl) 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg, 5mg; tabs.

Indications: Idiopathic Parkinson's disease.

Adults: Titrate gradually. Taking with food may reduce nausea. Initially 0.25mg 3 times daily, then increase by 0.25mg 3 times daily at 1-week intervals to 1mg 3 times daily to 4th week. May increase by 1.5mg/day at 1-week intervals up to 9mg/day, then by up to 3mg/day at 1-week intervals to max 24mg/day.

Children: Not recommended.

Also: Ropinirole

R

REQUIP XL

Ropinirole 2mg, 4mg, 6mg, 8mg, 12mg; ext-rel tabs.

Adults: Titrate gradually. Swallow whole. Taking with food may reduce nausea. Initially 2mg once daily for 1–2 weeks, then increase by 2mg/day at ≥ 1 -week intervals to max 24mg/day. Switching from immediate-release ropinirole: give initial dose to closely match total daily dose of immediate-release form.

Children: Not recommended.

Warnings/Precautions: See literature. Consider discontinuing if excessive daytime sleepiness or if sudden onset of sleep during daily activities occurs. Monitor for drowsiness or sleepiness, and

for orthostatic hypotension. Dyskinesia. Sleep disorders. Severe renal or hepatic impairment. Severe cardiovascular disease. Hypertension. Changes in heart rate. Psychotic disorders. Avoid abrupt cessation (withdraw over 1 week). Elderly may have higher risk of hallucinations. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Consider reducing concomitant levodopa dose. Alcohol, other CNS depressants may be potentiated. Potentiated by ciprofloxacin, possibly other CYP1A2 inhibitors. May be antagonized by dopamine antagonists (eg, phenothiazines, butyrophenones, metoclopramide). Adjust ropinirole dose if estrogens are added or discontinued. Monitor with drugs that induce CYP1A2 (eg, cigarette smoke).

Adverse reactions: Early parkinsonism (without levodopa); Nausea, somnolence (including sudden sleep onset), abdominal pain/discomfort, dizziness, headache, constipation; dyskinesia, vomiting, syncope, fatigue, dyspepsia, infections, pain, sweating, asthenia, edema, postural hypotension, hypertension, changes in heart rate, pharyngitis, confusion, hallucinations, abnormal vision, aggravated parkinsonism. Advanced disease (with levodopa): also arthralgia, tremor, anxiety, dry mouth, hypokinesia, paresthesia.

How supplied: Tabs-100; XL tabs (2mg, 4mg, 8mg)-30, 90; XL tabs (6mg, 12mg)-30

11D Seizure disorders

CARBAMAZEPINE

CARBATROL Shire

Dibenzazepine. Carbamazepine 100mg, 200mg, 300mg; ext-rel caps.

Indications: Generalized tonic-clonic, partial, or mixed seizures.

Adults: Initially 200mg twice daily; increase weekly if needed by 200mg/day. Usual maintenance: 800mg-1.2g/day. 12-15yrs: max 1g/day; >15yrs: usual max 1.2g/day (rarely, max 1.6g daily). All: in 2 divided doses.

Children: May convert from immediate-release forms of carbamazepine at doses above 400mg/day on a mg/mg basis using a twice-daily regimen. Usual max <35mg/kg per day.

Contraindications: History of bone marrow depression. Sensitivity to tricyclic antidepressants. During or within 14 days of MAOIs. Concomitant nefazodone, delavirdine.

Warnings/Precautions: Evaluate for presence of HLA-B*1502 allele (esp. in Asians), if present carbamazepine should not be used; increased risk of severe dermatological reactions. History of cardiac, hepatic, renal, or hematopoietic dysfunction. Do baseline CBCs then periodically; discontinue if significant bone marrow depression occurs. Monitor lipid profile, and ophthalmic, hepatic, and renal function. Consider discontinuing if hyponatremia

occurs. Increased intraocular pressure. Activation of latent psychosis. Suicidal tendencies (monitor). Reevaluate periodically. Avoid abrupt cessation. Elderly. Labor & delivery. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: See Contraindications. Possible hyperpyretic crisis, seizures and death with MAOIs. Carbamazepine levels increased by CYP3A4 inhibitors (eg, cimetidine, macrolides, danazol, delavirdine, diltiazem, fluoxetine, isoniazid, ketoconazole, loratadine, propoxyphene, itraconazole, nicotinamide, niacinamide, valproate, verapamil). Carbamazepine levels decreased by CYP3A4 inducers (eg, cisplatin, doxorubicin, felbamate, phenobarbital, phenytoin, primidone, rifampin, theophylline). May increase levels of clomipramine, phenytoin, primidone. May decrease levels of phenytoin, warfarin, oral contraceptives, doxycycline, theophylline, haloperidol, acetaminophen, alprazolam, clonazepam, clozapine, delavirdine, ethosuximide, valproate, others metabolized by CYP3A4. May increase lithium toxicity. May reduce effectiveness of hormonal contraceptives and delavirdine. May alter thyroid function with other anticonvulsants. May interfere with some pregnancy tests or thyroid function tests.

Adverse reactions: Dizziness, drowsiness, nausea, vomiting, CHF, edema, hyper- or hypotension, arrhythmias, liver or urinary disorders, dyspnea, lens opacities, arthralgia, fever; rarely: rash (may be serious, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), aplastic anemia, agranulocytosis, bone marrow depression, hypersensitivity reactions; others (see full labeling).

How supplied: Caps-120

CARBAMAZEPINE

EPITOL Teva US Generics

TGRETOL Novartis

Dibenzazepine. Carbamazepine 100mg +, 200mg; scored tabs; + chewable.

Indications: Generalized tonic-clonic, partial or mixed seizures.

Adults: Take with food. Initially 200mg twice daily; increase weekly if needed by 200mg/day in 3-4 divided doses. 12-15yrs: max 1g daily; >15yrs: usual max 1.2g daily (rarely, max 1.6g daily). Usual maintenance: 800mg-1.2g/day. All in 3-4 divided doses.

Children: Take with food. <6yrs: initially 10-20mg/kg per day in 2-3 divided doses; increase weekly if needed in 3-4 divided doses. Maintenance: usual max <35mg/kg per day in 3-4 divided doses. ≥6yrs: initially 100mg twice daily; increase weekly if needed by 100mg/day in 3-4 divided doses; max 1g daily in 3-4 divided doses. Usual maintenance: 400mg-800mg/day.

Also: Carbamazepine

TGRETOL-XR

Carbamazepine 100mg, 200mg, 400mg; ext-rel tabs.

Adults: Do not crush or chew. Take with food. Initially 200mg twice daily; increase weekly if needed

by 200mg/day in 2 divided doses. 12–15yrs: max 1g daily; >15yrs: usual max 1.2g daily (rarely, max 1.6g daily). Usual maintenance: 800mg–1.2g/day. All in 2 divided doses.

Children: Do not crush or chew. Take with food.

<6yrs: use other forms. ≥6yrs: initially 100mg twice daily; increase weekly if needed by 100mg/day in 2 divided doses; max 1g daily in 2 divided doses. Usual maintenance: 400mg–800mg/day.

Also: Carbamazepine
TEGRETOL SUSPENSION

Carbamazepine 100mg/5mL; citrus-vanilla flavor; contains sorbitol.

Adults: Take with food. Initially 100mg 4 times daily; increase weekly if needed by 200mg/day in 3–4 divided doses. 12–15yrs: max 1g daily; >15yrs: usual max 1.2g daily (rarely, max 1.6g daily). Usual maintenance: 800mg–1.2g/day. All in 3–4 divided doses.

Children: Take with food. <6yrs: initially 10–20mg/kg per day in 4 divided doses; increase weekly if needed in 3–4 divided doses. Maintenance: usual max <35mg/kg per day. ≥6yrs: initially 200mg/day in 4 divided doses; increase weekly if needed by 100mg/day in 3–4 divided doses; max 1g daily in 3–4 divided doses. Usual maintenance: 400mg–800mg/day.

Contraindications: History of bone marrow depression. Sensitivity to tricyclic antidepressants. During or within 14 days of MAOIs. Concomitant nefazodone.

Warnings/Precautions: Evaluate for presence of HLA-B*1502 allele (esp. in Asians), if present carbamazepine should not be used; increased risk of severe dermatologic reactions. History of cardiac, hepatic, renal, or hematopoietic dysfunction, or adverse hematologic reaction to other drugs. Do baseline CBCs then periodically; discontinue if significant bone marrow depression occurs. Monitor lipid profile, ophthalmic, hepatic, and renal function. Glaucoma. Mixed seizure disorder with atypical absence seizures (may increase generalized convulsions). Activation of latent psychosis. Suicidal tendencies (monitor). Use minimum effective dose and change dose gradually. Avoid abrupt cessation. Convert tabs to susp with same quantity of mg/day in smaller, more frequent doses; convert tabs to XR on mg/mg basis. Elderly. Labor & delivery. Pregnancy (Cat.D). Nursing mothers.

Interactions: See Contraindications. Possible hyperpyretic crisis, seizures and death with MAOIs. Increased plasma levels with CYP3A4 inhibitors (eg, aprepitant, cimetidine, ciprofloxacin, danazol, diltiazem, macrolides, erythromycin, troleandomycin, clarithromycin, fluoxetine, fluvoxamine, nefazodone, trazodone, loxapine, olanzapine, quetiapine, loratadine, terfenadine, omeprazole, oxybutynin, dantrolene, isoniazid, niacinamide, nicotinamide, ibuprofen, propoxyphene, ketoconazole, itraconazole, fluconazole, voriconazole, acetazolamide, verapamil, ticlopidine, grapefruit juice, protease inhibitors, valproate). Decreased plasma levels with CYP3A4 inducers (eg, cisplatin, doxorubicin,

felbamate, fosphenytoin, rifampin, phenobarbital, phenytoin, primidone, methsuximide, theophylline, aminophylline). May increase levels of clomipramine, phenytoin, primidone, cyclophosphamide. May decrease levels of phenytoin, warfarin, doxycycline, theophylline, haloperidol, acetaminophen, alprazolam, clozapine, oral contraceptives, anticonvulsants, aripiprazole, others metabolized by CYP3A4. May increase lithium toxicity. Monitor tacrolimus, temsirolimus, lapatinib (adjust dose). May alter thyroid function with other anticonvulsants. Do not give susp formulation simultaneously with other liquid drugs or diluents. May interfere with some pregnancy tests, thyroid function tests. Others (see full labeling).

Adverse reactions: Drowsiness, dizziness, GI upset, heart failure, edema, hyper- or hypotension, arrhythmias, liver and urinary disorders, dyspnea, lens opacities, arthralgia, fever, hyponatremia; rarely: rash (may be serious, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), aplastic anemia, agranulocytosis, bone marrow depression; drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity.

How supplied: Tabs–100; XR tabs–100; Susp–450mL

CLOBAZAM

CIV

ONFI Lundbeck

Antiepileptic (benzodiazepine). Clobazam 10mg, 20mg; scored tabs.

Also: Clobazam

CIV

ONFI ORAL SUSPENSION

Clobazam 2.5mg/mL; berry flavor.

Indications: Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS).

Adults and Children: <2yrs: not recommended.

Tabs may be swallowed whole, scored, or crushed and mixed in applesauce. ≥2yrs: Give in divided doses twice daily (except for 5mg dose). ≤30kg: initially 5mg, then increase to 10mg on Day 7, then increase to 20mg on Day 14. >30kg: initially 10mg, then increase to 20mg on Day 7, then increase to 40mg on Day 14. Elderly, CYP2C19 poor metabolizers, mild to moderate hepatic impairment (Child-Pugh score 5–9): initially 5mg/day; titrate according to weight (as shown above) but to half the dose, an additional titration to max dose (20mg/day or 40mg/day, depending on weight) may be started at Day 21.

Warnings/Precautions: Severe renal or hepatic impairment or ESRD. Monitor for emergence of or worsening depression, suicidal thoughts/behavior, and/or unusual changes in mood or behavior. Avoid abrupt cessation; taper by decreasing total daily dose by 5–10mg/day on a weekly basis. Drug abusers. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Increased somnolence, sedation with concomitant CNS depressants, alcohol. May be potentiated by CYP2C19 inhibitors (eg, fluconazole, fluvoxamine, ticlopidine, omeprazole), alcohol. May diminish effect of hormonal contraceptives (use non-

hormonal forms). May need to adjust dose of drugs metabolized by CYP2D6.

Adverse reactions: Somnolence, sedation, drooling, constipation, cough, UTI, aggression, insomnia, dysarthria, fatigue.

How supplied: Tabs-100; Susp-120mL (w. 2 dosing syringes)

CLONAZEPAM

CIV

KLONOPIN Roche

Benzodiazepine. Clonazepam 0.5mg +, 1mg, 2mg; tabs; + scored.

Also: Clonazepam

CIV

CLONAZEPAM ORALLY-DISINTEGRATING TABLETS (various)

Clonazepam 0.125mg, 0.25mg, 0.5mg, 1mg, 2mg; orally-disintegrating tabs.

Indications: Lennox-Gastaut syndrome, akinetic and myoclonic seizures. Absence seizures refractory to succinimides.

Adults: Initially up to 0.5mg 3 times daily. Increase if needed every 3 days by 0.5-1mg daily; max 20mg daily. Orally-disintegrating tabs: dissolve in mouth; swallow with or without water.

Children: <10yrs or <30kg: initially 0.01-0.03mg/kg per day, but not >0.05mg/kg per day in 2-3 divided doses. Increase if needed every 3 days by 0.25-0.5mg daily. Maintenance: 0.1-0.2mg/kg per day in 3 equally divided doses. Orally-disintegrating tabs: dissolve in mouth; swallow with or without water.

Contraindications: Significant liver disease. Acute narrow-angle glaucoma.

Warnings/Precautions: May increase or precipitate tonic-clonic seizures. Suicidal tendencies (monitor). Chronic respiratory disease. Renal impairment. Avoid abrupt cessation. Monitor blood counts, liver function. Elderly. Labor & delivery, pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Adjust anticonvulsants if needed. Absence seizures with valproate. Caution with drugs that inhibit CYP3A (eg, azole antifungals). Antagonized by CYP450 inducers (eg, phenytoin, carbamazepine, phenobarbital).

Adverse reactions: CNS effects (esp. depression), hypersalivation, liver disorders, GI upset, blood dyscrasias, paradoxical reactions.

How supplied: Tabs-100; Orally-disintegrating tabs-contact supplier

DIAZEPAM

CIV

DIASTAT Valeant

Benzodiazepine. Diazepam 2.5mg, 5mg, 10mg, 15mg, 20mg; per applicator; rectal gel.

Indications: Intermittent use in epilepsy to control bouts of increased seizure activity.

Adults and Children: Individualize dose. Calculate dose based on body weight (in kg) and round up to next available dosage strength; do not subdivide

fixed-dose products. Treat no more than 1 episode every 5 days and no more than 5 episodes per month. See literature for dosing chart. <2 years: not recommended. 2-5 yrs: 0.5mg/kg. 6-11 yrs: 0.3mg/kg. ≥12 yrs: 0.2mg/kg. Elderly or debilitated: reduce dose. May give 2nd dose 4-12 hrs after 1st dose. May use 2.5mg strength as supplemental dose.

Contraindications: Acute narrow-angle glaucoma.

Warnings/Precautions: See literature. Caregiver must be fully able to identify cluster seizures or prodrome, be able to decide when to treat, correctly administer rectal dose, monitor patient, and assess response. Not for use in untreated open-angle glaucoma. Renal or hepatic impairment. Compromised respiratory function. Avoid abrupt cessation. Drug or alcohol abuse. Chronic use of diazepam may increase tonic-clonic seizures. Elderly. Pregnancy (Cat.D), labor & delivery, nursing mothers: not recommended.

Interactions: CNS depression potentiated with valproate, alcohol, other CNS depressants. Caution with other psychotropics. Potentiated by sertraline. May be potentiated by inhibitors of CYP2C19 or CYP3A4 activity or antagonized by inducers of these enzymes. Diazepam may potentiate or antagonize other drugs metabolized by these enzymes.

Adverse reactions: Somnolence, dizziness, headache, pain, nervousness, vasodilation, diarrhea, ataxia, euphoria, incoordination, asthma, rhinitis, rash, hyperkinesia, hypoventilation, paradoxical excitement.

How supplied: 2.5mg, 5mg, 10mg (pediatric applicator)-2 (w. lubricant) 10mg, 15mg, 20mg (adult applicator)-2 (w. lubricant)

DIAZEPAM

CIV

VALIUM Roche

Benzodiazepine. Diazepam 2mg, 5mg, 10mg; scored tabs.

Indications: Adjunct in convulsive disorders.

Adults: 2-10mg 2-4 times daily. Elderly, debilitated: initially 2-2.5mg 1-2 times daily; increase gradually.

Children: <6months: not recommended. ≥6months: initially 1-2.5mg 3-4 times daily; increase gradually.

Also: Diazepam

CIV

DIAZEPAM INJECTION

Diazepam 5mg/mL; contains propylene glycol 40%, ethyl and benzyl alcohol.

Indications: Adjunct in status epilepticus and recurrent seizures.

Adults: Initially 5-10mg slow IV (5mg/min). May repeat every 10-15 minutes; max 30mg. Repeat in 2-4 hours if needed. Do not dilute. May give IM if IV impossible. Do not use small vein.

Children: Max 0.25mg/kg over 3 minutes; if no response after 3rd dose consider adjunctive therapy. Age <30 days: not recommended. 30 days-5yrs: 0.2-0.5mg slow IV every 2-5 minutes; max 5mg. >5yrs: 1mg slow IV every 2-5 minutes; max 10mg. Repeat in 2-4 hours if needed. Do not use small vein.

Contraindications: Acute narrow-angle glaucoma.

Warnings/Precautions: Not for use in untreated open-angle glaucoma. Inj not for use in shock, coma, acute alcohol intoxication, or obstetrical conditions. Discontinue if paradoxical reaction occurs. Drug or alcohol abuse. Depression. Suicidal tendencies. Renal or liver dysfunction. Avoid abrupt cessation. May increase tonic-clonic seizures. Reevaluate periodically. Monitor blood counts, liver function. Elderly. Debilitated. Psychosis, pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants (consider reducing opioid doses by at least 1/3). Increased serum levels with cimetidine. Potentiated by sertraline. Inj: hypotension, muscle weakness with narcotics, barbiturates, alcohol.

Adverse reactions: CNS depression, ataxia, memory impairment, paradoxical excitement, salivation changes, neutropenia, jaundice. Inj: apnea, cardiac arrest, venous thrombosis, phlebitis, status epilepticus (when treating petit mal).

How supplied: Tabs 2mg–100; Tabs 5mg, 10mg–100, 500; Vials (10mL)–contact supplier

DIVALPROEX

DEPAKOTE AbbVie

Divalproex sodium 125mg, 250mg, 500mg; delayed-release tabs.

Also: Divalproex

DEPAKOTE SPRINKLE

Divalproex sodium 125mg; coated particles in caps.

Indications: Absence seizures. Complex partial seizures.

Adults and Children: May swallow caps whole or sprinkle contents on soft food. <10yrs: not recommended. ≥10yrs: Absence seizures: initially 15mg/kg per day. Complex partial: initially 10–15mg/kg per day. Both: Give in 2–3 divided doses if total daily dose >250mg. Increase weekly if needed by 5–10mg/kg per day; max 60mg/kg per day.

Also: Divalproex

DEPAKOTE ER

Divalproex sodium 250mg, 500mg; ext-rel tabs.

Adults and Children: Take once daily. Swallow whole. <10yrs: not recommended. ≥10yrs: Absence seizures: initially 15mg/kg per day. Complex partial: initially 10–15mg/kg per day. Both: may increase weekly if needed by 5–10mg/kg per day; usual max 60mg/kg per day. Converting from other forms: see literature.

Contraindications: Hepatic disease. Significant hepatic dysfunction. Urea cycle disorders.

Warnings/Precautions: Discontinue if hepatic dysfunction, pancreatitis, thrombocytopenia, or hyperammonemic encephalopathy occurs. History of liver disease. Increased hepatotoxicity risk with congenital metabolic disorders, multiple AEDs, severe seizure disorders with mental retardation, organic brain disorders, in children <2 years of age. Monitor

liver function and symptoms (esp. 1st 6 months). Follow-up if symptoms of hyperammonemia occur. Suicidal tendencies (monitor). Depakote ER is not bioequivalent to delayed-release tabs on mg/mg basis. Avoid abrupt cessation. Monitor platelets, bleeding time (at baseline, before surgery, and in pregnancy); reevaluate periodically. May affect HIV or CMV viral load (*in vitro*). Elderly (monitor fluid and nutritional intake, and for somnolence). Pregnancy (Cat.D): apprise females of childbearing potential of risks to fetus (eg, neural tube defects). Nursing mothers: not recommended.

Interactions: Monitor levels of valproate, ethosuximide, other anticonvulsants, and whenever an enzyme inducer is added or withdrawn. Potentiates carbamazepine, diazepam, ethosuximide, lamotrigine, phenobarbital, phenytoin, tolbutamide, warfarin, zidovudine, amitriptyline, nortriptyline. Potentiated by aspirin, felbamate. Levels reduced by rifampin, phenytoin, carbamazepine, phenobarbital, carbapenem antibiotics. CNS depression with alcohol, other CNS depressants. Clonazepam may induce absence status in patients with history of absence seizures. May interfere with urine ketone and thyroid tests. Others: see literature.

Adverse reactions: Dizziness, headache, GI upset; dermatologic, CNS (esp. tremor, somnolence), and endocrine effects; weakness, blood dyscrasias, bone marrow suppression, hepatotoxicity, acute pancreatitis, thrombocytopenia, hyperammonemia, metabolic abnormalities, others.

How supplied: Tabs 125mg–100; Tabs 250mg, 500mg–100, 500; Sprinkle caps–100; ER 250mg–60; ER 250mg, 500mg–100, 500

ETHOSUXIMIDE

ZARONTIN Pfizer

Succinimide. Ethosuximide 250mg; caps.

Also: Ethosuximide

ZARONTIN SYRUP

Ethosuximide 250mg/5mL; oral soln; raspberry flavor.

Indications: Absence seizures.

Adults: Initially: 500mg daily. Increase every 4–7 days by 250mg daily according to response; max 1.5g daily in divided doses.

Children: <3yrs: not recommended. 3–6yrs: initially 250mg daily. >6yrs: initially 500mg daily. Increase both every 4–7 days by 250mg daily according to response; max 1.5g daily in divided doses. Usual maintenance: 20mg/kg/day in divided doses.

Warnings/Precautions: Impaired hepatic or renal function. Change dose gradually. May precipitate tonic-clonic seizures. Monitor skin, blood, urine and liver tests. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Monitor phenytoin, phenobarbital, valproic acid, others.

Adverse reactions: Blood dyscrasias, drowsiness, ataxia, dizziness, hepatic, renal, behavioral, psychological and GI disorders, SLE, Stevens-Johnson

syndrome (discontinue if occurs), headache, rash, gingival hyperplasia.

How supplied: Caps-100; Syrup-pt

GABAPENTIN

NEURONTIN CAPSULES Pfizer
Gabapentin 100mg, 300mg, 400mg.

Also: Gabapentin

NEURONTIN TABLETS

Gabapentin 600mg, 800mg; scored.

Also: Gabapentin

NEURONTIN ORAL SOLUTION

Gabapentin 250mg/5mL; strawberry-anise flavor.

Indications: Adjunct in partial seizures.

Adults: Add or remove other AEDs over at least 1 week. Initially 300mg three times daily. Usual range: 900–1800mg/day in 3 divided doses; max 2.4g/day (up to 3.6g/day has been used short-term; see literature); max 12 hrs between doses. Renal dysfunction: CrCl 30–59mL/min: 400–1400mg/day twice daily; CrCl 15–29mL/min: 200–700mg once daily; CrCl ≤15mL/min: 100–300mg once daily (see literature); hemodialysis: 125–350mg after session.

Children: <3yrs: not recommended. Give in 3 divided doses; max 12 hrs between doses; titrate over 3 days. 3–12 yrs: initially 10–15mg/kg per day. 3–4 yrs: titrate to 40mg/kg per day. ≥5yrs: titrate to 25–35mg/kg per day. Max 50mg/kg per day. Renal impairment: not recommended.

Warnings/Precautions: Renal dysfunction.

Suicidal tendencies (monitor). Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates CNS depression with alcohol, morphine, other CNS depressants. Give 2 hrs after antacids. May antagonize hydrocodone. May interfere with some urine protein tests (eg, Multistix-SG).

Adverse reactions: Somnolence, dizziness, ataxia, fatigue, nystagmus, visual disturbances, tremor, dyspepsia, dysarthria, amnesia, back pain, edema, dry mouth or throat, constipation, twitching, pruritus; children also: emotional lability, thought disorder, hyperkinesia, hostility.

How supplied: Caps, tabs-100; Soln-470mL

LACOSAMIDE

VIMPAT UCB

Sodium channel inactivator. Lacosamide 50mg, 100mg, 150mg, 200mg; tabs.

Also: Lacosamide

VIMPAT ORAL SOLUTION

Lacosamide 10mg/mL; strawberry-flavored; contains phenylalanine 0.32mg/20mL.

Indications: Adjunct in partial-onset seizures.

Also: Lacosamide

VIMPAT INJECTION

Lacosamide 10mg/mL; soln for IV infusion.

Indications: Adjunct in partial-onset seizures, when oral administration is not feasible.

Adults: Oral soln: use calibrated measuring device.

Inj: may give without diluting, or mix in appropriate diluent and give by IV infusion over 30–60min. For oral and inj: ≥17yrs: initially 50mg twice daily; may increase at weekly intervals by 100mg/day in 2 divided doses. Maintenance dose: 200–400mg/day.

Renal impairment (CrCl ≤30mL/min), ESRD, mild-moderate hepatic impairment: max 300mg/day.

Consider supplemental dose (50%) after hemodialysis. Avoid abrupt cessation (withdraw over 1 week).

Children: <17yrs: not established.

Warnings/Precautions: Severe hepatic impairment: not recommended. Cardiac conduction disturbances (eg, marked 1st or 2nd degree AV block, sick sinus syndrome unless paced). Severe cardiac disease (eg, myocardial ischemia, heart failure). Monitor for suicidal ideation, depression. Diabetic neuropathy. Elderly.

Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with other drugs that cause PR prolongation.

Adverse reactions: Dizziness, ataxia, diplopia, headache, nausea, syncope; PR interval prolongation, multiorgan hypersensitivity reaction (rare).

Note: To enroll in the UCB AED Pregnancy Registry call (888) 537-7734.

How supplied: Tabs-60; Oral soln-465mL; Single-use vials (20mL)-10

LAMOTRIGINE

LAMICTAL GlaxoSmithKline

Phenyltriazine. Lamotrigine 25mg, 100mg, 150mg, 200mg; scored tabs.

Also: Lamotrigine

LAMICTAL CHEWABLE DISPERSIBLE TABS

Lamotrigine 2mg, 5mg, 25mg; blackcurrant flavor.

Also: Lamotrigine

LAMICTAL ODT

Lamotrigine 25mg, 50mg, 100mg, and 200mg; orally-disintegrating tabs.

Indications: Adjunct in partial seizures, Lennox-Gastaut syndrome, or primary generalized tonic-clonic seizures in adults and children (≥2yrs). Conversion to monotherapy in adults (≥16yrs) with partial seizures who are on carbamazepine, phenytoin, phenobarbital, primidone, or valproate as a single antiepileptic drug (AED).

Adults: Chew tabs: give only whole tabs, round dose down to nearest whole tab (may be swallowed whole, chewed, or mixed in water or diluted fruit juice). ODT: dissolve on tongue and swallow with or without water. Adding to antiepileptic drug (AED) regimens that include valproate: initially 25mg every other day for 2 weeks, then 25mg once daily for 2 weeks; may increase by 25–50mg/day at 1–2 week intervals; usual maintenance 100–400mg/day in 1 or 2 divided doses. Adding to valproate only: usual maintenance 100–200mg/day. Adding to AED regimens other than carbamazepine, phenytoin, phenobarbital, primidone, or valproate: initially 25mg

once daily for 2 weeks; then 50mg once daily for 2 weeks; may increase by 50mg/day at 1–2 week intervals; usual maintenance 225–375mg/day in 2 divided doses. Adding to AED regimens without valproate: initially 50mg per day for 2 weeks, then 100mg daily in 2 divided doses for 2 weeks; may increase by 100mg/day at 1–2 week intervals; usual maintenance 300–500mg/day in 2 divided doses. Converting from one AED (not valproate) to lamotrigine monotherapy (first titrate lamotrigine, then withdraw AED): initially 50mg per day for 2 weeks, then 100mg daily in 2 divided doses for 2 weeks; may increase by 100mg/day at 1–2 week intervals to 500mg/day in 2 divided doses. Then reduce AED dose by 20% per week for 4 wks. Converting from valproate to lamotrigine monotherapy: see literature. Concomitant estrogen-containing oral contraceptives or hormone replacement therapy: see literature. Hepatic impairment: if moderate or severe (w/o ascites) reduce dose by 25%; if severe (w. ascites) reduce dose by 50%.

Children: Chew tabs: give only whole tabs, round dose down to nearest whole tab (may be swallowed whole, chewed, or mixed in water or diluted fruit juice). ODT: dissolve on tongue and swallow with or without water. <2yrs: not recommended. 2–12yrs: Adding to AED regimens that include valproate: initially 0.15mg/kg per day in 1 or 2 divided doses for 2 weeks, then 0.3mg/kg per day in 1 or 2 divided doses for 2 weeks; may increase by 0.3mg/kg per day at 1–2 week intervals in 1 or 2 divided doses; usual maintenance 1–5mg/kg per day; max 200mg/day in 1 or 2 divided doses. Adding to valproate only: usual maintenance 1–3mg/kg per day. Adding to AED regimens other than carbamazepine, phenytoin, phenobarbital, primidone, or valproate: initially 0.3mg/kg per day in 1 or 2 divided doses for 2 weeks, then 0.6mg/kg per day in 2 divided doses for 2 weeks; may increase by 0.6mg/kg per day at 1–2 week intervals; usual maintenance 4.5–7.5mg/kg per day; max 300mg/day in 2 divided doses. Adding to AED regimens without valproate: initially 0.6mg/kg per day in 2 divided doses for 2 weeks, then 1.2mg/kg per day in 2 divided doses for 2 weeks; may increase by 1.2mg/kg per day at 1–2 week intervals; usual maintenance 5–15mg/kg per day; max 400mg/day in 2 divided doses. Patients <30kg: may need higher (≤50%) maintenance dose.

Also: Lamotrigine

LAMICTAL XR

Lamotrigine 25mg, 50mg, 100mg, 200mg, 300mg; ext-rel tabs.

Indications: Adjunct in primary generalized tonic-clonic seizures or partial onset seizures with or without secondary generalization in patients ≥13yrs of age. Conversion to monotherapy in patients ≥13yrs of age with partial seizures who are receiving treatment with a single antiepileptic drug.

Adults: Swallow whole. Take once daily. Adjunctive therapy for primary generalized tonic-clonic and partial

onset seizures: ≥13yrs: adding to antiepileptic drug (AED) regimens that include valproate: initially 25mg every other day for 2 weeks, then 25mg once daily for 2 weeks, then 50mg once daily for 1 week, then 100mg once daily for 1 week, then 150mg once daily for 1 week; followed by maintenance range 200–250mg/day. For patients not taking carbamazepine, phenytoin, phenobarbital, primidone, or valproate: initially 25mg once daily for 2 weeks, then 50mg once daily for 2 weeks, then 100mg once daily for 1 week, then 150mg once daily for 1 week, then 200mg once daily for 1 week; followed by maintenance range 300–400mg/day. Adding to AED regimens without valproate: initially 50mg once daily for 2 weeks, then 100mg once daily for 2 weeks, then 200mg once daily for 1 week, then 300mg once daily for 1 week, then 400mg once daily for 1 week; followed by maintenance range 400–600mg/day. Conversion from adjunctive therapy with carbamazepine, phenytoin, phenobarbital, or primidone to monotherapy: after achieving a dosage of 500mg/day of Lamictal XR using guidelines above, withdraw concomitant AED by 20% decrements each week over a 4-week period, then 2 weeks after completion of withdrawal of AED, decrease Lamictal XR dose no faster than 100mg/day each week to achieve monotherapy maintenance dosage range of 250–300mg/day. Conversion from adjunctive therapy with valproate to monotherapy: Step 1: achieve dosage of Lamictal XR 150mg/day using guidelines above while maintaining stable dose of valproate; Step 2: maintain Lamictal XR 150mg/day while decreasing valproate dose by decrements no greater than 500mg/day each week to 500mg/day and then maintain for 1 week; Step 3: increase Lamictal XR to 200mg/day while simultaneously decreasing valproate to 250mg/day and maintain for 1 week; Step 4: increase Lamictal XR dose to 250 or 300mg/day and discontinue valproate. Conversion from adjunctive therapy with AED other than the above mentioned: after achieving a dosage of Lamictal XR 250–300mg/day using above guidelines, withdraw concomitant AED by 20% decrements each week for 4-week period; no adjustment to Lamictal XR monotherapy dose is needed. Converting from lamotrigine immediate-release tabs: give initial dose to equal total daily dose of immediate-release; monitor and adjust as needed. Concomitant estrogen-containing oral contraceptives or hormone replacement therapy: see literature. Hepatic impairment: if moderate or severe (w/o ascites) reduce dose by 25%; if severe (w. ascites) reduce dose by 50%.

Children: <13yrs: not recommended.

Warnings/Precautions: Discontinue at first sign of rash (unless clearly not drug related); avoid rechallenge. Avoid rapid dose increases and exceeding recommended dose (may increase risk of serious rash). History of allergy or rash to other AEDs (may increase frequency of nonserious rash).

Reevaluate if fever, rash, or other hypersensitivity reaction occurs; discontinue if hypersensitivity occurs. Impaired cardiac function. Moderate or severe hepatic impairment. Significant renal impairment: consider reduced dose. Suicidal tendencies (monitor). Increased risk of aseptic meningitis; evaluate and treat if signs/symptoms develop. Avoid abrupt cessation; taper over at least 2 weeks if possible. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Lamotrigine levels increased by valproate. Lamotrigine levels decreased by phenytoin, carbamazepine, phenobarbital, primidone, rifampin. Monitor with other anticonvulsants. Lamotrigine levels may be decreased by oral contraceptives and increased when they are stopped (if monotherapy: adjust dose), and may affect hormonal replacement therapy or other hormonal contraceptive efficacy. May potentiate other folate inhibitors (eg, trimethoprim). Valproate may increase risk of serious rash. Increased incidence of dizziness, diplopia, ataxia, blurred vision with carbamazepine. No apparent effect on lithium levels.

Adverse reactions: Adults (adjunctive): dizziness, ataxia, somnolence, headache, diplopia, blurred vision, nausea, vomiting. Adults (monotherapy): vomiting, coordination abnormalities, dyspepsia, nausea, dizziness, rhinitis, anxiety, insomnia, pain, weight loss, chest pain, dysmenorrhea, nystagmus, lymphadenopathy. Children (adjunctive): infection, vomiting, fever, dizziness, GI upset, ataxia, tremor, asthenia, bronchitis, flu syndrome, diplopia. Rare: rash (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, or benign), hypersensitivity, multiorgan failure, blood dyscrasias. XR: also, cerebellar coordination/balance disorder, asthenic conditions, vertigo.

Note: Register pregnant patients exposed to lamotrigine by calling (800) 336-2176.

How supplied: Tabs 25mg, 100mg-100; 150mg, 200mg-60; Chewable Dispersible tabs 2mg-30; 5mg, 25mg-100; Starter kit 25mg × 35 tabs-1; 25mg × 84 tabs + 100mg × 14 tabs-1; 25mg × 42 tabs + 100mg × 7 tabs-1; ODT Maintenance Packs-30; ODT Titration Kit 25mg × 21 tabs + 50mg × 7 tabs-1; 50mg × 42 tabs + 100mg × 14 tabs-1; 25mg × 14 tabs, 50mg × 14 tabs, 100mg × 7 tabs-1; XR tabs-30; XR Titration Kit 25mg × 21 tabs + 50mg × 7 tabs-1; 50mg × 14 tabs + 100mg × 14 tabs + 200mg × 7 tabs-1; 25mg × 14 tabs + 50mg × 14 tabs + 100mg × 7 tabs-1

LEVETIRACETAM

KEPPRA UCB

Levetiracetam 250mg, 500mg, 750mg, 1000mg; scored tabs.

Also: Levetiracetam

KEPPRA ORAL SOLUTION

Levetiracetam 100mg/mL; grape flavor; dye-free.

Indications: Adjunct in partial onset seizures in patients ≥1month old. Adjunct in myoclonic seizures in patients ≥12yrs old with juvenile myoclonic epilepsy. Adjunct in primary generalized tonic-clonic seizures in patients ≥6yrs old with idiopathic generalized epilepsy.

Adults: Partial onset: ≥16yrs: Initially 500mg twice daily. May increase at 2-week intervals in increments of 1g/day; max 3g/day. Myoclonic: Initially 500mg twice daily; increase at 2-week intervals in increments of 1g/day to target dose of 3g/day. Tonic-clonic: ≥16yrs: Initially 500mg twice daily; increase at 2-week intervals by 1g/day to target dose of 3g/day. Renal impairment: CrCl 50–80mL/min: 500mg–1g every 12 hours; CrCl 30–50mL/min: 250–750mg every 12 hours; CrCl <30mL/min: 250–500mg every 12 hours; ESRD patients on dialysis: 500mg–1g every 24 hours and a supplement of 250–500mg post-dialysis.

Children: Give in 2 divided doses. Partial onset: 1month–<6 months: 14mg/kg/day; increase at 2-week intervals by 14mg/kg/day to target dose of 42mg/kg/day. 6months–<4yrs: 20mg/kg/day; increase at 2-week intervals by 20mg/kg/day to target dose of 50mg/kg/day. 4–16yrs: 20mg/kg/day; increase at 2-week intervals by 20mg/kg/day to target dose of 60mg/kg/day. May reduce dose if intolerant. Myoclonic: <12yrs: not recommended. Tonic-clonic: <6yrs: not recommended. 6–16yrs: 20mg/kg/day; increase at 2-week intervals by 20mg/kg/day to target dose of 60mg/kg/day. All: if body wt. ≤20kg: use oral soln.

Also: Levetiracetam

KEPPRA XR

Levetiracetam 500mg, 750mg; ext-rel tabs.

Indications: Adjunct in partial onset seizures in patients ≥16yrs old.

Adults: ≥16yrs: Initially 1g once daily; may increase at 2-week intervals in increments of 1g/day; max 3g/day. Renal impairment: CrCl 50–80mL/min: 1–2g every 24 hours; CrCl 30–50mL/min: 500mg–1.5g every 24 hours; CrCl <30mL/min: 500mg–1g every 24 hours; ESRD patients on dialysis: use immediate-release levetiracetam.

Children: <16yrs: not recommended.

Also: Levetiracetam

KEPPRA INJECTION

Levetiracetam 100mg/mL; IV infusion after dilution.

Indications: Use when oral administration is temporarily not feasible: as adjunct in partial onset seizures; and adjunct in myoclonic seizures in patients with juvenile myoclonic epilepsy; and as adjunct in primary generalized tonic-clonic seizures in adults with idiopathic generalized epilepsy.

Adults: ≥16yrs: Infuse over 15 minutes. Partial onset: Initially 500mg twice daily; may increase at 2-week intervals in increments of 1g/day; max 3g/day. Myoclonic and primary generalized tonic-clonic: Initially 500mg twice daily; increase at 2-week intervals in increments of 1g/day to target dose

of 3g/day. Renal impairment: CrCl 50–80mL/min: 500mg–1g every 12 hours; CrCl 30–50mL/min: 250–750mg every 12 hours; CrCl <30mL/min: 250–500mg every 12 hours; ESRD patients on dialysis: 500mg–1g every 24 hours and a supplement of 250–500mg post-dialysis.

Children: <16yrs: not recommended.

Warnings/Precautions: Renal impairment. Suicidal tendencies (monitor). Avoid abrupt cessation. Elderly (consider monitoring renal function). Labor & delivery. Pregnancy (Cat.C); monitor carefully esp. during 3rd trimester. Nursing mothers: not recommended.

Adverse reactions: Somnolence, asthenia, infection, dizziness, coordination difficulties (eg, ataxia, abnormal gait), mood and behavioral abnormalities (eg, irritability, anger, depression, anxiety, apathy), neck pain, pharyngitis, hematologic abnormalities, dermatological reactions; may be serious (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), discontinue if occurs; rare: psychotic symptoms. Children: also accidental injury, hostility, nervousness; BP increases in children 1month–4yrs. XR: also nausea.

Note: Register pregnant patients exposed to levetiracetam by calling (888) 537-7734.

How supplied: Tabs 250mg, 500mg, 750mg–120; 1000mg–60; XR–60; Soln–pt; Single-use vials (5mL)–10

OXCARBAZEPINE

TRILEPTAL Novartis
Dibenzazepine. Oxcarbazepine 150mg, 300mg, 600mg; tabs.

Also: Oxcarbazepine
TRILEPTAL SUSPENSION

Oxcarbazepine 300mg/5mL; lemon flavor; contains alcohol.

Indications: Monotherapy or adjunct in partial seizures in adults and children 4–16 years of age.

Adults: Give in two equally divided doses. Monotherapy: initially 600mg/day; increase by 300mg/day every 3rd day to 1.2g/day. Adjunctive therapy: initially 600mg/day; may increase by up to 600mg/day at weekly intervals to 1.2g/day. Converting to monotherapy: initially 600mg/day; increase by 600mg/day at weekly intervals to usual max of 2.4g/day; attempt to reach oxcarbazepine max dose in 2–4 weeks while withdrawing other AED over 3–6 weeks (reduce dose of other AED when starting oxcarbazepine). Renal impairment (CrCl <30mL/min): reduce initial dose by ½ and titrate more slowly.

Children: Give in two equally divided doses. <2yrs: not recommended. 4–16yrs: Monotherapy: initially 8–10mg/kg per day; increase by 5mg/kg per day every 3rd day to max dose (varies with weight; see full labeling); Adjunctive therapy: initially 8–10mg/kg per day; usual max 600mg/day; target maintenance doses (attain over 2 weeks): 20–29 kg: 900mg/day; 29.1–39 kg: 1.2 g/day; >39 kg:

1.8g/day; Converting to monotherapy: initially 8–10mg/kg per day; increase by 10mg/kg per day at weekly intervals to max dose (see full labeling) while withdrawing other AED over 3–6 weeks (reduce dose of other AED when starting oxcarbazepine). Renal impairment (CrCl <30mL/min): reduce initial dose by ½ and titrate more slowly.

Warnings/Precautions: Carbamazepine allergy. Renal or severe hepatic impairment. Suicidal tendencies (monitor). Monitor for hyponatremia. Discontinue if multi-organ hypersensitivity is suspected. Monitor for seizures during pregnancy and through the postpartum period. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Monitor plasma levels of other AEDs (esp. during titration) and adjust if needed; withdraw gradually. Potentiates CNS depression with alcohol, other CNS depressants. Potentiates phenobarbital, phenytoin. Antagonized by carbamazepine, phenobarbital, phenytoin, valproic acid, verapamil. May affect, or be affected by, other drugs metabolized by CYP2C19, CYP3A4/5 (eg, dihydropyridine calcium channel blockers). Increases clearance of felodipine, hormonal contraceptives (use non-hormonal method). May affect thyroid (T₄) tests. Caution with other drugs that cause hyponatremia.

Adverse reactions: Dizziness, somnolence, diplopia, fatigue, nausea, vomiting, ataxia, tremor, abnormal vision or gait, abdominal pain, dyspepsia, nystagmus, rash, (may be serious, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), headache, cognitive effects, hyponatremia; rare: pancytopenia, agranulocytosis, leukopenia (discontinue if occurs); also: patients <4yrs: infections and infestations.

Note: To enroll in the North American Antiepileptic Drug Pregnancy Registry call (888) 233-2334.

How supplied: Tabs–100; Susp–250mL (w. dosing syringe)

PHENYTOIN

DILANTIN Pfizer

Hydantoin. Phenytoin sodium 30mg, 100mg; ext-rel caps.

Indications: Tonic-clonic, psychomotor and neurosurgically induced seizures.

Adults: Initially: 100mg 3 times daily. Increase weekly if needed; max 200mg 3 times daily. Once-a-day dosing only with ext-rel caps for patients controlled on 300mg daily.

Children: Initially 5mg/kg per day in 2–3 equally divided doses. Increase weekly if needed. Usual maintenance: 4–8mg/kg per day; max 300mg daily.

Also: Phenytoin

DILANTIN INFATABS

Phenytoin 50mg; chewable tabs.

Adults: May be chewed or swallowed whole. Initially 2 tabs 3 times daily. Maintenance dose: 6–8 tabs daily in divided doses; may increase to 12 tabs daily if necessary.

Children: Initially 5mg/kg per day in 2–3 equally divided doses. Increase weekly if needed. Usual maintenance: 4–8mg/kg per day; max 300mg daily.

**Also: Phenytoin
DILANTIN SUSPENSION**

Phenytoin 125mg/5mL; max alcohol 0.6%.

Adults: 1 teaspoonful 3 times daily; may increase to 5 teaspoonfuls daily if necessary.

Children: Initially 5mg/kg per day in 2–3 equally divided doses. Increase weekly if needed. Usual maintenance: 4–8mg/kg per day; max 300mg daily.

Contraindications: Concomitant delavirdine.

Warnings/Precautions: Suicidal tendencies (monitor). Diabetes. Impaired liver function. Change dose gradually. Discontinue if rash develops. Monitor serum levels when switching between sodium salt of phenytoin (capsules) and free acid form (suspension, Infatabs). Use proper dental hygiene. Hormonal contraception. Porphyria. Elderly. Debilitated. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Potentiated by acute alcohol ingestion, amiodarone, antiepileptic agents (felbamate, topiramate, oxcarbazepine), azoles (fluconazole, ketoconazole, itraconazole, voriconazole), benzodiazepines (eg, chlorthalidopexide, diazepam), chloramphenicol, dicumol, disulfiram, estrogens, fluorouracil, fluoxetine, fluvoxamine, halothane, H₂ blockers (eg, cimetidine), isoniazid, methylphenidate, omeprazole, phenothiazines, phenylbutazone, salicylates, sertraline, succinamides (eg, ethosuximide), sulfonamides, ticlopidine, tolbutamide, trazodone, warfarin. Antagonized by anticancer drugs (eg, bleomycin, carboplatin, cisplatin, doxorubicin, methotrexate), chronic alcohol ingestion, carbamazepine, nelfinavir, reserpine, ritonavir, sucralate, vigabatrin. Antagonizes HIV antivirals (eg, amprenavir, efavirenz, lopinavir/ritonavir, indinavir, nelfinavir, ritonavir, saquinavir), antiepileptic agents (felbamate, topiramate, oxcarbazepine, quetiapine), azoles (fluconazole, ketoconazole, itraconazole, voriconazole), tricyclic antidepressants, oral anticoagulants (eg, warfarin), oral contraceptives, estrogens, corticosteroids, doxycycline, digitoxin, furosemide, irinotecan, paclitaxel, paroxetine, sertraline, teniposide, theophylline, rifampin, quinidine, vitamins D and K, others. Concomitant with fosamprenavir/ritonavir may potentiate amprenavir. Concomitant neuromuscular blockers (eg, pancuronium, vecuronium, rocuronium, cisatracurium); may need higher infusion rate. Variable effects with phenobarbital, valproic acid, divalproex, others. Absorption decreased by calcium, antacids.

Adverse reactions: Nystagmus, ataxia, slurred speech, decreased coordination, dizziness, GI disturbances, gingival hyperplasia, osteomalacia, blood dyscrasias, lymphadenopathy, hepatic disease, rash, hyperglycemia, SLE, hypertrichosis.

Note: To register pregnant patients on Dilantin call (888) 233-2334.

How supplied: Caps, Tabs-100; Susp-8oz

PHENYTOIN

R

PHENYTEK Bertek

Hydantoin. Phenytoin sodium, ext-rel 200mg, 300mg; caps.

Indications: Tonic-clonic, psychomotor and neurosurgically induced seizures.

Adults: Initially: 100mg 3 times daily. Increase weekly if needed; max 200mg 3 times daily. Once-a-day dosing only with 300mg caps for patients controlled on 300mg daily.

Children: Initially 5mg/kg per day in 2–3 equally divided doses. Increase weekly if needed. Usual maintenance: 4–8mg/kg per day; max 300mg daily.

Warnings/Precautions: Diabetes. Impaired liver function. Change dose gradually. Discontinue if rash develops. Monitor serum levels. Use proper dental hygiene. Hormonal contraception. Porphyria. Elderly. Debilitated. Pregnancy. Nursing mothers: not recommended.

Interactions: Potentiated by acute alcohol ingestion, amiodarone, benzodiazepines (eg, diazepam), chloramphenicol, dicumol, disulfiram, estrogens, halothane, H₂ blockers, isoniazid, methylphenidate, phenothiazines, phenylbutazone, salicylates, succinamides (eg, ethosuximide), sulfonamides, tolbutamide, trazodone, others. Antagonized by chronic alcohol ingestion, carbamazepine, reserpine, others. Antagonizes tricyclic antidepressants, oral anticoagulants, oral contraceptives, estrogens, corticosteroids, doxycycline, digitoxin, furosemide, theophylline, rifampin, quinidine, vitamins D and K, others. Variable effects with phenobarbital, valproic acid, divalproex, others. Absorption decreased by calcium, antacids.

Adverse reactions: Nystagmus, ataxia, slurred speech, decreased coordination, dizziness, GI disturbances, gingival hyperplasia, osteomalacia, blood dyscrasias, lymphadenopathy, hepatic disease, rash, hyperglycemia, SLE, hypertrichosis.

How supplied: Caps-30, 100

PHENYTOIN

R

PHENYTOIN INJECTION (various)

Hydantoin. Phenytoin 50mg/mL; contains alcohol, propylene glycol.

Indications: Status epilepticus (tonic-clonic). Seizure prophylaxis and treatment in neurosurgery.

Adults: Status epilepticus: IV not to exceed 50mg/min. Loading dose: 10–15mg/kg followed by maintenance doses of 100mg orally or IV every 6–8 hrs. Do not dilute solution in IV fluids. Neurosurgical procedures: see full labeling.

Children: Status epilepticus: IV not to exceed 1–3mg/kg/min. Loading dose: 15–20mg/kg. Neurosurgical procedures: see full labeling.

Contraindications: Heart block and sinus bradycardia. Adams-Stokes syndrome. Concomitant delavirdine.

Warnings/Precautions: Increased cardiovascular risk associated with rapid infusion; monitor during

and after therapy; rate reduction or discontinuation may be needed. Hypotension. Severe myocardial insufficiency. Monitor ECG, BP, respiration, phenytoin levels. Diabetes. Impaired liver function. Change dose gradually. Monitor for signs/symptoms of serious dermatological reactions; discontinue if rash develops. Maintain proper dental hygiene. Oral contraception. Porphyrin. Elderly. Debilitated. Pregnancy (see full labeling). Nursing mothers: not recommended.

Interactions: See Contraindications. Potentiated by acute alcohol ingestion, amiodarone, benzodiazepines (eg, chlorthalidopexide, diazepam), chloramphenicol, dicumarol, disulfiram, estrogens, fluoxetine, halothane, H₂ blockers (eg, cimetidine), isoniazid, methylphenidate, phenothiazines, phenylbutazone, salicylates, succinamides (eg, ethosuximide), sulfonamides, tolbutamide, trazodone, others. Antagonized by chronic alcohol ingestion, carbamazepine, reserpine, others. Antagonizes tricyclic antidepressants, oral anticoagulants, oral contraceptives, estrogens, corticosteroids, doxycycline, digitoxin, furosemide, theophylline, rifampin, quinidine, vitamins D and K, others. Variable effects with phenobarbital, valproic acid, divalproex, others. Absorption decreased by calcium.

Adverse reactions: Nystagmus, drowsiness, dizziness, insomnia, dyskinesias, ataxia, GI disturbances, gingival hyperplasia, osteomalacia, blood dyscrasias, atrial and ventricular conduction depression, slurred speech, lymphadenopathy, hepatic disease, rash, hyperglycemia, SLE, hypertrichosis, immunoglobulin abnormalities; multiorgan hypersensitivity (may be fatal), local toxicity (eg, purple glove syndrome).

How supplied: Contact supplier.

PREGABALIN

LYRICA Pfizer

alpha2-delta ligand. Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg; caps.

Also: Pregabalin

LYRICA ORAL SOLUTION

Pregabalin 20mg/mL

Indications: Adjunct in partial onset seizures.

Adults: ≥ 18 yrs: Give in 2–3 divided doses. Initially 150mg/day, max 600mg/day. Renal impairment (CrCl < 60 mL/min): reduce dose (see literature); hemodialysis: give supplemental dose after session.

Children: < 18 yrs: not recommended.

Warnings/Precautions: Avoid abrupt cessation (taper over ≥ 1 week). Discontinue if angioedema, hypersensitivity reactions, myopathy or markedly elevated creatine kinase levels occur. CHF. Ocular conditions. Diabetes (monitor skin integrity). Suicidal tendencies (monitor). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Additive edema, weight gain with thiazolidinediones.

CV

CV

Adverse reactions: Dizziness, somnolence, other CNS effects, dry mouth, edema, ocular/visual effects (eg, blurring), weight gain, thinking abnormal (primarily difficulty with concentration/attention), infection, asthenia, paresthesias, elevated creatine kinase, decreased platelets, arrhythmias (PR prolongation); male-mediated teratogenicity; may be tumorigenic.

How supplied: Caps—90; Soln—16oz

TIAGABINE

GABITRIL Teva CNS

GABA reuptake inhibitor. Tiagabine HCl 2mg, 4mg, 12mg, 16mg; tabs.

Indications: Adjunct in partial seizures.

Adults: Take with food. Use lower doses and titrate slower if not on concomitant enzyme-inducing drug(s). 12–18 yrs: 4mg once daily for 1 week; may increase to 8mg/day in 2 divided doses for 1 week; then may increase by 4–8mg weekly to clinical response or up to 32mg/day in 2–4 divided doses. ≥ 18 yrs: 4mg once daily for 1 week; may increase by 4–8mg weekly to clinical response or up to 56mg/day in 2–4 divided doses.

Children: Not recommended.

Warnings/Precautions: Hepatic impairment: reduce dose. Reduce dose or discontinue if generalized weakness occurs. Adjust dose if spike and wave changes on EEG with cognitive or neuropsychiatric events occur. Suicidal tendencies (monitor). Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: CNS depression potentiated by alcohol, triazolam, other CNS depressants. Tiagabine levels reduced by enzyme inducers (eg, phenytoin, carbamazepine, primidone, phenobarbital). May interact with valproate (monitor). May affect or be affected by highly protein bound drugs.

Adverse reactions: Dizziness, asthenia, somnolence, fatigue, GI upset/pain, nervousness, tremor, abdominal pain, concentration difficulties, dysphasia, confusion, other CNS effects, serious rash; possible long-term ophthalmologic effects.

How supplied: Tabs—100

TOPIRAMATE

TOPAMAX TABLETS Janssen

Sulfamate. Topiramate 25mg, 50mg, 100mg, 200mg.

Also: Topiramate

TOPAMAX SPRINKLE CAPS

Topiramate 15mg, 25mg; coated beads in caps.

Indications: Initial monotherapy and adjunct in partial-onset or primary generalized tonic-clonic seizures. Adjunct in Lennox-Gastaut syndrome.

Adults: May swallow caps whole or sprinkle contents onto soft food (swallow immediately). Give in two equally divided doses. Monotherapy: initially 50mg/day, increase at 1-week intervals by increments of 50mg/week for the 1st 4 weeks, then increase by 100mg/week for weeks 5–6 to target

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dose of 400mg/day. Adjunctive therapy: ≥ 17 years: Initially 25–50mg/day, increase at 1-week intervals by 25–50mg/day every week (see literature) to target dose of 200–400mg/day (partial onset seizures or Lennox-Gastaut) or 400mg/day (primary generalized tonic-clonic seizures); usual max 1.6g/day. Renal impairment (CrCl < 70 mL/min): reduce dose by $\frac{1}{2}$. Hemodialysis: may need extra dose.

Children: May swallow caps whole or sprinkle contents onto soft food (swallow immediately). Give in two equally divided doses. Monotherapy: < 2 yrs: not recommended. 2 to < 10 yrs: (dosing based on weight) initially 25mg/day in the PM for the 1st week, then increase to 50mg/day in the 2nd week; subsequently, may increase weekly by 25–50mg/day as tolerated. Titration to the minimum or maximum maintenance dose should be attempted over 5–7 weeks: see literature. ≥ 10 yrs: initially 50mg/day, increase at 1-week intervals by increments of 50mg/week for the 1st 4 weeks, then increase by 100mg/week for weeks 5–6 to target dose of 400mg/day. Adjunctive therapy: < 2 yrs: not recommended. 2–16 yrs: Initially 1–3mg/kg (max 25mg) per day given in the PM for 1 week, increase at 1–2 week intervals by 1–3mg/kg/day to target range of 5–9mg/kg/day in 2 divided doses. Renal impairment (CrCl < 70 mL/min): reduce dose by $\frac{1}{2}$. Hemodialysis: may need extra dose.

Warnings/Precautions: Discontinue if acute myopia and secondary angle-closure glaucoma occur. Hepatic or renal impairment. Kidney stones. Maintain adequate hydration and caloric intake; avoid ketogenic diets. Monitor serum bicarbonate during therapy; consider reducing dose or discontinuing if acidosis occurs. Inborn errors of metabolism, reduced mitochondrial activity: increased risk of hyperammonemia; measure ammonia levels if encephalopathic symptoms occur. Monitor closely for oligohydrosis and hyperthermia (esp. children). Suicidal tendencies (monitor). Avoid abrupt cessation. Fetal toxicity. Labor & delivery. Pregnancy (Cat.D). Nursing mothers.

Interactions: Contraindicated with metformin during metabolic acidosis condition. Avoid concomitant other carbonic anhydrase inhibitors (eg, zonisamide, acetazolamide, dichlorophenamide). Phenytoin, carbamazepine, valproic acid, lamotrigine reduce topiramate levels. Topiramate reduces valproic acid levels. May increase phenytoin levels. May antagonize digoxin, oral contraceptives, risperidone. CNS depression potentiated with alcohol, other CNS depressants. Hyperammonemia (w/ and w/o encephalopathy) and/or hypothermia possible with valproic acid. Caution with other drugs that interfere with temperature regulation (eg, anticholinergics, carbonic anhydrase inhibitors). Monitor lithium levels with high-dose topiramate.

Adverse reactions: Paresthesia, anorexia, weight decrease, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, difficulty with

memory, difficulty with concentration/attention, cognitive problems, confusion, mood problems, fever, infection, flushing; kidney stones, hyperchloremic acidosis, hyperammonemia.

How supplied: Tabs, caps–60

TOPIRAMATE

R

TROKENDI XR Supernus

Sulfamate. Topiramate 25mg, 50mg, 100mg, 200mg; ext-rel caps.

Indications: Initial monotherapy and adjunct in partial-onset or primary generalized tonic-clonic seizures. Adjunct in Lennox-Gastaut Syndrome.

Adults: Swallow whole. Do not sprinkle on food, chew, or crush. Monotherapy: initially 50mg once daily, increase at 1-week intervals by increments of 50mg/week for the first 4 weeks, then increase by 100mg/week for Weeks 5–6 to target dose of 400mg once daily. Adjunctive therapy: ≥ 17 yrs: initially 25–50mg once daily, increase at 1-week intervals by 25–50mg/week until target dose of 200–400mg once daily (partial onset seizures or Lennox-Gastaut) or 400mg once daily (primary generalized tonic-clonic seizures); usual max 1.6g/day. Renal impairment (CrCl < 70 mL/min): reduce dose by $\frac{1}{2}$. Hemodialysis: may need extra dose.

Children: Swallow whole. Do not sprinkle on food, chew, or crush. Monotherapy: < 10 yrs: not recommended. ≥ 10 yrs: initially 50mg once daily, increase at 1-week intervals by increments of 50mg/week for the first 4 weeks, then increase by increments of 100mg/week for Weeks 5–6 to target dose of 400mg once daily. Adjunctive therapy: < 6 yrs: not recommended. 6–16 yrs: initially 1–3mg/kg (max 25mg) once in the PM for one week, increase at 1- or 2-week intervals by increments of 1–3mg/kg to target range of 5–9mg/kg once daily or until optimal clinical response. Renal impairment (CrCl < 70 mL/min): reduce dose by $\frac{1}{2}$. Hemodialysis: may need extra dose.

Contraindications: Recent alcohol use (within 6hrs prior to and 6hrs after topiramate ext-rel). Concomitant metformin during metabolic acidosis.

Warnings/Precautions: Discontinue if acute myopia and secondary angle-closure glaucoma occur. Hepatic or renal impairment. Kidney stones. Maintain adequate hydration and caloric intake; avoid ketogenic diets. Obtain baseline and periodic serum bicarbonate during therapy; consider reducing dose or discontinuing if acidosis occurs. Inborn errors of metabolism, reduced mitochondrial activity: increased risk of hyperammonemia; measure ammonia levels if encephalopathic symptoms occur. Monitor for oligohydrosis and hyperthermia (esp. children). Suicidal tendencies (monitor). Avoid abrupt cessation. Fetal toxicity. Labor & delivery. Pregnancy (Cat.D). Nursing mothers.

Interactions: See Contraindications. Avoid concomitant other carbonic anhydrase inhibitors (eg, zonisamide, acetazolamide, dichlorophenamide).

Phenytoin, carbamazepine, valproic acid, lamotrigine reduce topiramate levels. May increase phenytoin levels. May antagonize oral contraceptives and valproic acid levels. CNS depression potentiated with alcohol, other CNS depressants. Hyperammonemia (w/o or w/o encephalopathy) and/or hyperthermia possible with valproic acid. Caution with other drugs that interfere with temperature regulation (eg, anticholinergics, carbonic anhydrase inhibitors). Monitor lithium levels with high-dose topiramate.

Adverse reactions: Paresthesia, anorexia, weight decrease, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, difficulty with memory, difficulty with concentration/attention, cognitive problem, confusion, mood problems, fever, infection, flushing; metabolic acidosis, kidney stones, hyperammonemia, vision disorders.

How supplied: XR caps-100

VALPROIC ACID

DEPAKENE AbbVie
Valproic acid 250mg; caps.

Also: Valproic acid
DEPAKENE SYRUP

Valproic acid (as sodium salt) 250mg/5mL.

Indications: Monotherapy or adjunct in complex partial seizures; simple or complex absence seizures. Adjunct in multiple seizure types.

Adults and Children: Swallow whole. Partial seizures: <10yrs: not recommended. ≥10yrs: Initially 10–15mg/kg per day, may increase by 5–10mg/kg per week. Conversion to monotherapy: see literature. Absence seizures: Initially 15mg/kg per day; may increase weekly by 5–10mg/kg per day. All: give in divided doses if total daily dose >250mg; max 60mg/kg per day.

Contraindications: Hepatic disease or significant hepatic dysfunction. Urea cycle disorders.

Warnings/Precautions: Discontinue if hepatic dysfunction, pancreatitis, thrombocytopenia, or hyperammonemia occurs. History of liver disease; monitor liver function and clinical symptoms (esp. for 1st 6 months). Reevaluate periodically. Avoid abrupt cessation. Evaluate for urea cycle disorders. Increased risk of hepatotoxicity in patients with congenital metabolic disorders, multiple AEDs, severe seizure disorders with mental retardation, organic brain disorders, in children <2 years of age. Monitor platelets, bleeding time (at baseline, before surgery, and in pregnancy); reevaluate periodically. May affect viral load in HIV or CMV infection. Suicidal tendencies (monitor). Elderly (monitor fluid and nutritional intake, and for dehydration, somnolence, tremor, other adverse reactions). Pregnancy (Cat.D): apprise female patients of childbearing potential of risks to fetus (eg, neural tube defects). Nursing mothers.

Interactions: Monitor levels of valproate, ethosuximide, other anticonvulsants, and when an enzyme inducer is added or withdrawn. Potentiates carbamazepine, diazepam, ethosuximide, lamotrigine,

phenobarbital, phenytoin, tolbutamide, warfarin, zidovudine, amitriptyline, nortriptyline. Potentiated by aspirin, felbamate. Levels reduced by rifampin, phenytoin, carbamazepine, phenobarbital. CNS depression with alcohol, other CNS depressants. Clonazepam may induce absence status in patients with absence seizures. Concomitant topiramate may cause hyperammonemic encephalopathy. May interfere with urine ketone and thyroid tests. Others: see literature.

Adverse reactions: GI upset, somnolence, dizziness, asthenia, abdominal pain, rash, increased appetite, tremor, weight gain, back pain, alopecia, headache, fever, anorexia, constipation, diplopia, blurred vision, ataxia, nystagmus, emotional lability, abnormal thinking, amnesia, flu syndrome, infection, bronchitis, rhinitis, ecchymosis, peripheral edema, insomnia, nervousness, depression, pharyngitis, dyspnea, tinnitus; hepatotoxicity, pancreatitis, thrombocytopenia, hyperammonemia, hypothermia, multi-organ hypersensitivity syndrome.

How supplied: Caps-100
Syrup-pt

VIGABATRIN

SABRIL TABLETS Lundbeck
Antiepileptic. Vigabatrin 500mg; tabs.

Indications: Adjunctive therapy in adult patients with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Not a first line agent for CPS.

Adults: >18yrs: Use tabs. Initially 500mg twice daily; titrate if needed by 500mg per week to 1.5g twice daily. CrCl >50–80mL/min: reduce dose by 25%; CrCl >30–50mL/min: reduce dose by 50%; CrCl >10–<30mL/min: reduce dose by 75%. Reevaluate periodically. Withdraw gradually (reduce by 1g/day at weekly intervals).

Children: Not recommended.

Also: Vigabatrin

SABRIL FOR ORAL SOLUTION

Vigabatrin 500mg/packet; pwd for oral soln.

Indications: Monotherapy for infantile spasms in patients ages 1 month–2 years, when the potential benefits outweigh the risk of vision loss.

Adults: Not applicable.

Children: <1 month: not recommended.

1month–2yrs: use soln. Initially 50mg/kg/day twice daily; titrate by 25–50mg/kg/day at 3-day intervals to max 150mg/kg/day. Renal dysfunction: reduce dose (see literature). Withdraw gradually (reduce by 25–50mg/kg every 3–4 days).

Warnings/Precautions: Monitor vision, including visual acuity and dilated indirect ophthalmoscopy, and visual fields, at baseline (within 4 weeks) and every 3 months, and for 3–6 months after discontinuing; risk of vision loss increases as dose and cumulative exposure increased. Discontinue if no substantial benefit after treating for 3 months (in adults) or

2–4 weeks (in infants); sooner if obvious treatment failure. Monitor for depression, suicidal ideation, changes in mood/behavior. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: May antagonize phenytoin. Avoid others that can cause visual or ophthalmic dysfunction. May interfere with liver function tests (eg, ALT), others (see literature).

Adverse reactions: Vision loss (may be severe and permanent), other visual changes (blurring, diplopia, asthenopia, eye pain), headache, nystagmus, anemia, somnolence, fatigue, peripheral neuropathy, weight gain, edema, arthralgia, dizziness, tremor, CNS/neurological effects, rash; abnormal MRI signal changes in infants.

Note: Available only through restricted distribution program. To register call (888) 45-SHARE. Encourage pregnant patients exposed to vigabatrin to call (888) 233-2334. To report ADRs: (800) 455-1141.

How supplied: Tabs–100; Pwd packets–50

SECTION 12:

NUTRITION

12A Anorexia/cachexia

DRONABINOL

MARINOL AbbVie

Cannabinoid. Dronabinol 2.5mg, 5mg, 10mg; caps; contains sesame oil.

Indications: Anorexia with weight loss in AIDS patients.

Adults: Individualize. Initially 2.5mg twice daily before lunch and supper. If intolerable, may reduce to 2.5mg once in the evening. May increase gradually to max 20mg/day in divided doses.

Children: Not recommended.

Warnings/Precautions: Seizure or cardiac disorders. History of psychiatric disorders (eg, mania, depression, schizophrenia) or substance abuse.

Write $\mathbb{R}$ for smallest practical amount. Keep patient under responsible adult supervision (esp. when dose is adjusted). Children. Elderly (monitor: esp. with dementia). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with benzodiazepines, barbiturates, alcohol, other CNS depressants and other psychoactive substances (avoid). May affect, or be affected by other drugs that are highly protein bound (eg, sympathomimetics, anticholinergics, tricyclic antidepressants). Antagonizes theophylline.

Adverse reactions: Psychomimetic reactions, euphoria, depression, behavior disorders, drowsiness, dizziness, fatigue, somnolence, altered mental status, seizures (discontinue if occurs), ataxia, anxiety, paresthesia, tachycardia, hypotension, vasodilation, tolerance and withdrawal syndrome.

How supplied: Caps–60

CIII

MEGESTROL

$\mathbb{R}$

MEGACE ORAL SUSPENSION

Bristol-Myers Squibb

Progestin. Megestrol acetate 40mg/mL; lemon-lime flavor.

Indications: Anorexia, cachexia, or unexplained significant weight loss in patients diagnosed with AIDS.

Adults: Initially 800mg/day.

Children: Not recommended.

Contraindications: Nursing mothers.

Warnings/Precautions: History of thromboembolic disease. Diabetes. Pregnancy (Cat.X): not recommended.

Interactions: May increase insulin requirements. Decreases indinavir levels.

Adverse reactions: GI upset, impotence, flatulence, rash, hypertension, fever, decreased libido, breakthrough bleeding, hyperglycemia, insomnia.

How supplied: Susp (40mg/mL)–80z

12B Vitamins/minerals/supplements

L-CYSTEINE

$\mathbb{R}$

L-CYSTEINE HCl INJECTION (various)

Amino acid. L-Cysteine HCl 50mg/mL; soln for IV infusion after dilution; contains aluminum, sulfur; preservative-free.

Indications: An additive to crystalline amino acid injections to meet essential nutritional requirements for infants given TPNs.

Adults: Not applicable.

Children: See literature. Rotate inj site. Give by central venous infusion. Add 0.5g L-Cysteine with 12.5g crystalline amino acid injection; dilute as indicated.

Contraindications: Hepatic coma. Metabolic disorders (eg, impaired nitrogen utilization).

Warnings/Precautions: Hepatic, renal, pulmonary, or cardiac insufficiency. Hyperkalemia. Metabolic or respiratory alkalosis. Monitor hepatic and renal function; discontinue if BUN levels exceed normal postprandial limits and continue to rise. Monitor blood (eg, CBC, ammonia, glucose, electrolytes, cholesterol, acid-base balance, serum proteins, osmolality), urine osmolality and glucose during therapy. Premature neonates. Pregnancy.

Interactions: Concomitant tetracycline reduces nitrogen sparing effects.

Adverse reactions: Local reactions (eg, warm sensation, erythema, phlebitis, thrombosis), flushing, fever, nausea.

How supplied: Single-dose vials (10mL)–10

PHYTONADIONE**MEPHYTON** ValeantPhytonadione (Vit. K₁) 5mg; scored tabs.**Indications:** Secondary hypoprothrombinemia.**Adults:** Initially 2.5–25mg as a single dose depending on severity and response; max 50mg.**Children: Not recommended.****Warnings/Precautions:** Does not counteract effects of heparin. Thromboembolism. Hepatic disease. Absorption requires endogenous bile supply. Neonates. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Reduced absorption with mineral oil, cholestyramine. Antagonizes coumarin or indanediol derivative anticoagulants.**Adverse reactions:** Gastric disturbances, rash.**How supplied:** Tabs–100

Rx

days elapse between taking the 28th tablet of one pack and the first tablet of the next pack. Menses usually occurs during the tablet-free or inert tablet days; the next pack should be started whether or not menses has occurred. Tablets should be taken at the same time each day for maximum efficacy, and should be taken in the correct order. Some products (eg, **Mircette**, **Kariva**), use two inert tablets between an initial 21-day phase combining a progestin with an estrogen and a second 5-day phase that consists of an estrogen alone. **Seasonique** and **LoSeasonique** are extended-cycle oral contraceptives that both consist of an 84-day cycle of combined estrogen and progestin tablets followed by 7-days of low-dose estrogen tablets.

Several different regimens are recommended for beginning the first cycle of the various pill types, including Day 1 and Sunday starts. Day 1 is the first day of menses. In the Day 1 start regimen, the first pill of the first cycle is taken on the day menses begins. In the Sunday start regimen, the first pill is taken on the first Sunday after menses begins; if menses begins on a Sunday, then the first pill is taken that day. The Sunday-start regimen necessitates back-up contraceptive measures during the first cycle. In the event of a missed pill, the product labeling should be consulted; additional contraception may be needed until a normal menses begins, ensuring contraception for that cycle.

Contraindications: High risk of arterial or venous thrombotic disease (eg, smokers or migraineurs over age 35, history of DVT or thromboembolism, cerebrovascular or coronary artery disease, thrombogenic valvular disease, atrial fibrillation, subacute bacterial endocarditis, hypercoagulopathies, uncontrolled hypertension, diabetes with vascular disease, headaches with focal neurologic symptoms). Breast or other estrogen or progestin-sensitive neoplasms. Undiagnosed abnormal uterine bleeding. Hepatic disease or tumors. Pregnancy (Cat.X). For **Yasmin**, **Yaz**, **Beyaz**, **Safyral**, **Loryna**, **Syeda**: also renal or adrenal insufficiency.

SECTION 13:**OB/GYN****13A Contraception****PRESCRIBING NOTES**

Oral contraceptives are classified on the basis of their estrogen and progestin content.

COMBINED ESTROGEN AND PROGESTIN PREPARATIONS

(combined oral contraceptives—COCs—and other combination hormonal products) suppress ovulation by imitating the feedback inhibition of endogenous estrogen and progesterone on the pituitary and hypothalamus. This reduces the secretion of follicle-stimulating hormone and luteinizing hormone (which are necessary for growth and maturation of the follicle and for ovulation). These combinations also cause the endometrium to become thin and the cervical mucus to become resistant to sperm penetration. Tubal motility and secretion are also affected.

Most **combination, biphasic, and triphasic oral contraceptives** are available in both 21-tablet packs and 28-tablet packs. In the 21-tablet packs, all 21 tablets contain active ingredients. After the last pill in a pack is taken, a 7 day tablet-free period is followed by initiation of the next pack. In the 28-tablet packs, the first 21 or 24 pills contain active ingredients and the remaining pills contain inactive ingredients. No tablet-free

Warnings/Precautions: Discontinue if thrombotic event, unexplained visual changes, or jaundice occurs, and at least 4 weeks before through 2 weeks after surgery associated with increased risk of thromboembolism. Diabetes. Prediabetes. Depression. Uncontrolled dyslipidemias. Pregnancy-related cholestasis. Evaluate significant changes in headaches, irregular uterine bleeding, amenorrhea. Monitor blood pressure. Nursing mothers: not recommended. For **Yasmin, Yaz, Beyaz, Safyral, Loryna, Syeda**: also, monitor K⁺ during 1st cycle if risk of hyperkalemia.

Interactions: May be antagonized by CYP3A4 or other enzyme inducers (eg, barbiturates, bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate) (use backup contraception). May be affected by protease inhibitors. May antagonize lamotrigine. May affect lab tests (eg, coagulation factors, lipids, glucose tolerance, binding proteins). May need dose adjustment of thyroid hormones. For **Yasmin, Yaz, Beyaz, Safyral, Loryna, Syeda**: also, monitor K⁺ during 1st cycle with drugs that increase potassium (eg, ACE inhibitors, angiotensin receptor blockers, NSAIDs, K⁺ sparing diuretics).

Adverse reactions: Headache, irregular uterine bleeding, mastodynia, GI upset, acne, increased weight; hypertension, transient delay of ovulation after discontinuation, edema, chloasma. Increased risk of gallbladder disease, thromboembolic disorders.

PROGESTIN-ONLY oral contraceptives, or progestin-only pills (POPs, or "mini-pills") alter cervical mucus, exert a progestational effect on the endometrium, interfering with implantation, and, in some patients, suppress ovulation. These pills are taken daily, every day, without a drug-free interval. It is particularly important that these be taken at the same time every day (preferably 4 to 6 hours before expected intercourse) and that back-up contraceptive measures are taken in the event of even one missed or late pill.

Contraindications: Breast carcinoma. Undiagnosed abnormal genital bleeding. Liver tumors. Pregnancy (Cat.X).

Precautions: Cigarette smoking. Do physical exams at least annually. Discontinue if migraine or other serious headaches occur. Use back-up contraception for 48 hours if POP is taken 3 hours or more late. Nursing mothers: if not exclusively breastfeeding may start POP 3 weeks after delivery; if fully breastfeeding may start POP 6 weeks after delivery.

Interactions: Antagonized by hepatic enzyme-inducing drugs (eg, phenobarbital, rifampin).

Adverse reactions: Menstrual irregularities, frequent or irregular bleeding, mastodynia, headache, nausea, dizziness; androgenic effects (rare).

DESOGESTREL + ETHINYL ESTRADIOL

R

APRI Teva US Generics

Progestin + estrogen. Desogestrel 0.15mcg, ethinyl estradiol 30mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

DESOGESTREL + ETHINYL ESTRADIOL

R

KARIVA Teva US Generics

Progestin + estrogen. Desogestrel 0.15mcg, ethinyl estradiol 20mcg (21 tabs); inert (2 tabs); ethinyl estradiol 10mcg (5 tabs).

Indications: Oral contraception.

Adults: Take in correct sequence at same time each day; max 24 hours between doses. 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

DESOGESTREL + ETHINYL ESTRADIOL

R

MIRCETTE Teva Women's Health

Progestin + estrogen. Desogestrel 0.15mcg, ethinyl estradiol 20mcg (21 tabs); inert (2 tabs); ethinyl estradiol 10mcg (5 tabs).

Indications: Oral contraception.

Adults: Take in correct sequence at same time each day; max 24 hours between doses. 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

DESOGESTREL + ETHINYL ESTRADIOL

R

VELIVET Teva US Generics
Progestin + estrogen. Desogestrel 0.1mg, ethinyl estradiol 25mcg (7 tabs); desogestrel 0.125mg, ethinyl estradiol 25mcg (7 tabs); desogestrel 0.15mg, ethinyl estradiol 25mcg (7 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

DROSPIRENONE + ETHINYL ESTRAIOL

R

OCELLA Teva US Generics
Progestin + estrogen. Drospirenone 3mg, ethinyl estradiol 30mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-3

DROSPIRENONE + ETHINYL ESTRADIOL + LEVOMEFOLATE

R

BEYAZ Bayer
Progestin + estrogen + folate. Drospirenone 3mg + ethinyl estradiol (as betadex clathrate) 20mcg + levomefolate calcium 0.451mg (24 pink tabs); levomefolate calcium 0.451mg (4 light orange tablets).

Indications: Oral contraception. To raise folate levels in women who choose to use an oral contraceptive for contraception.

Adults: 1 tablet daily for 28 days; repeat. Take at the same time daily. Use Day 1 or Sunday start for 1st cycle; use backup method for first 7 days. Allow at least 4 weeks postpartum, if not breastfeeding, to begin cycle.

Children: Premenarchal: not recommended.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-3 (3×28 day cycles)

DROSPIRENONE + ETHINYL ESTRADIOL + LEVOMEFOLATE

R

SAFYRAL Bayer

Progestin + estrogen + folate. Drospirenone 3mg, ethinyl estradiol 30mcg, levomefolate calcium 0.451mg (21 tablets); levomefolate calcium 0.451mg (7 tablets).

Indications: Oral contraception. To raise folate levels in women who choose to use an OC for contraception.

Adults: 1 tablet daily for 28 days; repeat. Take at the same time daily. Use Day 1 or Sunday start for 1st cycle; use backup method for first 7 days.

Children: Premenarchal: not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-3 (3×28 day cycles)

ETHYNODIOL DIACETATE + ETHINYL ESTRADIOL

R

KELNOR 1/35 Teva US Generics
Progestin + estrogen. Ethynodiol diacetate 1mg, ethinyl estradiol 35mcg, 21 tabs; inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-3

ETONOGESTREL

R

IMPLANON Merck

Progestin. Etonogestrel 68mg; implantable rod; latex-free.

Indications: Subdermal contraception.

Adults: See literature. Insert 1 implant subdermally in the inner side of upper (non-dominant) arm. Remove no later than 3 years after insertion.

Children: Premenarchal: not applicable.

Contraindications: Thromboembolic disorders. Liver tumors. Active liver disease. Undiagnosed abnormal genital bleeding. Breast carcinoma. Pregnancy.

Warnings/Precautions: Overweight women (may be less effective). Do complete physical exam before insertion and at least annually. Exclude pregnancy (see literature for switching from other contraceptive methods); use back-up contraception if appropriate. See literature for insertion and removal technique; perform only if properly qualified. Remove implant if jaundice or thrombotic event occurs, or if a pregnancy is maintained; consider removing implant in prolonged immobilization. Hypertension. Renal disease. Depression. Monitor diabetes, hyperlipidemias. Nursing mothers: may use after 4th postpartum week.

Interactions: Chronic antiepileptic or other potent hepatic enzyme-inducing drugs (eg, barbiturates,

phenytoin, carbamazepine, rifampin, felbamate, modafinil): not recommended. May be antagonized by other hepatic enzyme inducers (eg, St. John's wort, protease inhibitors); use non-hormonal contraception. Levels increased by ketoconazole, itraconazole, other hepatic enzyme inhibitors. May affect measurement of sex hormone-binding globulin, thyroxine.

Adverse reactions: Headache, vaginitis, weight increase, acne, mastodynia, menstrual irregularities (eg, amenorrhea, changes in bleeding patterns), abdominal pain (exclude ectopic pregnancy), leukorrhea, dizziness, back pain, emotional lability, nausea, depression, insertion site pain; thrombotic events, others (see literature).

Note: Provide adequate counseling. Obtain signed written consent (see literature).

How supplied: Rod implant (w. insertion device)-1

ETONOGESTREL + BARIUM SULFATE R

NEXPLANON Merck

Progestin. Etonogestrel 68mg, barium sulfate 15mg; radiopaque; implantable rod; latex-free.

Indications: Subdermal contraception.

Adults: See literature. Insert 1 implant subdermally in the inner side of upper (non-dominant) arm. Remove no later than 3 years after insertion.

Children: Premenarchal: not applicable.

Contraindications: Thromboembolic disorders. Liver tumors. Active liver disease. Undiagnosed abnormal genital bleeding. Breast carcinoma. Pregnancy.

Warnings/Precautions: Overweight women (may be less effective). Do complete physical exam before insertion and at least annually. Exclude pregnancy (see literature for switching from other contraceptive methods); use backup contraception if appropriate. See literature for insertion and removal technique; perform only if properly qualified. Remove implant if jaundice or thrombotic event occurs, or if a pregnancy is maintained; consider removing implant in prolonged immobilization. Hypertension. Renal disease. Depression. Monitor diabetes, hyperlipidemias, visual changes. Nursing mothers: may use after 4th postpartum week.

Interactions: May be antagonized by other hepatic enzyme inducers (eg, barbiturates, bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate, protease inhibitors, non-nucleoside reverse transcriptase inhibitors); use non-hormonal contraception. Levels increased by ketoconazole, itraconazole, other hepatic enzyme inhibitors. May affect measurement of sex hormone-binding globulin, thyroxine.

Adverse reactions: Change in menstrual bleeding pattern, headache, vaginitis, weight increase, acne, breast pain, abdominal pain (exclude ectopic pregnancy), pharyngitis, leukorrhea, influenza-like symptoms, dizziness, back pain, emotional lability, nausea, depression, insertion site pain; thrombotic events, others (see literature).

Note: Provide adequate counseling. Obtain signed written consent (see literature).

How supplied: Single rod implant (in pre-loaded disposable applicator)-1

ETONOGESTREL + ETHINYL ESTRADIOL R

NUVARING Merck

Hormonal vaginal contraceptive (progestin + estrogen). Etonogestrel 120mcg/day, ethinyl estradiol 15mcg/day; vaginal ring.

Indications: Contraception.

Adults: Insert 1 ring vaginally (prior to or on Day 5 of cycle) and leave in place for 3 weeks, then remove for 1 ring-free week; repeat; backup method (eg, condoms) recommended during first week. Switching from combination oral contraceptives: insert 1 ring any time within 7 days after last tablet and no later than the day a new cycle of pills was to start (no backup method needed). Switching from progestin-only contraceptives: see literature.

Children: Premenarchal: not applicable.

Contraindications: See literature.

Thrombophlebitis or thromboembolic disorders. Breast or other estrogen-dependent neoplasms. Undiagnosed abnormal genital bleeding. Cholestatic jaundice of pregnancy or jaundice with prior hormonal contraceptive use. Pregnancy (Cat.X).

Warnings/Precautions: Predisposition to vaginal irritation, ulceration, or expulsion of ring (eg, vaginal stenosis, cervical prolapse, rectoceles, cystoceles). Smokers (>15 cigarettes/day) >35 years of age: not recommended. Discontinue if jaundice, visual disturbances, migraine or other severe headaches occur. Uncontrolled hypertension. Do regular complete physical exams. Nursing mothers: not recommended.

Interactions: Do not use with diaphragm (ring device may interfere with diaphragm positioning). Antagonized by hepatic enzyme inducing drugs (eg, rifampin, griseofulvin, St. John's wort, protease inhibitors), possibly others.

Adverse reactions: Vaginitis, leukorrhea, ring device related events (eg, foreign body sensation, coital problems, ring device expulsion), hypertension, nausea, vomiting, breakthrough bleeding, amenorrhea, transient delay of ovulation after discontinuation, edema, mastodynia, weight gain, headache. Increased risk of gallbladder disease, thromboembolic events. See literature.

How supplied: Rings-1, 3

IUD R

PARAGARD T380A Teva Women's Health
IUD. Copper-bearing intrauterine contraceptive device.

Indications: Intrauterine contraception.

Adults: See literature. ≥ 16 yrs: Insert into uterine cavity. Check placement shortly after first menses. Replace at least every 10 years.

Children: <16 yrs: not recommended.

Contraindications: Uterine abnormality. Uterine or cervical malignancy. Pelvic inflammatory disease or risk thereof. Postpartum or postabortal endometritis in the past 3 months. Genital actinomycosis. Abnormal genital bleeding. Cervicitis. Wilson's disease. Retained IUD. Pregnancy or suspicion of pregnancy.

Warnings/Precautions: Vaginal bleeding. Ectopic pregnancy. Immunocompromised. Immunosuppressive therapy. Avoid medical diathermy. Assure suitable uterine anatomy before insertion. Remove the device if evidence of partial expulsion, perforation, or breakage.

Adverse reactions: Bleeding, cramps, anemia, dyspareunia, pelvic infection, infertility, ectopic pregnancy, uterine or cervical perforation, embedment or fragmentation of device, septicemia (during pregnancy), spontaneous abortion, vasovagal reactions (during insertion or removal).

How supplied: Device-1, 5

LEVONORGESTREL

OTC

PLAN B ONE-STEP Teva Women's Health
Emergency contraceptive. Levonorgestrel 1.5mg; tabs.

Indications: Prevention of pregnancy after known or suspected contraceptive failure or unprotected intercourse. Not for use as regular contraceptive.

Adults: Rule out pregnancy first. Take one single-dose as soon as possible but no later than 72hrs after unprotected intercourse. If vomiting occurs within 2hrs, may consider repeating dose.

Children: Not applicable.

Contraindications: See full labeling. Known or suspected pregnancy.

Warnings/Precautions: See full labeling. Ectopic pregnancy. Does not protect against STI/HIV.

Interactions: Drugs (eg, barbiturates, carbamazepine, phenytoin) or herbal products (eg, St. John's wort) that induce certain enzymes (eg, CYP3A4) may decrease effectiveness.

Adverse reactions: Heavier menstrual bleeding, nausea, abdominal pain, fatigue, headache, dizziness, breast tenderness, delay of menses (>7days).

How supplied: Tabs-1

LEVONORGESTREL + ETHINYL ESTRADIOL

Rx

AVIANE Teva US Generics
Progestin + estrogen. Levonorgestrel 0.1mg, ethinyl estradiol 20mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

LEVONORGESTREL + ETHINYL ESTRADIOL

Rx

CAMRESE Teva US Generics

Progestin + estrogen. Levonorgestrel 0.15mg, ethinyl estradiol 30mcg (84 tabs); ethinyl estradiol 10mcg (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 91 days; repeat. Use Sunday-start regimen. Take pills in order (84 levonorgestrel + ethinyl estradiol tabs, then 7 ethinyl estradiol tabs).

Children: Premenarchal: not recommended.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Tablet dispenser-2 × 91 tablets

LEVONORGESTREL + ETHINYL ESTRADIOL

Rx

CAMRESE LO Teva US Generics

Progestin + estrogen. Levonorgestrel 0.1mg, ethinyl estradiol 20mcg (84 tabs); ethinyl estradiol 10mcg (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 91 days; repeat. Use Sunday-start regimen. Take pills in order (84 levonorgestrel + ethinyl estradiol tabs, then 7 ethinyl estradiol tabs).

Children: Premenarchal: not recommended.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Tablet dispenser-2 × 91 tablets

LEVONORGESTREL + ETHINYL ESTRADIOL

Rx

ENPRESSE Teva US Generics

Progestin + estrogen. Levonorgestrel 0.05mg, ethinyl estradiol 30mcg (6 tabs); levonorgestrel 0.075mg, ethinyl estradiol 40mcg (5 tabs); levonorgestrel 0.125mg, ethinyl estradiol 30mcg (10 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

LEVONORGESTREL + ETHINYL ESTRADIOL

Rx

JOLESSA Teva US Generics

Progestin + estrogen. Levonorgestrel 0.15mg, ethinyl estradiol 30mcg (84 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 91 days; repeat. Use Sunday start for first cycle.

Children: Pre-menarchal: not recommended.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs–3

LEVONORGESTREL + ETHINYL ESTRADIOL R

LESSINA Teva US Generics

Progestin + estrogen. Levonorgestrel 0.1mg, ethinyl estradiol 20mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: Take at same time each day; max 24 hours between doses of active tabs. 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs–6

LEVONORGESTREL + ETHINYL ESTRADIOL R

LOSEASONIQUE Teva Women's Health

Progestin + estrogen. Levonorgestrel 0.1mg + ethinyl estradiol 20mcg (84 orange tabs); ethinyl estradiol 10mcg (7 yellow tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 91 days; repeat. Take at the same time daily. Use Sunday start for 1st cycle; use backup method until orange tabs are taken for 7 consecutive days. Allow at least 4 weeks postpartum, if not breastfeeding, to begin cycle. Use backup method if 2 consecutive orange tabs are missed (see literature).

Children: Pre-menarchal: not recommended.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Dispensers–2 (2 × 91 day cycles)

LEVONORGESTREL + ETHINYL ESTRADIOL R

PORZIA Teva US Generics

Progestin + estrogen. Levonorgestrel 0.15mg, ethinyl estradiol 30mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs–6

LEVONORGESTREL + ETHINYL ESTRADIOL R

SEASONIQUE Teva Women's Health

Progestin + estrogen. Levonorgestrel 0.15mg, ethinyl estradiol 30mcg (84 tabs); ethinyl estradiol 10mcg (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 91 days; repeat. Use Sunday-start regimen. Take pills in order (84 levonorgestrel + ethinyl estradiol tabs, then 7 ethinyl estradiol tabs).

Children: Premenarchal: not recommended.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Tabs–91

LEVONORGESTREL + ETHINYL ESTRADIOL R

TRIPHASIL-28 Wyeth

Progestin + estrogen. Levonorgestrel 0.05mg, ethinyl estradiol 30mcg (6 tabs); levonorgestrel 0.075mg, ethinyl estradiol 40mcg (5 tabs); levonorgestrel 0.125mg, ethinyl estradiol 30mcg (10 tabs).

Also: Levonorgestrel + Ethinyl estradiol R
TRIPHASIL-21

Levonorgestrel 0.05mg, ethinyl estradiol 30mcg (6 tabs); levonorgestrel 0.075mg, ethinyl estradiol 40mcg (5 tabs); levonorgestrel 0.125mg, ethinyl estradiol 30mcg (10 tabs).

Indications: Oral contraception.

Adults: Triphasil-28: 1 tab daily for 28 days; repeat.

Triphasil-21: 1 tab daily for 21 days, then 7 tablet-free days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs–3

LEVONORGESTREL + IUD R

MIRENA Bayer

Progestin IUD. Levonorgestrel 52mg; intrauterine contraceptive system (IUD).

Indications: Intrauterine contraception in women who have had at least 1 child, and are in a stable, mutually monogamous relationship.

Adults: See literature. Insert into uterine cavity as directed. Reexamine after next menses (within 3 months). Replace at least every 5 years.

Children: Not recommended.

Contraindications: Uterine abnormality. History or risk of ectopic pregnancy. History of pelvic inflammatory disease (PID) unless subsequent intrauterine pregnancy occurred. Postpartum endometritis or septic abortion in past 3 months. Uterine or cervical neoplasia. Unresolved abnormal Pap smear. Abnormal genital bleeding. Untreated acute cervicitis or vaginitis. Acute liver disease or liver tumor. Immunosuppressed. IV drug abuse. Multiple sexual partners for patient or partner. Genital actinomycosis. Retained IUD. Breast carcinoma. Pregnancy (Cat.X).

Warnings/Precautions: Assure suitable uterine anatomy before inserting. Endocarditis risk.

Anticoagulant therapy or coagulopathies. Cervical stenosis. Predisposition to syncope, bradycardia, other neurovascular episodes. Remove device if any of these occur: menorrhagia, metrorrhagia producing anemia, STDs, AIDS, endometritis, severe dyspareunia, intractable pelvic pain, uterine or cervical perforation, pregnancy, any sign of expulsion. Consider removal if first migraine, transient cerebral ischemia, severe headache, jaundice, marked increase in BP, or severe arterial disease occurs. Check placement regularly. Nursing mothers (increased risk of uterine perforation).

Interactions: May be antagonized by CYP3A4 inducers (eg, barbiturates, bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate).

Adverse reactions: Amenorrhea, irregular bleeding, cramps, adhesions, peritonitis, intestinal perforations or obstruction, abscesses, erosion, ovarian cysts, PID, ectopic pregnancy, GI disturbances, leukorrhea, headache, vaginitis, breast or back pain, acne, depression, hypertension, nervousness, weight gain, glucose intolerance, decreased libido, abnormal Pap smear. Syncope, bradycardia, other neurovascular episodes, perforation, loss of pregnancy, sepsis (during insertion or removal). If pregnancy occurs: sepsis, miscarriage, premature labor or delivery.

How supplied: System-1

MEDROXYPROGESTERONE

R

DEPO-PROVERA Pfizer

Progestin. Medroxyprogesterone acetate 150mg/mL; IM inj.

Indications: Injectable contraception.

Adults: 150mg IM every 3 months. Give 1st dose within 5 days of onset of normal menses. Do not use for >2 years unless other methods are inadequate.

Children: Not applicable.

Also: Medroxyprogesterone

R

DEPO-SUBQ PROVERA

Medroxyprogesterone acetate 104mg/0.65mL; SC inj; contains parabens.

Adults: Inject 104mg SC every 3 months. Give 1st dose within 5 days of onset of normal menses. Do not use for >2 years unless other methods are inadequate.

Children: Not applicable.

Contraindications: Undiagnosed vaginal bleeding. Breast carcinoma. Cerebrovascular disease. Hepatic dysfunction. Pregnancy (Cat.X).

Warnings/Precautions: Conditions aggravated by fluid retention (eg, migraine). Depression. Pretreatment exam should include Pap smear. Risk of osteoporosis (eg, metabolic bone disease, anorexia, family history). Discontinue if jaundice, visual disturbances, migraine or thrombotic disorders occur. Nursing mothers.

Interactions: May be antagonized by aminoglutethimide. May reduce bone mass with

anticonvulsants, corticosteroids; avoid alcohol, tobacco.

Adverse reactions: Irregular bleeding, edema, weight or cervical changes, decreased bone mineral density, cholestatic jaundice, depression, breast tenderness, acne, hirsutism, inj site reactions.

How supplied: Vials-1, 25; Prefilled syringes (1mL)-1, 6, 24; SubQ (prefilled syringe)-1 (w. needle)

NORETHINDRONE

R

CAMILA Teva US Generics

Progestin. Norethindrone 0.35mg (28 tabs).

Indications: Oral contraception.

Adults: Continuous regimen: 1 tab daily.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

NORETHINDRONE

R

ERRIN Teva US Generics

Progestin. Norethindrone 0.35mg (28 tabs).

Indications: Oral contraception.

Adults: Continuous regimen: 1 tab daily.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

NORETHINDRONE + ETHINYL ESTRADIOL

R

ARANELLE Teva US Generics

Progestin + estrogen. Norethindrone 0.5mg, ethinyl estradiol 35mcg (7 tabs); norethindrone 1mg, ethinyl estradiol 35mcg (9 tabs); norethindrone 0.5mg, ethinyl estradiol 35mcg (5 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

NORETHINDRONE + ETHINYL ESTRADIOL

R

BALZIVA Teva US Generics

Progestin + estrogen. Norethindrone 0.4mg, ethinyl estradiol 35mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

NORETHINDRONE + ETHINYL ESTRADIOL

GENERESS FE Actavis
Progestin + estrogen. Norethindrone 0.8mg, ethinyl estradiol 25mcg (24 tabs); inert + (4 tabs); + contains ferrous fumarate 75mg; chewable tabs; spearmint flavor.

Indications: Oral contraception.

Adults: Chew 1 tab daily without water for 28 days; repeat. Take at the same time daily, in the correct order. Start Day 1 of menstrual cycle. Allow at least 4 weeks postpartum, if not breastfeeding, to begin cycle; use backup method for first 7 days.

Children: Premenarchal: not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-3

NORETHINDRONE + ETHINYL ESTRADIOL

NORTREL 1/35-28 Teva US Generics
Progestin + estrogen. Norethindrone 1mg, ethinyl estradiol 35mcg (21 tabs); inert (7 tabs).

Also: Norethindrone + Ethinyl estradiol
NORTREL 0.5/35

Norethindrone 0.5mg, ethinyl estradiol 35mcg (21 tabs); inert (7 tabs).

Also: Norethindrone + Ethinyl estradiol
NORTREL 1/35-21

Norethindrone 1mg, ethinyl estradiol 35mcg (21 tabs).

Indications: Oral contraception.

Adults: 28-day products: 1 tab daily for 28 days; repeat. 21-day product: 1 tab daily for 21 days, then 7 tablet-free days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

NORETHINDRONE + ETHINYL ESTRADIOL

NORTREL 7/7/7 Teva US Generics
Progestin + estrogen. Norethindrone 0.5mg, ethinyl estradiol 35mcg (7 tabs); norethindrone 0.75mg, ethinyl estradiol 35mcg (7 tabs); norethindrone 1mg, ethinyl estradiol 35mcg (7 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-6

NORETHINDRONE ACETATE + ETHINYL ESTRADIOL

LO LOESTRIN FE Warner Chilcott
Progestin + estrogen. Norethindrone acetate 1mg, ethinyl estradiol 10mcg (24 tabs); ethinyl estradiol 10mcg (2 tabs); inert + (2 tabs); + contains ferrous fumarate 75mg.

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat. Take at the same time daily, in the correct order. Start Day 1 of menstrual cycle. Allow at least 4 weeks postpartum, if not breastfeeding, to begin cycle; use backup method for first 7 days.

Children: Premenarchal: not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-5

NORETHINDRONE ACETATE + ETHINYL ESTRADIOL

LOESTRIN FE 1/20 Teva Women's Health
Progestin + estrogen. Norethindrone acetate 1mg, ethinyl estradiol 20mcg (21 tabs); inert + (7 tabs). + contains ferrous fumarate 75mg.

Also: Norethindrone acetate + Ethinyl estradiol

LOESTRIN FE 1.5/30

Norethindrone acetate 1.5mg, ethinyl estradiol 30mcg (21 tabs); inert + (7 tabs). + contains ferrous fumarate 75mg.

Also: Norethindrone acetate + Ethinyl estradiol

LOESTRIN 21 1/20

Norethindrone acetate 1mg, ethinyl estradiol 20mcg (21 tabs).

Also: Norethindrone acetate + Ethinyl estradiol

LOESTRIN 21 1.5/30

Norethindrone acetate 1.5mg, ethinyl estradiol 30mcg (21 tabs).

Also: Norethindrone acetate + Ethinyl estradiol

LOESTRIN 24 FE Warner Chilcott
 Norethindrone acetate 1mg, ethinyl estradiol 20mcg (24 tabs); inert + (4 tabs). + contains ferrous fumarate 75mg.

Indications: Oral contraception.

Adults: 28-day products: 1 tab daily for 28 days; repeat. 21-day products: 1 tab daily for 21 days, then 7 tablet-free days; repeat.

Children: Not applicable.

Contraindications: Thrombophlebitis or thromboembolic disorders. Cerebral vascular or coronary artery disease. Breast or other estrogen-dependent neoplasms. Undiagnosed abnormal genital bleeding. Cholestatic jaundice of pregnancy

or jaundice with prior OC use. Hepatic adenoma or carcinoma. Pregnancy (Cat.X).

Warnings/Precautions: Smokers over 35 years of age: not recommended. Uncontrolled hypertension. Hypertriglyceridemia. Discontinue if jaundice, visual disturbances, migraine or other severe headaches occur. Do regular complete physical exams. May need barrier contraception with Sunday starts or postpartum use (see literature). Nursing mothers: not recommended.

Interactions: Antagonized by hepatic enzyme inducing drugs (eg, rifampin, griseofulvin, St. John's wort), possibly others. May affect measurement of sex hormone-binding globulin levels.

Adverse reactions: Hypertension, nausea, vomiting, breakthrough bleeding, amenorrhea, transient delay of ovulation after discontinuation, edema, chloasma, mastodynia, headache, intolerance to contact lenses. Increased risk of gallbladder disease, thromboembolic disorders.

How supplied: Packs (24 Fe, 21-1/20, 21-1.5/30)-5 Packs (Fe 1/20, Fe 1.5/30)-5, 30

NORETHINDRONE ACETATE + ETHINYL ESTRADIOL R

JUNEL FE 1/20 Teva US Generics
Progestin + estrogen. Norethindrone acetate 1mg, ethinyl estradiol 20mcg (21 tabs); inert+ (7 tabs); +contains ferrous fumarate 75mg.

Also: Norethindrone acetate + Ethinyl estradiol R

JUNEL FE 1.5/30
Norethindrone acetate 1.5mg, ethinyl estradiol 30mcg (21 tabs); inert+ (7 tabs); +contains ferrous fumarate 75mg.

Also: Norethindrone acetate + Ethinyl estradiol R

JUNEL 21 1/20
Norethindrone acetate 1mg, ethinyl estradiol 20mcg (21 tabs).

Also: Norethindrone acetate + Ethinyl estradiol R

JUNEL 21 1.5/30
Norethindrone acetate 1.5mg, ethinyl estradiol 30mcg (21 tabs).

Indications: Oral contraception.

Adults: 28-day products: 1 tab daily for 28 days; repeat. 21-day products: 1 tab daily for 21 days, then 7 tablet-free days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-5

NORETHINDRONE ACETATE + ETHINYL ESTRADIOL R

TRI-LEGEST FE Teva US Generics
Progestin + estrogen. Norethindrone acetate 1mg, ethinyl estradiol 20mcg (5 tabs), norethindrone

acetate 1mg, ethinyl estradiol 30mcg (7 tabs), norethindrone acetate 1mg, ethinyl estradiol 35mcg (9 tabs); inert+ (7 tabs); + contains ferrous fumarate 75mg.

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-5

NORGESTIMATE + ETHINYL ESTRADIOL R

ORTHO TRI-CYCLEN 28 Janssen
Progestin + estrogen. Norgestimate 0.18mg, ethinyl estradiol 35mcg (7 tabs); norgestimate 0.215mg, ethinyl estradiol 35mcg (7 tabs); norgestimate 0.25mg, ethinyl estradiol 35mcg (7 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-1

NORGESTIMATE + ETHINYL ESTRADIOL R

ORTHO TRI-CYCLEN LO Janssen
Progestin + estrogen. Norgestimate 0.18mg, ethinyl estradiol 25mcg (7 tabs); norgestimate 0.215mg, ethinyl estradiol 25mcg (7 tabs); norgestimate 0.25mg, ethinyl estradiol 25mcg (7 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-1

NORGESTIMATE + ETHINYL ESTRADIOL R

PREVIFEM Qualitest
Progestin + estrogen. Norgestimate 0.25mg, ethinyl estradiol 35mcg (21 tabs); inert (7 tabs).

Indications: Oral contraception.

Adults: 1 tab daily for 28 days; repeat.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs-1

NORGESTIMATE + ETHINYL ESTRADIOL

R

SPRINTEC Teva US Generics*Progestin + estrogen.* Norgestimate 0.25mg, ethinyl estradiol 35mcg (21 tabs); inert (7 tabs).**Indications:** Oral contraception.**Adults:** 1 tab daily for 28 days; repeat.**Children:** Not applicable.**Contraindications, precautions, interactions, adverse reactions:** See Note at start of section.**How supplied:** Packs—6**NORGESTIMATE + ETHINYL ESTRADIOL**

R

TRI-PREVIFEM Qualitest*Progestin + estrogen.* Norgestimate 0.18mg, ethinyl estradiol 35mcg (7 tabs); norgestimate 0.215mg, ethinyl estradiol 35mcg (7 tabs); norgestimate 0.25mg, ethinyl estradiol 35mcg (7 tabs); inert (7 tabs).**Indications:** Oral contraception.**Adults:** 1 tab daily for 28 days; repeat.**Children:** Not applicable.**Contraindications, precautions, interactions, adverse reactions:** See Note at start of section.**How supplied:** Packs—1**NORGESTIMATE + ETHINYL ESTRADIOL**

R

TRI-SPRINTEC Teva US Generics*Progestin + estrogen.* Norgestimate 0.18mg, ethinyl estradiol 35mcg (7 tabs); norgestimate 0.215mg, ethinyl estradiol 35mcg (7 tabs); norgestimate 0.25mg, ethinyl estradiol 35mcg (7 tabs); inert (7 tabs).**Indications:** Oral contraception.**Adults:** 1 tab daily for 28 days; repeat.**Children:** Not applicable.**Contraindications, precautions, interactions, adverse reactions:** See Note at start of section.**How supplied:** Packs—6**NORGESTREL + ETHINYL ESTRADIOL**

R

CRYSSELLE Teva US Generics*Progestin + estrogen.* Norgestrel 0.3mg, ethinyl estradiol 30mcg (21 tabs); inert (7 tabs).**Indications:** Oral contraception.**Adults:** 1 tab daily for 28 days; repeat.**Children:** Not applicable.**Contraindications, precautions, interactions, adverse reactions:** See Note at start of section.**How supplied:** Packs—6**13B Dysmenorrhea****CELECOXIB**

R

CELEBREX Pfizer*NSAID (COX-2 inhibitor).* Celecoxib 50mg, 100mg, 200mg, 400mg; caps.**Indications:** Dysmenorrhea.**Adults:** ≥18yrs: 400mg once then 200mg more on 1st day if needed, then 200mg twice daily. <50kg: start at lowest recommended dose.**Children:** Not recommended.**Contraindications:** Sulfonamide or aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.**Warnings/Precautions:** Advanced renal disease or severe hepatic impairment: not recommended. Renal or liver dysfunction; reduce dose by 50% in moderate hepatic insufficiency (Child-Pugh class B). Discontinue if liver disease or systemic effects (eg, eosinophilia, rash) develops. History or risk of GI bleed/ulcer (monitor). Fluid retention. Heart failure. Hypertension. Asthma. Alcoholism. Dehydrated. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** Caution with drugs that inhibit CYP2C9 (eg, fluconazole) or are metabolized by CYP2D6. May antagonize, or increase risk of renal failure with ACEIs, diuretics. Increased risk of GI bleed with aspirin (except low-dose), corticosteroids, smoking, anticoagulants. May potentiate lithium. Monitor warfarin.**Adverse reactions:** GI upset/pain, edema, pharyngitis, increase AST/ALT, GI ulcer/bleed; rare: intracranial bleed, liver failure. See literature re: risk of cardiovascular events.**How supplied:** Caps 100mg, 200mg—100, 500; 50mg, 400mg—60**DICLOFENAC POTASSIUM**

R

CATAFLAM Novartis*NSAID (benzeneacetic acid deriv.).* Diclofenac potassium 50mg; tabs.**Indications:** Dysmenorrhea.**Adults:** 50mg 3 times daily; may give 100mg initially.**Children:** Not applicable.**Contraindications:** Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.**Warnings/Precautions:** Advanced renal disease: not recommended. Peptic ulcer. GI bleeding. Monitor AST/ALT within 4 weeks and then periodically; also blood, hepatic, and renal function in chronic use. Edema. Cardiac failure. Hypertension. Hepatic porphyria. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** Digoxin, methotrexate, cyclosporine, lithium toxicity. Antagonizes diuretics. May increase

serum potassium level with K⁺-sparing diuretics. Avoid aspirin. Monitor oral anticoagulants, insulin and sulfonyleureas. Increased risk of GI bleed with alcohol.

Adverse reactions: Peptic ulcer, GI bleeding, elevated AST/ALT, abdominal discomfort, constipation, diarrhea, indigestion, nausea, abdominal distention, headache, dizziness, fluid retention, rash (discontinue if occurs), pruritus, tinnitus. See literature re: risk of cardiovascular events.

How supplied: Tabs-100

IBUPROFEN

IBUPROFEN TABLETS (various)
NSAID (propionic acid deriv.). Ibuprofen 400mg, 600mg, 800mg.

Also: Ibuprofen

IBUPROFEN CHEWABLE TABLETS
Ibuprofen 50mg, 100mg; citrus flavor; contains phenylalanine.

Indications: Dysmenorrhea.

Adults: 400mg every 4 hours; max 3.2g/day. May take with food or milk.

Children: Not applicable.

Contraindications: Aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. History of upper GI disease. Active peptic ulcer. Impaired renal or hepatic function. Edema. Hypertension. Cardiac failure. Bleeding disorders. Diabetes. Monitor blood, hepatic, renal, and ocular function in chronic use. Discontinue if visual or liver dysfunction occurs. Dehydration. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid aspirin. May increase bleeding with anticoagulants. Increases serum lithium levels. May increase toxicity of methotrexate. May decrease effect of furosemide, thiazide diuretics. Increased risk of GI bleed with alcohol.

Adverse reactions: Peptic ulcer or perforation, GI bleeding, vision disorders, nausea, epigastric pain, heartburn, dizziness, rash (discontinue if occurs), edema, renal papillary necrosis, jaundice, hepatitis. See literature re: risk of cardiovascular events.

How supplied: Contact supplier.

MEFENAMIC ACID

PONSTEL Shionogi
NSAID (fenamate). Mefenamic acid 250mg; caps.

Indications: Dysmenorrhea.

Adults: Take with food. ≥14yrs: 500mg once, then 250mg every 6 hrs; usually for up to 2-3 days.

Children: <14yrs: not recommended.

Contraindications: Aspirin allergy. GI ulceration or inflammation. Renal dysfunction. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Active or history of hepatic dysfunction. Bleeding disorders. Fluid

retention. Heart failure. Hypertension. Asthma. Monitor for GI ulcer/bleed (risk is increased if patient is otherwise at high-risk, extended drug treatment, high doses, smokers, alcoholics, history of GI bleed or ulcer); blood, renal, hepatic, and ocular function in chronic use. Dehydrated. Debilitated. Elderly (>65yrs). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid aspirin. Increased risk of GI bleed with anticoagulants, aspirin, corticosteroids. May potentiate methotrexate, oral anticoagulants, lithium; monitor. May be potentiated by magnesium-containing antacids. May antagonize antihypertensives, diuretics. May antagonize or increase risk of renal failure with concomitant ACE inhibitors or diuretics. Caution with inhibitors of CYP2C9.

Adverse reactions: GI disturbances (eg, abdominal pain, constipation, diarrhea, dyspepsia, nausea, flatulence, GI ulceration or bleeding), anemia, dizziness, edema, renal or hepatic dysfunction, headache, pruritus, rash (discontinue if occurs), tinnitus, drowsiness, photosensitivity, CNS effects, alopecia, blurred vision. See literature re: risk of cardiovascular events.

How supplied: Caps-100

NAPROXEN

NAPROSYN Roche
NSAID (arylacetic acid deriv.). Naproxen 250mg, 375mg, 500mg; tabs.

Also: Naproxen

NAPROSYN SUSPENSION

Naproxen 125mg/5mL; pineapple-orange flavor.

Indications: Dysmenorrhea.

Adults: Initially 500mg, then 500mg every 12 hrs or 250mg every 6-8 hrs; max 1.25g (first day), then max 1g/day.

Children: Not applicable.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation). Advanced renal disease: not recommended. Active peptic ulcer. History of GI or inflammatory bowel disease. Impaired renal or hepatic function. Hypovolemia. Heart failure. Salt depletion. Edema. Hypertension. Preexisting asthma. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid concomitant aspirin. May potentiate protein-bound drugs (eg, hydantoins, sulfonamides, sulfonyleureas). Monitor oral anticoagulants. Increased risk of GI bleeding with oral corticosteroids, SSRIs, smoking, alcohol. May antagonize diuretics, β-blockers, ACEIs, ARBs or other antihypertensives. Increased renal toxicity with

ACEIs or ARBs. Methotrexate excretion reduced. Increases serum lithium levels. Probenecid increases plasma levels and delays elimination. Concomitant H₂ blockers, sucralfate, intensive antacid therapy: use immediate-release forms of naproxen. Cholestyramine may delay absorption.

Adverse reactions: GI bleeding, peptic ulcer, constipation, heartburn, abdominal pain, nausea, headache, dizziness, drowsiness, pruritus, rash (discontinue if occurs), tinnitus, edema, nephritis, nephrotic syndrome, jaundice, hepatitis. See full labeling re: risk of cardiovascular or GI events.

How supplied: Tabs-100; Susp-pt

NAPROXEN SODIUM

ANAPROX Roche

NSAID (arylacetic acid deriv.). Naproxen sodium 275mg; tabs.

Also: Naproxen sodium

ANAPROX DS

Naproxen sodium 550mg; tabs.

Indications: Dysmenorrhea.

Adults: Initially 550mg, then 550mg every 12 hrs or 275mg every 6-8 hrs; max 1.375g (first day), then max 1.1g/day.

Children: Not applicable.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation). Advanced renal disease: not recommended. Active peptic ulcer. History of GI or inflammatory bowel disease. Impaired renal or hepatic function. Hypovolemia. Heart failure. Salt depletion. Edema. Hypertension. Preexisting asthma. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid concomitant aspirin. May potentiate protein-bound drugs (eg, hydantoins, sulfonamides, sulfonylureas). Monitor oral anticoagulants. Increased risk of GI bleeding with oral corticosteroids, SSRIs, smoking, alcohol. May antagonize diuretics, β -blockers, ACEIs, ARBs, or other antihypertensives. Increased renal toxicity with ACEIs or ARBs. Methotrexate excretion reduced. Increases serum lithium levels. Probenecid increases plasma levels and delays elimination. Concomitant H₂ blockers, sucralfate, intensive antacid therapy: use immediate-release forms of naproxen. Cholestyramine may delay absorption.

Adverse reactions: GI bleeding, peptic ulcer, constipation, heartburn, abdominal pain, nausea, headache, dizziness, drowsiness, pruritus, rash (discontinue if occurs), tinnitus, edema, nephritis, nephrotic syndrome, jaundice, hepatitis. See full labeling re: risk of cardiovascular or GI events.

How supplied: Tabs 275mg-100; 550mg-100

13C Labor and delivery

DINOPROSTONE

R

CERVIDIL Forest

Dinoprostone 10mg; controlled-release vaginal insert w. retrieval system.

Indications: Cervical ripening in patients at or near term when there is an indication for labor induction.

Adults: See literature.

Children: Not applicable.

Contraindications: Fetal distress where delivery is not imminent. Unexplained vaginal bleeding. Presence or suspicion of cephalopelvic disproportion. Where oxytocics or prolonged uterine contractions are inappropriate, including previous cesarean section, major uterine surgery. Multipara with ≥ 6 previous term pregnancies. Concomitant oxytocics. Remove insert if uterine hyperstimulation, labor, sustained uterine contractions, or other fetal/maternal adverse reactions occur and prior to amniotomy.

Warnings/Precautions: For hospital use when appropriate obstetric care is present. Ruptured membranes. Non-vertex, non-singleton presentation. Previous uterine hypertony. Glaucoma. History of childhood asthma. Monitor uterine activity, fetal status, cervical dilatation/effacement. Pregnancy (Cat.C).

Interactions: Potentiates oxytocics; delay administration of oxytocics at least 30 minutes after removal of insert.

Adverse reactions: Uterine hyperstimulation, fetal distress.

How supplied: Insert-1

DINOPROSTONE

R

PREPIDIL Pfizer

PGE₂ oxytocic. Dinoprostone 0.5mg/3g; endocervical gel.

Indications: Ripening an unfavorable cervix in pregnant women at or near term.

Adults: See literature.

Children: Not applicable.

Contraindications: Where oxytocics or prolonged uterine contractions are inappropriate, including: history of cesarean section, major uterine surgery, presence of cephalopelvic disproportion, difficult labor, traumatic delivery, 6 or more previous term pregnancies, nonvertex presentation, hyperactive or hypertonic uterine patterns, fetal distress where delivery is not imminent. Ruptured membranes. Placenta previa or unexplained vaginal bleeding. When vaginal delivery is not indicated. Concomitant oxytocics.

Warnings/Precautions: For hospital use only when immediate intensive care and acute surgical facilities can be provided. Avoid contact with skin. Monitor uterine activity, fetal status, cervix. History of/or asthma. Glaucoma or increased intraocular pressure. Renal or hepatic dysfunction. Pregnancy (Cat.C).

Interactions: Potentiates oxytocics. Oxytocin: a dosing interval of 6–12 hrs is needed, if used following Prepidil administration.

Adverse reactions: Maternal: Uterine rupture, uterine contraction abnormality, GI upset, back pain, warm feeling in vagina, fever, premature rupture of membranes. Fetal: Heart rate abnormality, fetal depression, fetal acidosis. Amnionitis and intrauterine fetal sepsis associated with extra-intrauterine administration.

How supplied: Prefilled-syringe applicator (w. catheters)–5

OXYTOCIN

PITOCIN JHP

Oxytocin 10Units/mL; IV or IM inj.

Indications: Initiation or improvement of uterine contractions in vaginal delivery. Adjunct in abortion. Control of postpartum bleeding.

Adults: Induction of labor: individualize. Initially 0.5–1milliunit/minute (see literature); adjust by 1–2 milliunits/minute at 30–60 minute intervals. Usual max at term: 9–10 milliunits/minute. Bleeding: IV, see literature. IM: 10Units after delivery of placenta. Abortion: see literature.

Children: Not applicable.

Contraindications: In antepartum use: Cephalopelvic disproportion. Unfavorable fetal position. When surgical intervention necessary. Fetal distress if labor is not imminent. Unsatisfactory progress in presence of adequate uterine activity. Hyperactive or hypertonic uterus. Invasive cervical carcinoma, active herpes genitalis, total placenta previa, vasa previa, cord presentation or prolapse or other cases where vaginal delivery is contraindicated or if predisposition for uterine rupture exists.

Warnings/Precautions: Use only in presence of qualified personnel. Monitor intrauterine pressure, fetal heart rate, maternal blood pressure.

Interactions: Avoid use within 4 hours of prophylactic vasoconstriction with caudal block anesthesia. Avoid cyclopropane anesthetics.

Adverse reactions: Maternal: anaphylaxis, postpartum or subarachnoid hemorrhage, arrhythmias, fatal afibrinogenemia, nausea, vomiting, premature ventricular contraction, pelvic hematoma, water intoxication, hypersensitivity resulting in uterine hypertonicity, spasm, tetany, or rupture. Fetal: bradycardia, arrhythmias, CNS damage, seizure, low Apgar scores, jaundice, retinal hemorrhage, death.

How supplied: Single-dose vial (1mL)–25
Multi-dose vial (10mL)–1, 25

R

Indications: Moderate to severe vasomotor symptoms of menopause. Atrophic vaginitis. Hypoestrogenism. Osteoporosis prevention.

Adults: Menopause, hypoestrogenism: 1–2mg daily, given cyclically (3 weeks on, 1 week off). Osteoporosis prevention (begin therapy soon after menopause): 0.5mg daily for 3 weeks, then stop for 1 week, then recycle; adjust. Reevaluate periodically.

Children: Not applicable.

Contraindications: Breast or estrogen-dependent cancer. Thrombophlebitis. Thromboembolic disorders. Undiagnosed abnormal genital bleeding. Pregnancy (Cat.X).

Warnings/Precautions: Patients with intact uterus should almost always receive a progestin to avoid endometrial hyperplasia. Asthma (2mg tabs). Hepatic dysfunction. Conditions aggravated by fluid retention. Familial hyperlipoproteinemia. Do initial complete physical examination and repeat annually (include BP, mammogram, and PAP smear). Discontinue if jaundice occurs. Nursing mothers.

Adverse reactions: See literature. Mastodynia, breast secretion, uterine bleeding, dysmenorrhea, amenorrhea, GI upset, headache, hypertension, edema, hypercalcemia, gallbladder or thromboembolic disease, skin changes.

How supplied: Tabs–100

ESTRADIOL + NORETHINDRONE ACETATE

R

MIMVEY Teva US Generics

ACTIVEVELLA 1mg/0.5mg Novo Nordisk

Estrogen + progestin. Estradiol 1mg, norethindrone acetate 0.5mg; tabs.

Also: Estradiol + Norethindrone acetate R

ACTIVEVELLA 0.5mg/0.1mg

Estradiol 0.5mg, norethindrone acetate 0.1mg; tabs.

Indications: In women with an intact uterus: moderate to severe vasomotor symptoms of menopause; vulvar and vaginal atrophy; prevention of postmenopausal osteoporosis.

Adults: 1 tab daily. Vasomotor symptoms, postmenopausal osteoporosis: 1mg/0.5mg or 0.5mg/0.1mg strength. Vulvar and vaginal atrophy: 1mg/0.5mg strength. Reevaluate periodically.

Children: Not applicable.

Contraindications: Breast or estrogen-dependent carcinoma. Thromboembolic disorders. Undiagnosed abnormal genital bleeding. Liver dysfunction or disease. Pregnancy (Cat.X).

Warnings/Precautions: Use for shortest duration and lowest dose consistent with treatment goals and risks. Not for prevention of cardiovascular disease or dementia. Endometrial hyperplasia. Gallbladder disease. Hypercoagulability. Familial hypercholesterolemia. Bone disease associated with hypercalcemia. Do initial complete physical (include BP, mammogram, PAP smear) and repeat annually. Conditions aggravated by fluid retention.

R

13D Menopause and HRT

ESTRADIOL

ESTRACE Warner Chilcott

Estrogen. Estradiol 0.5mg, 1mg, 2mg+; scored tabs; +contains tartrazine.

Discontinue if visual disturbances or jaundice occurs and during immobilization, or at least 2 weeks before surgery associated with thromboembolism. Manage risk factors for cardiovascular disease and venous thromboembolism appropriately. May aggravate asthma, diabetes, epilepsy, migraine, porphyria, SLE, hepatic hemangiomas. May interfere with lab tests (eg, thyroid, PT, glucose tolerance, HDL-C/LDL-C). Nursing mothers.

Adverse reactions: See literature. Increased risk of gallbladder disease, thromboembolic disorders, dementia, breast and ovarian cancer. GI upset/pain, irregular bleeding, headache, edema, hypertension, mastodynia, chloasma, others.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Packs (28 tabs)–1

ESTROGENS, CONJUGATED, A Rx

CENESTIN Teva Women's Health

Estrogen. Synthetic conjugated estrogens, A 0.3mg, 0.45mg, 0.625mg, 0.9mg, 1.25mg; tabs.

Indications: Moderate to severe vasomotor menopausal symptoms. Vulvar and vaginal atrophy.

Adults: Give cyclically (3 weeks on, 1 week off). Menopause symptoms: initially 0.625mg/day, may titrate to 1.25mg/day. Atrophic vaginitis: 0.3mg/day. Reevaluate periodically.

Children: Not applicable.

Contraindications: Breast or estrogen-dependent carcinoma (unless palliative). Undiagnosed abnormal vaginal bleeding. Thromboembolic disorders. Thrombophlebitis. Liver dysfunction or disease. Pregnancy (Cat.X).

Warnings/Precautions: Increased risk of endometrial carcinoma or hyperplasia in women with an intact uterus (consider adding progestin). Renal dysfunction. Gallbladder disease. Familial hyperlipoproteinemia. Conditions aggravated by fluid retention. Bone disease associated with hypercalcemia. Depression. Do initial complete physical and repeat every 6–12 months (include BP, mammogram, PAP smear). Discontinue if jaundice occurs and during immobilization or 2 weeks before surgery associated with thromboembolism. Nursing mothers: not recommended.

Adverse reactions: Nausea, vomiting, abdominal pain, irregular bleeding, headache, insomnia, edema, weight changes, hypertonia, leg cramps, hypertension, mastodynia, chloasma. Long-term continuous use may increase risk of estrogen-dependent cancers, others. Increased risk of gallbladder disease, thromboembolic disorders.

How supplied: Tabs–30, 100, 1000

ESTROGENS, CONJUGATED, B Rx

ENJUVIA Teva Women's Health

Estrogen. Synthetic conjugated estrogens, B, 0.3mg, 0.45mg, 0.625mg, 0.9mg, 1.25mg; tabs.

Indications: Moderate to severe vasomotor symptoms of menopause. Moderate to severe vaginal

dryness and pain with intercourse, symptoms of vulvar and vaginal atrophy, associated with menopause.

Adults: Use lowest effective dose. Initially 0.3mg once daily. Reevaluate periodically.

Children: Not applicable.

Contraindications: Breast or estrogen-dependent carcinoma. Undiagnosed abnormal vaginal bleeding. Thromboembolic disorders (eg, stroke or MI within one year, DVT, pulmonary embolism). Thrombophlebitis. Liver dysfunction or disease. Pregnancy (Cat.X).

Warnings/Precautions: Increased risk of endometrial carcinoma or hyperplasia in women with intact uterus (adding progestin is essential). Renal dysfunction. Gallbladder disease. Familial hyperlipoproteinemia. Conditions aggravated by fluid retention. Bone disease associated with hypercalcemia. Do initial complete physical; repeat annually (include BP, mammogram, PAP smear). Discontinue if jaundice occurs and during immobilization or 2 weeks before planned mammogram or surgery associated with thromboembolism. Nursing mothers.

Interactions: May be antagonized by CYP3A4 inducers. May be potentiated by CYP3A4 inhibitors.

Adverse reactions: GI upset, abdominal pain, irregular bleeding, vaginitis, dysmenorrhea, headache, edema, hypertension, mastodynia, chloasma, visual abnormalities (reevaluate if occur), leg cramps, hypertriglyceridemia. Long-term use may increase risk of estrogen-dependent cancers (eg, breast and/or endometrial), dementia, others. Increased risk of thromboembolic disorders, gallbladder disease.

How supplied: Tabs–100

ESTROPIMATE Rx

UGEN Pfizer

Estrogen. Estrone sodium sulfate (as estropimate) 0.625mg, 1.25mg, 2.5mg; scored tabs.

Indications: Moderate to severe vasomotor symptoms of menopause. Atrophic vaginitis.

Osteoporosis prevention. Hypoestrogenism.

Adults: Menopause: 0.625–5mg daily, given cyclically (3 weeks on, 1 week off). Osteoporosis prevention (begin therapy soon after menopause): 0.625mg daily, given cyclically (25 days of a 31-day cycle). Hypoestrogenism: 1.25–7.5mg daily for 3 weeks. Repeat course if withdrawal bleeding does not occur within 8–10 days after discontinuing. See literature. Reevaluate periodically.

Children: Not applicable.

Contraindications: Breast or estrogen-dependent carcinoma. Undiagnosed abnormal genital bleeding. Thromboembolic disorders. Thrombophlebitis. Pregnancy (Cat.X).

Warnings/Precautions: Patients with an intact uterus should almost always receive a progestin to avoid endometrial hyperplasia. Cardiovascular disease. Hepatic dysfunction. Gallbladder disease. Conditions aggravated by fluid retention. Bone disease associated with hypercalcemia. Do initial complete physical and repeat annually (include BP, mammogram, and

PAP smear). Discontinue if jaundice or hypertension occurs and at least 2 weeks before surgery associated with thromboembolism. Nursing mothers.

Adverse reactions: See literature. GI upset, breakthrough bleeding, edema, weight changes, mastodynia, hypertension, intolerance to contact lenses.

How supplied: Tabs-100

MEDROXYPROGESTERONE

R_x

PROVERA Pfizer

Progestin. Medroxyprogesterone acetate 2.5mg, 5mg, 10mg; scored tabs.

Indications: To prevent endometrial hyperplasia in postmenopausal women with an intact uterus receiving conjugated estrogens. Secondary amenorrhea, abnormal uterine bleeding due to hormonal imbalance without organic pathology.

Adults: Endometrial hyperplasia prophylaxis: 5-10mg daily for 12-14 days per month starting on Day 1 or Day 16. Amenorrhea: 5-10mg daily for 5-10 days; to induce optimum secretory transformation of primed endometrium: 10mg daily for 10 days; may start at any time. Abnormal bleeding: 5-10mg daily for 5-10 days starting on Day 16 or 21 of menstrual cycle; to induce optimum secretory transformation of primed endometrium: 10mg daily for 10 days starting on Day 16.

Children: Not applicable.

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Tabs 2.5mg, 5mg-30, 100 10mg-30, 100, 500

NORETHINDRONE ACETATE

R_x

AYGESTIN Teva Women's Health

Progestin. Norethindrone acetate 5mg; scored tabs.

Indications: Secondary amenorrhea, abnormal uterine bleeding due to hormonal imbalance without organic pathology.

Adults: 2.5-10mg daily for 5-10 days during 2nd half of theoretical menstrual cycle after estrogens if needed.

Children: Not applicable.

Contraindications: Thromboembolic disorders. Hepatic dysfunction. Undiagnosed vaginal bleeding. Breast or genital carcinoma. Missed abortion. Pregnancy (Cat.X).

Warnings/Precautions: Cardiac or renal dysfunction. Depression. Include PAP smear in pretreatment exam. Conditions aggravated by fluid retention. Discontinue if jaundice, visual disturbances, migraine, or thrombotic disorders occur. Nursing mothers.

Interactions: Rifampin may increase metabolism.

Adverse reactions: Menstrual and cervical changes, edema, jaundice, rash, depression, mastodynia, decreased glucose tolerance, weight changes, thromboembolic disease, breakthrough bleeding, melasma, chloasma.

How supplied: Tabs-50

PROGESTERONE

R_x

PROMETRIUM AbbVie

Progesterone (micronized) 100mg, 200mg, 300mg; caps; contains peanut oil.

Indications: To prevent endometrial hyperplasia in postmenopausal women with an intact uterus receiving conjugated estrogens. Secondary amenorrhea.

Adults: Endometrial hyperplasia prevention: 200mg once daily in the PM for 12 sequential days of each 28-day cycle. Amenorrhea: 400mg once daily in the PM for 10 days.

Children: Not recommended.

Contraindications: Peanut allergy. Pregnancy (Cat.B).

Contraindications, precautions, interactions, adverse reactions: See Note at start of section.

How supplied: Caps-100

13E Menorrhagia

LEVONORGESTREL + IUD

R_x

MIRENA Bayer

Progestin IUD. Levonorgestrel 52mg; intrauterine contraceptive system (IUD).

Indications: Treatment of heavy menstrual bleeding in women who choose to use intrauterine contraception as their method of contraception.

Adults: See literature. Insert into uterine cavity as directed. Reexamine after next menses (within 3 months). Replace at least every 5 years.

Children: Not recommended.

Contraindications: Uterine abnormality. History or risk of ectopic pregnancy. History of pelvic inflammatory disease (PID) unless subsequent intrauterine pregnancy occurred. Postpartum endometritis or septic abortion in past 3 months. Uterine or cervical neoplasia. Unresolved abnormal Pap smear. Abnormal genital bleeding. Untreated acute cervicitis or vaginitis. Acute liver disease or liver tumor. Immunosuppressed. IV drug abuse. Multiple sexual partners for patient or partner. Genital actinomycosis. Retained IUD. Breast carcinoma. Pregnancy (Cat.X).

Warnings/Precautions: Assure suitable uterine anatomy before inserting. Endocarditis risk. Anticoagulant therapy or coagulopathies. Cervical stenosis. Predisposition to syncope, bradycardia, other neurovascular episodes. Remove device if any of these occur: menorrhagia, metrorrhagia producing anemia, STDs, AIDS, endometritis, severe dyspareunia, intractable pelvic pain, uterine or cervical perforation, pregnancy, any sign of expulsion. Consider removal if first migraine, transient cerebral ischemia, severe headache, jaundice, marked increase in BP, or severe arterial disease occurs. Check placement regularly. Nursing mothers (increased risk of uterine perforation).

Interactions: May be antagonized by CYP3A4 inducers (eg, barbiturates, bosentan, carbamazepine,

felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate).

Adverse reactions: Amenorrhea, irregular bleeding, cramps, adhesions, peritonitis, intestinal perforations or obstruction, abscesses, erosion, ovarian cysts, PID, ectopic pregnancy, GI disturbances, leukorrhea, headache, vaginitis, breast or back pain, acne, depression, hypertension, nervousness, weight gain, glucose intolerance, decreased libido, abnormal Pap smear. Syncope, bradycardia, other neurovascular episodes, perforation, loss of pregnancy, sepsis (during insertion or removal). If pregnancy occurs: sepsis, miscarriage, premature labor or delivery.

How supplied: System-1

TRANEXAMIC ACID

LYSTEDA Ferring

Antifibrinolytic. Tranexamic acid 650mg; tabs.

Indications: Cyclic heavy menstrual bleeding.

Adults: Treat for up to 5 days during menses. Swallow whole. ≥ 18 yrs: Normal renal function (serum creatinine ≤ 1.4 mg/dL): 1300mg three times daily; Cr > 1.4 –2.8 mg/dL: 1300mg twice daily; Cr > 2.8 –5.7 mg/dL: 1300mg once daily; Cr > 5.7 mg/dL: 650mg once daily.

Children: < 18 yrs: not studied.

Contraindications: Active thromboembolic (eg, DVT, pulmonary embolism, cerebral thrombosis). History or risk of thrombosis or thromboembolism (eg, retinal vein or artery occlusion; thrombotic valvular disease, thrombotic cardiac rhythm disease, hypercoagulopathy).

Warnings/Precautions: Exclude endometrial pathology first. Renal impairment. Subarachnoid hemorrhage (cerebral edema/infarction may occur). Acute promyelocytic leukemia treated with oral tretinoin (increased procoagulant effect). Pregnancy (Cat.B). Nursing mothers.

Interactions: Increased risk of thrombotic events (eg, stroke, MI) with hormonal contraceptives, Factor IX products, anti-inhibitor coagulant concentrates, oral tretinoin. Tissue plasminogen activators may decrease efficacy of both tranexamic acid and tPAs.

Adverse reactions: Headache, sinus/nasal symptoms, pain (back, abdomen, musculoskeletal, joint), muscle cramps, migraine, anemia, fatigue; visual/ocular events (retinal occlusion; discontinue if occurs), severe allergic reaction.

How supplied: Tabs-30, 100, 500

13F Vaginal infections

CLINDAMYCIN

CLEOCIN VAGINAL CREAM Pfizer

Lincosamide. Clindamycin (as phosphate) 2%.

Indications: Bacterial vaginosis.

Adults: 1 applicatorful intravaginally at bedtime. Nonpregnant: treat for 3 or 7 days. Pregnant (2nd or 3rd trimester): treat for 7 days.

Children: Not recommended.

Also: Clindamycin

CLEOCIN VAGINAL OVULES

Clindamycin (as phosphate) 100mg; supp.

Adults: Nonpregnant: 1 supp intravaginally at bedtime for 3 days.

Children: Pre-menarchal: not recommended.

Contraindications: History of enteritis or colitis.

Warnings/Precautions: Monitor for pseudomembranous colitis. Do not use contraceptive diaphragm or condom for at least 72 hours after treatment. Do not have vaginal intercourse or use tampons or douches during treatment with ovules. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: May potentiate neuromuscular blockers.

Adverse reactions: Candidiasis, vaginitis, vulvovaginal disorder, fungal infection, pruritus, abnormal labor.

How supplied: Crm-21g, 40g (w. applicators) Ovules-3 (w. applicator)

FLUCONAZOLE

DIFLUCAN 150MG Pfizer

Azole antifungal. Fluconazole 150mg; tabs.

Indications: Vaginal candidiasis.

Adults: 150mg orally once.

Children: Not recommended.

Contraindications: Concomitant pimozide, quinidine.

Warnings/Precautions: Proarrhythmic conditions. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Risk of cardiotoxicity with erythromycin; avoid. Concomitant voriconazole: not recommended; if needed, monitor closely esp. when given within 24hrs after fluconazole. Potentiates warfarin, theophylline, oral hypoglycemics, midazolam. May increase serum levels of phenytoin, cyclosporine, zidovudine, sulfonyleureas, carbamazepine. Thiazides increase fluconazole levels. Monitor levels and/or effects of cyclosporine, phenytoin, sulfonyleureas, rifabutin, tacrolimus, theophylline, warfarin. Cimetidine (oral), rifampin may decrease fluconazole levels. Oral contraceptives: see literature. Avoid other hepatotoxic drugs. Caution with other drugs metabolized by CYP450.

Adverse reactions: Headache, nausea, abdominal pain, GI upset, dizziness, taste perversion; hepatotoxicity, exfoliative dermatitis (rare).

How supplied: Tabs 150mg-1

METRONIDAZOLE

FLAGYL Pfizer

Antiprotozoal/antibacterial. Metronidazole 250mg, 500mg; scored tabs.

Indications: Trichomoniasis.

Adults: 250mg 3 times daily for 1 wk. Or, if patient is not pregnant, 2g in 1–2 divided doses on same

day. Before repeating course, reconfirm diagnosis and allow 4–6 wks between courses. Treat consorts also.

Children: Not recommended.

Also: Metronidazole

FLAGYL 375

Metronidazole 375mg; caps.

Adults: 375mg twice daily for 1 wk. Treat consorts also.

Children: Not recommended.

Also: Metronidazole

FLAGYL ER

Metronidazole 750mg; ext-rel tabs.

Indications: Bacterial vaginosis.

Adults: Take 1 hr before or 2 hrs after meals. 750mg once daily for 7 days.

Children: Not recommended.

Contraindications: Pregnancy (1st trimester for trichomoniasis).

Warnings/Precautions: CNS disease. Discontinue if neurological symptoms occur. Severe hepatic disease: reduce dose. History of blood dyscrasias. Monitor leukocytes before and after therapy. Elderly: monitor serum levels. Pregnancy (Cat.B, 2nd and 3rd trimesters). Nursing mothers: not recommended.

Interactions: Avoid alcohol during and for 3 days after use. Do not give within 2 weeks of disulfiram (possible psychotic reactions). May potentiate oral anticoagulants, phenytoin, lithium. Antagonized by phenobarbital, phenytoin, other hepatic enzyme inducers. May impair phenytoin clearance. Potentiated by cimetidine, other hepatic enzyme inhibitors. Interferes with serum chemistry tests.

Adverse reactions: GI upset, headache, metallic taste, dysuria, cystitis, incontinence, *Candida* overgrowth, seizures, peripheral neuropathy, ECT changes; neutropenia, pancreatitis (rare).

How supplied: Tabs–50, 100; ER–30; Caps 375mg–50

METRONIDAZOLE

METROGEL-VAGINAL Medicis

Antibacterial (imidazole). Metronidazole 0.75%; vaginal gel; contains parabens.

Indications: Bacterial vaginosis.

Adults: One applicatorful once daily at bedtime, or twice daily, for 5 days.

Children: Not recommended.

Warnings/Precautions: Discontinue if abnormal neurological signs develop. CNS or hepatic disease. Abstain from vaginal intercourse during therapy. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Avoid concomitant alcohol. May potentiate oral anticoagulants, lithium. May be potentiated by cimetidine.

Adverse reactions: Superinfection, local irritation, GI discomfort/upset, headache, abnormal taste, dizziness, decreased appetite, change in WBC counts.

How supplied: Gel–70g (w. applicators)

NYSTATIN

NYSTATIN VAGINAL TABLETS (various)

Polyene antifungal. Nystatin 100000 Units.

Indications: Vulvovaginal candidiasis.

Adults: 1 tab vaginally once daily for 2 weeks; insert tab high into the vagina using applicator.

Children: Not recommended.

Warnings/Precautions: Discontinue if sensitization/irritation occurs. Confirm diagnosis by KOH smears +/or cultures. If ineffective, reconfirm diagnosis before repeating therapy. Pregnancy (Cat.A).

Adverse reactions: Irritation/sensitization (rare).

How supplied: Tabs–15, 30 (w. applicator)

TINIDAZOLE

TINDAMAX Mission

Nitroimidazole. Tinidazole 250mg, 500mg; scored tabs.

Indications: Trichomoniasis. Bacterial vaginosis in non-pregnant women.

Adults: Take with food. Trichomoniasis: 2g as a single dose; treat consorts also. Bacterial vaginosis: 2g once daily for 2 days or 1g once daily for 5 days.

Children: Not recommended.

Contraindications: Pregnancy (1st trimester).

Warnings/Precautions: CNS disorders. Discontinue if neurological effects occur. Hepatic dysfunction. Candidiasis. Blood dyscrasias. Monitor leukocytes before and after therapy. Elderly. Pregnancy (Cat.C) (2nd and 3rd trimesters). Nursing mothers: not recommended during and for 3 days after last dose.

Interactions: Avoid alcohol during and for 3 days after use. Do not give within 2 weeks of disulfiram. May potentiate oral anticoagulants, lithium, phenytoin. Monitor cyclosporine, tacrolimus, fluorouracil. May be antagonized by CYP450 inducers (eg, phenobarbital, rifampin), others. May be potentiated by CYP450 inhibitors (eg, cimetidine, ketoconazole). May interfere with serum chemistry tests.

Adverse reactions: GI upset, abdominal pain, metallic taste, anorexia, constipation, fatigue, dizziness, headache, transient leukopenia/neutropenia; rare: seizures, peripheral neuropathy.

How supplied: Tabs 250mg–40; 500mg–20

13G Miscellaneous Ob/Gyn conditions

LEUPROLIDE

LUPRON DEPOT 3.75MG AbbVie

GnRH analogue. Leuprolide acetate 3.75mg; depot susp for IM inj; preservative-free.

Indications: Presurgical treatment of patients with anemia due to uterine leiomyomata (fibroids), with iron therapy if iron therapy alone is inadequate.

Adults: ≥18 years: 3.75mg IM once per month for up to 3 months.

Children: <18 years: not applicable.

Also: Leuprolide**LUPRON DEPOT-3 MONTH 11.25mg**

Leuprolide acetate 11.25mg; depot susp for IM inj; preservative-free.

Adults: ≥ 18 years: 11.25mg IM once every 3 months (1 injection). Do not split doses.

Children: < 18 years: **not applicable.**

Contraindications: Undiagnosed abnormal vaginal bleeding. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Exclude pregnancy before starting; use nonhormonal contraception during therapy; discontinue if pregnancy occurs. Risk factors for decreased bone mineral density (eg, chronic alcohol, tobacco, anticonvulsants, corticosteroids). Missing successive doses may cause breakthrough bleeding or ovulation. Elderly.

Adverse reactions: Hot flashes, headache, vaginitis, depression, emotional lability, pain, decreased libido, breast changes, amenorrhea, mastodynia, joint disorder, asthenia, GI upset, edema, bone density loss, local reactions, acne, memory disorders, others; rarely: anaphylaxis, asthma, increased serum transaminases or lipids.

How supplied: Kit-1 (single-dose syringe w. diluent, supplies)

MEDROXYPROGESTERONE**DEPO-SUBQ PROVERA Pfizer**

Progestin. Medroxyprogesterone acetate 104mg/0.65mL; SC inj; contains parabens.

Indications: Pain due to endometriosis.

Adults: Inject 104mg SC every 3 months. Give 1st dose within 5 days of onset of normal menses. Do not use for > 2 years unless other methods are inadequate.

Children: **Not applicable.**

Contraindications: Undiagnosed vaginal bleeding. Breast carcinoma. Cerebrovascular disease. Hepatic dysfunction. Pregnancy (Cat.X).

Warnings/Precautions: May be used as contraceptive; other hormonal contraceptives: not recommended. Conditions aggravated by fluid retention (eg, migraine). Depression. Pretreatment exam should include Pap smear. Risk of osteoporosis (eg, metabolic bone disease, anorexia, family history). Discontinue if jaundice, visual disturbances, migraine or thrombotic disorders occur. Nursing mothers.

Interactions: May be antagonized by aminoglutethimide. May reduce bone mass with anticonvulsants, corticosteroids; avoid alcohol, tobacco.

Adverse reactions: Irregular bleeding, edema, weight or cervical changes, decreased bone mineral density, cholestatic jaundice, depression, breast tenderness, acne, hirsutism, inj site reactions.

How supplied: Prefilled syringe-1 (w. needle)

METHYLERGONOVINE**METHERGINE Validus**

Ergot alkaloid. Methylergonovine maleate 0.2mg; tabs.

Indications: Following delivery of the placenta, for routine management of uterine atony, hemorrhage,

and subinvolution of the uterus. For control of uterine hemorrhage in the second stage of labor following delivery of the anterior shoulder.

Adults: 0.2mg 3-4 times a day in the puerperium for max 1 week.

Children: **Not established.**

Also: Methylergonovine**METHERGINE INJECTION**

Methylergonovine maleate 0.2mg/mL; amp.

Adults: IM: 0.2mg after delivery of the anterior shoulder, after delivery of the placenta, or during the puerperium; may be repeated as required at intervals of 2-4 hours. IV: 0.2mg given slowly over a period of no less than 60 seconds.

Children: **Not established.**

Contraindications: Hypertension. Toxemia.

Pregnancy (Cat.C).

Warnings/Precautions: Avoid intra-arterial, periarterial injection. Coronary artery disease or risk factors; may be more susceptible to developing MI and infarction associated with methylergonovine-induced vasospasm. Sepsis. Obliterative vascular disease. Hepatic or renal disease. 2nd stage of labor. Nursing mothers: not recommended (wait at least 12hrs after last dose before initiating or resuming feeding).

Interactions: Potentiated by vasoconstrictors, other ergot alkaloids, prostaglandins, beta-blockers. Potent CYP3A4 inhibitors (eg, macrolides, protease inhibitors, reverse transcriptase inhibitors, azole antifungals): not recommended. Use caution with less potent CYP3A4 inhibitors (eg, saquinavir, nefazodone, fluconazole, grapefruit juice, fluoxetine, fluvoxamine, zileuton, clotrimazole). Antagonized by strong inducers of CYP3A4 (eg, nevirapine, rifampicin), anesthetics (eg, halothane, methoxyflurane). Antagonizes glyceryl trinitrate, other antianginal drugs.

Adverse reactions: Hypertension associated with seizure and/or headache, hypotension, abdominal pain, GI upset; rare: cardiovascular effects (eg, vasoconstriction, acute MI, transient chest pains).

How supplied: Tabs-100; Inj (1mL amps)-20

MIFEPRISTONE**MIFEPREX Danco**

Abortifacient. Mifepristone 200mg; tabs.

Indications: Termination of intrauterine pregnancy through day 49 of pregnancy.

Adults: Physician must sign and return Prescriber's Agreement; patient must read and sign Patient Agreement and read Medication Guide. Day 1: mifepristone 600mg as a single oral dose. Day 3: misoprostol 400micrograms as a single oral dose unless abortion confirmed. Day 14: confirm that complete termination of pregnancy has occurred by clinical exam or ultrasonographic scan.

Children: **Not recommended.**

Contraindications: Ectopic pregnancy or undiagnosed adnexal mass. IUD in place. Chronic adrenal failure. Prostaglandin allergy. Hemorrhagic disorders. Inherited porphyrias. Concurrent long-term

corticosteroid therapy. Anticoagulants. Patients unable to understand effects of treatment or to comply with regimen, or those without adequate access to appropriate medical facilities.

Warnings/Precautions: To be given only by or under the supervision of physicians who have signed and returned the Prescriber's Agreement; are able to assess gestational age of embryo and diagnose ectopic pregnancy; who have access to facilities for emergency treatment of incomplete abortion, severe bleeding, or resuscitation; and who meet requirements for storage, dose tracking, etc. Do surgical termination if mifepristone and misoprostol fail. Procedures to prevent rhesus immunization must be used. Hemostatic disorders. Hypocoagulability. Severe anemia. Chronic medical conditions (eg, cardiovascular, hypertensive, hepatic, respiratory, or renal disease). Women >35yrs of age who smoke ≥ 10 cigarettes per day. Pregnancy: treatment failure may result in fetal malformation. Nursing mothers: see literature (consider suspending breastfeeding for a few days after therapy).

Interactions: See Contraindications. May potentiate CYP3A4 substrates. May be potentiated by ketoconazole, itraconazole, erythromycin, grapefruit juice. May be antagonized by rifampin, dexamethasone, St. John's wort, phenytoin, phenobarbital, carbamazepine.

Adverse reactions: Vaginal bleeding (may be prolonged or severe), cramping, GI upset, headache, dizziness, fatigue, back pain, fever, vaginitis, rigors, insomnia, asthenia, leg pain, anxiety, anemia, leukorrhea, syncope; rare: serious bacterial infections, sepsis (may be fatal).

Note: Report serious adverse events by calling (877) 432-7596.

How supplied: Single-dose pack (3 tabs)-1

SECTION 14:

ONCOLOGY

14A Cytoprotective and supportive care agents

AMIFOSTINE

ETHYOL MedImmune

Amifostine 500mg/vial; pwd for IV infusion after reconstitution.

Indications: To reduce cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced ovarian cancer. To reduce xerostomia in patients undergoing post-op radiation therapy for head and neck cancer where the radiation port includes a substantial portion of the parotid glands.

Adults: Pretreat with antiemetics. Reduction of renal toxicity: 910mg/m² by IV infusion over 15 minutes once daily, starting 30 minutes before chemotherapy; monitor BP every 5 minutes during

infusion and thereafter, interrupt infusion if systolic BP decreases significantly; if BP returns to normal after 5 minutes, may restart; if full dose cannot be given, then give dose of 740mg/m² for subsequent cycles. Xerostomia: 200mg/m² by IV infusion over 3 minutes once daily, starting 15–30 minutes before standard fraction radiation therapy; monitor BP before and immediately after infusion.

Children: Not recommended.

Warnings/Precautions: Do not use for other malignancies in which chemotherapy can produce a significant survival benefit or in patients receiving definitive radiotherapy (except in a clinical trial). Not recommended for hypotensive or dehydrated patients. Stop BP medication 24 hours before therapy when using as a chemoprotectant (do not give to patients unable to stop antihypertensives). Permanently discontinue if severe cutaneous reactions or acute allergic reactions occur. Ensure adequate hydration. Keep patient in supine position. Hypocalcemia risk (eg, nephrotic syndrome, multiple doses of Ethylol); monitor serum calcium. Cardiovascular or cerebrovascular disease (ischemic heart disease, arrhythmias, CHF, stroke or TIA). Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with drugs that can cause hypotension.

Adverse reactions: Hypotension, hypersensitivity, nausea, vomiting, flushing, chills, fever, dizziness, somnolence; rarely: severe skin reactions, reversible loss of consciousness, hypocalcemia, cardiac arrest, renal failure, arrhythmias, hypertension, seizures, syncope.

How supplied: Single-use vials-3

CINACALCET

R

SENSIPAR Amgen

Calcimimetic. Cinacalcet 30mg, 60mg, 90mg, tabs.

Indications: Hypercalcemia in patients with parathyroid carcinoma.

Adults: Swallow whole; take with food. Individualize. ≥ 18 yrs: initially 30mg twice daily. May titrate dose every 2–4 weeks through sequential doses of 30mg twice daily, 60mg twice daily, 90mg twice daily, and 90mg 3–4 times daily until serum calcium normalizes.

Children: <18yrs: not recommended.

Warnings/Precautions: Do not initiate if serum calcium <8.4mg/dL. Obtain serum calcium within 1 week after start of therapy, during dose adjustment, then every 2 months. Suspend if serum calcium <7.5mg/dL or persistent hypocalcemia symptoms occur; may restart at next lowest dose if resolved. Monitor for adynamic bone disease; if iPTH levels decrease below target range (150–300pg/mL), reduce dose or discontinue. History of seizures. Cardiovascular disorders. Moderate and severe hepatic impairment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates CYP2D6 substrates (eg, metoprolol, carvedilol, flecainide, vinblastine,

thioridazine, and TCAs). Potentiated by CYP3A4 inhibitors (eg, ketoconazole, itraconazole, erythromycin); may need to adjust dose.

Adverse reactions: Nausea, vomiting, hypocalcemia.

How supplied: Tabs-30

DENOSUMAB

R

XGEVA Amgen

Osteoclast inhibitor (RANKL inhibitor). Denosumab 120mg/vial (70mg/mL); soln for SC inj; preservative-free.

Indications: Prevention of skeletal-related events (SRE) in patients with bone metastases from solid tumors. Not for preventing SRE with multiple myeloma.

Adults: Give by SC inj into upper arm, upper thigh, or abdomen. 120mg once every 4 weeks.

Children: Not established (interferes with bone growth and dentition).

Warnings/Precautions: Correct hypocalcemia before starting; ensure adequate daily calcium, magnesium, and Vit.D intake, esp. in renal impairment (CrCl <30mL/min). Monitor calcium, phosphorus, magnesium levels in susceptible patients (eg, severe renal impairment, receiving dialysis). Monitor for osteonecrosis of the jaw. Perform oral exam and preventive dentistry before and regularly during therapy. Maintain good oral hygiene. Avoid invasive dental procedures during treatment. Pregnancy (Cat.D); use highly effective contraception during therapy, and for at least 5 months after last dose. Nursing mothers: avoid (may impair mammary gland development/lactation).

Interactions: Concomitant drugs that can lower calcium levels; monitor.

Adverse reactions: Fatigue, asthenia, hypophosphatemia, nausea, dyspnea, osteonecrosis of jaw, severe hypocalcemia (may be fatal).

How supplied: Single-use vial (1.7mL)-1

DEXRAZOXANE

R

TOTECT Biocodex USA

Detoxifying agent. Dexrazoxane 500mg; per vial; pld for IV infusion after reconstitution and dilution; preservative-free.

Indications: To treat extravasation resulting from IV anthracycline chemotherapy.

Adults: Give once daily for 3 consecutive days by IV infusion over 1-2 hours. Initiate 1st dose as soon as possible and within 1st 6 hours after extravasation. Days 1 and 2: 1000mg/m²; max 2000mg. Day 3: 500mg/m²; max 1000mg. Renal impairment (CrCl <40mL/min): reduce dose by 50%.

Children: Not recommended.

Warnings/Precautions: Renal or hepatic impairment (monitor liver enzymes). Monitor for myelosuppression; obtain blood counts periodically. Elderly. Labor & delivery. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid dimethylsulfoxide (DMSO). Caution with concurrent cytotoxic chemotherapy (additive cytotoxicity).

Adverse reactions: Inj site reactions, GI upset, stomatitis, leukopenia, neutropenia, thrombocytopenia, elevated liver enzymes, pyrexia, infections.

How supplied: Kit-10 single-use vials (w. diluent)

DEXRAZOXANE

R

ZINECARD Pfizer

Chelating agent. Dexrazoxane 250mg, 500mg; per vial; pld for IV infusion after reconstitution and dilution.

Indications: To reduce the incidence and severity of cardiomyopathy associated with doxorubicin administration in women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300mg/m² and will continue to receive doxorubicin therapy to maintain tumor control.

Adults: Give by slow IV push or rapid drip IV infusion. Doxorubicin should be administered within 30 minutes after starting Zinecard infusion. Administer in 10:1 ratio (eg, 500mg/m² Zinecard: 50mg/m² doxorubicin). Renal impairment (CrCl <40mL/min): reduce ratio to 5:1 (eg, 250mg/m² Zinecard: 50mg/m² doxorubicin). Hepatic impairment: may need to reduce doxorubicin dose, therefore Zinecard dose must be reduced (maintaining 10:1 ratio).

Children: Not recommended.

Contraindications: Chemotherapy regimens that do not contain an anthracycline.

Warnings/Precautions: Not recommended for use with initiation of doxorubicin. Renal or hepatic impairment. Monitor cardiac function and for myelosuppression; obtain CBCs frequently. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Adverse reactions: Inj site pain, myelosuppression, possible secondary malignancies (see literature).

How supplied: Single-use vial-1 (w. diluent)

DIAZOXIDE

R

PROGLYCEM SUSPENSION

Teva US Generics

Nondiuretic benzothiadiazine derivative. Diazoxide 50mg/mL; chocolate-mint flavor; contains alcohol 7.25%

Indications: Management of hypoglycemia due to hyperinsulinism associated with: inoperable islet cell adenoma or carcinoma, or extrapancreatic malignancy in adults; leucine sensitivity, islet cell hyperplasia, nesidioblastosis, extrapancreatic malignancy, islet cell adenoma, or adenomatosis in infants and children.

Adults and Children: Individualize. Infants and newborns: Initially 10mg/kg/day divided into 3 equal doses every 8hrs. Usual range: 8-15mg/kg divided into 2-3 equal doses every 8-12hrs. Adults and children: Initially 3mg/kg/day divided into 3 equal doses every 8hrs. Usual range: 3-8mg/kg divided into 2-3 equal doses every 8-12hrs. Refractory hypoglycemia: may require higher dosages. Discontinue if not effective after 2-3 weeks.

Contraindications: Functional hypoglycemia. Thiazide hypersensitivity.

Warnings/Precautions: Compromised cardiac reserve: may precipitate CHF. Hyperuricemia. History of gout. Renal impairment: consider reducing dose; evaluate serum electrolyte levels. Newborns with increased bilirubinemia. Monitor blood glucose, BUN, creatinine clearance, hematocrit, platelets, total and differential leukocyte counts, AST, serum uric acid periodically until stabilized. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Antihypertensives potentiated. Concomitant coumarin: may need to reduce dose of anticoagulant. Concomitant diphenylhydantoin may result in loss of seizure control. Concomitant thiazides, other diuretics may potentiate hyperglycemic and hyperuricemic effects. Inhibits glucagon-stimulated insulin release and causes false-negative insulin response to glucagon.

Adverse reactions: Sodium and fluid retention, diabetic ketoacidosis, hyperosmolar nonketotic coma, hirsutism, hyperglycemia, glycosuria, GI upset, tachycardia, palpitations, increased serum uric acid, thrombocytopenia (may require discontinuation), neutropenia, rash, headache, weakness, malaise.

How supplied: Susp-30mL (w. dropper)

GALLIUM NITRATE

GANITE Genta

Calcium resorption inhibitor. Gallium nitrate 25mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: Cancer-related hypercalcemia that has not responded to adequate hydration.

Adults: Give by continuous IV infusion over 24hrs. Usually 200mg/m² daily for 5 consecutive days. Mild hypercalcemia and few symptoms: may consider 100mg/m² daily for 5 days. If serum calcium levels are normalized in <5 days, may discontinue treatment early.

Children: Not recommended.

Contraindications: Severe renal impairment (serum creatinine >2.5mg/dL).

Warnings/Precautions: Confirm satisfactory urine output (2L/day) prior to therapy. Maintain adequate hydration; avoid overhydration with compromised cardiovascular status. Moderate renal impairment. Monitor serum creatinine and BUN; discontinue if serum creatinine >2.5mg/dL. Obtain baseline serum calcium and phosphorus levels daily and twice weekly, respectively. Discontinue if hypocalcemia occurs; calcium therapy may be necessary. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid other nephrotoxic drugs (eg, aminoglycosides, amphotericin B) that may increase risk of renal insufficiency. Avoid using diuretics prior to correcting hypovolemia. Concomitant cyclophosphamide and prednisone may cause complex of dyspnea, mouth soreness, and asthenia.

Adverse reactions: Hypophosphatemia, hypocalcemia, renal failure, anemia; rare: acute optic neuritis, tinnitus, partial auditory acuity loss.

How supplied: Single-dose vials (20mL)-5

GLUCARPIDASE

VORAXAZE BTG International

Carboxypeptidase enzyme. Glucarpidase; 1,000 Units/vial; lyophilized pwd for IV inj after reconstitution; preservative-free.

Indications: Treatment of toxic plasma methotrexate (MTX) concentrations (>1 micromole per liter) in patients with delayed MTX clearance due to impaired renal function.

Adults and Children: <1 month: not recommended. ≥1 month: Give as bolus IV inj over 5 minutes. 50Units/kg as a single injection.

Continue leucovorin therapy until the MTX concentration is below the leucovorin treatment threshold for at least 3 days. Do not administer leucovorin within 2hrs before or after a dose of glucarpidase. First 48hrs after glucarpidase: administer same leucovorin dose as given prior to glucarpidase. Beyond 48hrs after glucarpidase: give leucovorin dose based on the measured MTX concentration.

Warnings/Precautions: Not indicated for use in patients who exhibit the expected clearance of MTX (plasma MTX concentrations within 2 standard deviations of the mean MTX excretion curve specific for the dose of MTX administered) or those with normal or mildly impaired renal function. Monitor MTX concentrations only by chromatographic methods within 48hrs following administration. Continue hydration and alkalization of urine as indicated. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Adults and children. Other exogenous substrates including reduced folates and folate antimetabolites may cause interference.

Adverse reactions: Paresthesia, flushing, nausea, vomiting, hypotension, headache; rare: allergic reactions, antibody formation.

How supplied: Single-use vials-1

LEUCOVORIN

LEUCOVORIN Teva US Generics

Folic acid derivative. Leucovorin calcium 100mg/vial, 350mg/vial; lyophilized pwd for IV or IM inj after reconstitution; preservative-free.

Indications: Rescue treatment after high-dose methotrexate therapy in osteosarcoma.

Adults: Max IV infusion rate: 160mg/min. Based on methotrexate dose. Normal methotrexate elimination: 15mg IM or IV every 6 hours for 10 doses starting 24 hours after the beginning of the methotrexate infusion. Delayed late or delayed early methotrexate elimination, and/or evidence of acute renal injury, impaired methotrexate elimination or inadvertent overdose: see literature.

Children: See literature.

Contraindications: Pernicious anemia and other megaloblastic anemias due to Vit. B₁₂ deficiency.

Warnings/Precautions: Do not administer intrathecally. Monitor serum methotrexate concentration. CNS metastases. Monitor CBCs with differential, platelets, electrolytes, liver function tests prior to each treatment, then periodically. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates toxicity of 5-fluorouracil; use lower 5-fluorouracil dose. May antagonize phenobarbital, phenytoin, and primidone. Caution with trimethoprim-sulfamethoxazole.

Adverse reactions: Leukopenia, thrombocytopenia, infection, GI upset, stomatitis, constipation, lethargy, malaise, fatigue, alopecia, dermatitis, anorexia; seizures, syncope.

How supplied: Single-use vials-1

LEVOLEUCOVORIN

R_x

FUSILEV Spectrum

Folate analogue. Levoleucovorin (as calcium pentahydrate) 50mg/vial; pld for IV inj after reconstitution; contains mannitol 50mg/vial; 175mg/17.5mL; soln for IV inj; preservative-free.

Indications: In osteosarcoma, to reduce toxicity of high-dose methotrexate (MTX) therapy. To reduce toxicity and counteract effects of impaired MTX elimination and of inadvertent overdose of folic acid antagonists.

Adults and Children: <6yrs: see literature.

≥6yrs: Give by IV inj; max rate 160mg/min.

High-dose MTX rescue: Start 24hrs after the beginning of MTX infusion (based on MTX dose of 12g/m² over 4hrs). Normal MTX elimination: give levoleucovorin 7.5mg (approximately 5mg/m²) every 6hrs for 10 doses. Delayed late MTX elimination: continue levoleucovorin 7.5mg every 6hrs until MTX <0.05micromolar; delayed early MTX elimination and/or evidence of acute renal injury: levoleucovorin 75mg every 3hrs until MTX <1micromolar, then 7.5mg every 3hrs until MTX <0.05micromolar. May continue another 24hrs for subsequent courses in cases of significant clinical toxicity. Inadvertent MTX overdose: Start as soon as possible or within 24hrs if delayed MTX excretion. Levoleucovorin 7.5mg every 6hrs until MTX <0.05micromolar. See literature.

Warnings/Precautions: Not for treating pernicious anemia and megaloblastic anemia. Monitor serum creatinine and MTX levels every 24hrs. Delayed early MTX elimination may cause reversible renal failure; provide hydration, alkalize urine with sodium bicarbonate, closely monitor fluid and electrolytes until serum MTX <0.05 micromolar and renal failure resolves. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates 5-fluorouracil toxicity. Antagonizes TMP/SMZ. Antagonizes anticonvulsants (eg, phenobarbital, primidone, phenytoin). May be affected by drugs that affect MTX elimination.

Adverse reactions: Stomatitis, vomiting, nausea.

How supplied: Single-use vial (pld, soln)-1

MESNA

R_x

MESNEX TABLETS Bristol-Myers Squibb
Cytoprotective agent. Mesna 400mg; tabs.

Also: Mesna

R_x

MESNEX INJECTION

Mesna 100mg/mL; soln for IV inj after dilution; contains benzyl alcohol.

Indications: Prophylactic agent in reducing the incidence of ifosfamide-induced hemorrhagic cystitis.

Adults: See literature. IV Schedule: Give as IV bolus injection in a dosage equal to 20% of the ifosfamide dose at the time of ifosfamide administration and 4 and 8 hours after each dose of ifosfamide; total daily dose is 60% of the ifosfamide dose. IV and oral dosing: Give as IV bolus injection in a dosage equal to 20% of the ifosfamide dose at the time of ifosfamide administration, followed by the tablets given orally in a dosage equal to 40% of the ifosfamide dose 2 and 6 hours after each dose of ifosfamide; total daily dose is 100% of the ifosfamide dose. Repeat schedule on each day ifosfamide is given. If vomiting occurs within 2hrs of oral mesna, repeat dose or give IV mesna.

Children: Not recommended.

Contraindications: Hypersensitivity to thiol compounds.

Warnings/Precautions: Monitor morning specimen of urine for the presence of hematuria each day prior to ifosfamide therapy; consider dose reduction or discontinue if hematuria occurs. Elderly. Pregnancy (Cat.B). Nursing mothers: not recommended.

Adverse reactions: GI upset, fever, anorexia, flatulence, constipation, rhinitis, rigors, back pain, rash, conjunctivitis, arthralgia, headache, inj site reactions, flushing, dizziness, pharyngitis, hyperaesthesia, flu-like symptoms, coughing; hypersensitivity reactions.

Note: Patients taking mesna should drink at least a quart of liquid a day.

How supplied: Tabs-10

Multidose vials-1, 10

PALIFERMIN

R_x

KEPIVANCE Biovitrum

Keratinocyte growth factor (recombinant). Palifermin 6.25mg/vial; pld for IV inj after reconstitution; preservative-free; contains mannitol.

Indications: To decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies receiving myelotoxic therapy requiring hematopoietic stem cell support.

Adults: See literature. Give as IV bolus inj for 6 doses total. 60micrograms/kg per day for 3 consecutive days before myelotoxic therapy (give 3rd dose 24-48 hrs before myelotoxic therapy); then 60micrograms/kg per day for 3 consecutive days starting at least 24 hours after myelotoxic therapy (give 1st dose after, but on same day as, hematopoietic stem cell infusion, at least 4 days after last palifermin dose).

Children: Not recommended.

Warnings/Precautions: Non-hematologic malignancies. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: May bind heparin; if heparin is used to maintain IV line, rinse line with saline before and after palifermin use.

Adverse reactions: Skin or oral toxicities (eg, rash, erythema, edema, pruritus, dysesthesia, dysgeusia, tongue discoloration/thickening), arthralgia, fever, GI upset, respiratory events, antibody formation.

How supplied: Single-use vials—6

PAMIDRONATE

R

PAMIDRONATE DISODIUM INJECTION (various)
Bisphosphonate. Pamidronate disodium 30mg, 90mg; per vial; pwd for IV infusion after reconstitution; contains mannitol.

Indications: Hypercalcemia of malignancy.

Adults: Give by IV infusion. Assure adequate hydration; give as a single dose infused over 2–24hrs; moderate disease (albumin-corrected serum calcium 12–13.5mg/dL): 60–90mg; severe disease (albumin-corrected serum calcium >13.5mg/dL): 90mg; allow at least 7 days before retreatment. Max single dose: 90mg.

Children: Not recommended.

Warnings/Precautions: Severe renal impairment in patients with bone metastases: not recommended. Renal or hepatic insufficiency. Check serum creatinine before each dose: withhold until serum creatinine is within 10% of baseline if serum creatinine increases 0.5mg/dL from normal pre-treatment levels, or by 1mg/dL from an abnormal pre-treatment level. Monitor electrolytes (esp. calcium, magnesium, phosphate, potassium), CBC/differential, hematocrit/hemoglobin. Pre-existing blood disorders (eg, anemia, leukopenia, thrombocytopenia); monitor closely for first 2 weeks after treatment. Avoid dental surgery (do preventative dental work before therapy). Evaluate if thigh or groin pain develops and consider discontinuing if atypical femur fracture is suspected. Pregnancy (Cat.D): not recommended. Nursing mothers.

Interactions: Caution with other nephrotoxic drugs (eg, thalidomide).

Adverse reactions: Infusion-site reactions, fever, headache, dizziness, paresthesia, increased sweating, GI upset, anemia, fatigue, musculoskeletal pain (may be severe), electrolyte disturbances, hypertension, dyspnea, renal toxicity; jaw osteonecrosis, atypical subtrochanteric and diaphyseal femoral fractures.

How supplied: Contact supplier.

ZOLEDRONIC ACID

R

ZOMETA Novartis
Bisphosphonate. Zoledronic acid 4mg/5mL concentrated soln for IV infusion after dilution; 4mg/100mL ready-to-use soln for IV infusion.

Indications: Hypercalcemia of malignancy.

Adults: Give by IV infusion over at least 15 minutes. Albumin-corrected serum calcium ≥ 12 mg/dL: max 4mg; allow at least 7 days before retreatment.

Children: Not recommended.

Warnings/Precautions: Not recommended for use in patients with bone metastases and severe renal impairment. Renal or hepatic insufficiency. Check serum creatinine before each dose: withhold until serum creatinine is within 10% of baseline if serum creatinine increases by 0.5 mg/dL from a normal pre-treatment level, or by 1 mg/dL from an abnormal pre-treatment level, within 2 weeks of next dose. Assure adequate hydration when treating hypercalcemia of malignancy. Closely monitor electrolytes (esp. calcium, magnesium, phosphate), CBC/differential, hematocrit, hemoglobin. Evaluate if thigh or groin pain develops and consider discontinuing if atypical femur fracture is suspected. Aspirin-sensitive asthma. Avoid dental surgery (do preventative dental work before therapy). Elderly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Avoid concomitant other bisphosphonates. Additive hypocalcemic effect with aminoglycosides, loop diuretics. Caution with other nephrotoxic drugs (eg, thalidomide).

Adverse reactions: Fever, flu-like syndrome, GI upset, constipation, anemia, dyspnea, electrolyte disturbances, musculoskeletal pain (may be severe), hypotension, CNS effects, rigors, headache, paresthesia, renal toxicity; jaw osteonecrosis, atypical subtrochanteric and diaphyseal femoral fractures.

How supplied: Single-use vial, ready-to-use bottle—1

14B Oncology agents

ALDESLEUKIN

R

PROLEUKIN Promethues

Interleukin-2, recombinant. Aldesleukin 22 million IU/vial; pwd for IV infusion after reconstitution and dilution; contains mannitol; preservative-free.

Indications: Metastatic renal cell carcinoma. Metastatic melanoma.

Adults: ≥ 18 yrs: 600,000 IU/kg (0.037mg/kg) every 8 hours by IV infusion over 15 minutes for a max of 14 doses, followed by 9 days rest, then repeat for another 14 doses (max 28 doses/course), as tolerated. Retreatment and dose adjustments: see literature.

Children: <18 yrs: not established.

Contraindications: Abnormal thallium stress test or pulmonary function tests. Organ allografts. Previous drug related toxicity (eg, sustained ventricular tachycardia [≥ 5 beats], uncontrolled or unresponsive arrhythmias, chest pain with ECG changes consistent with angina, or MI, cardiac tamponade, intubation >72hrs, renal failure requiring dialysis >72hrs, coma or toxic psychosis >48hrs, repetitive or difficult seizures, bowel ischemia or perforation, GI bleeding requiring surgery).

Warnings/Precautions: See literature. History of cardiac or pulmonary disease. Renal, hepatic, or CNS impairment. Seizure disorder. Bacterial infections (treat prior to starting therapy; esp. patients with indwelling central lines). Withhold dose if organ perfusion is not maintained, urine output is reduced, systolic BP <90mmHg, CHF, cardiac ischemia or arrhythmias occur; or if moderate-to-severe lethargy or somnolence (continuing may result in coma) develops. Evaluate and treat CNS metastases; obtain negative scan before starting treatment. Do thallium stress test; monitor vital signs, weight, fluid intake and output daily. Correct hypovolemia or fluid accumulations if occur. Obtain CBCs, differential and platelets, blood chemistries (electrolytes, renal and hepatic function tests), chest X-rays, serum creatinine (should be ≤ 1.5 mg/dL before starting therapy), pulmonary function tests, arterial blood gases. Monitor for capillary leak syndrome, mental status changes, thyroid changes, diabetes onset. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Psychotropics may increase CNS toxicity. Increased toxicity with other nephrotoxic, hepatotoxic, myelotoxic, or cardiotoxic drugs. Hypersensitivity reactions with other antineoplastics. Myocardial injury and rhabdomyolysis risk increased with interferon- α . Antagonized by glucocorticoids (avoid). β -blockers and other antihypertensives may potentiate hypotension. Delayed reactions to iodinated contrast media. May increase risk of allograft rejection.

Adverse reactions: Hypotension, GI upset, oliguria, flu-like syndrome, respiratory disorders (eg, dyspnea), CNS effects (eg, confusion, somnolence), rash, metabolic and nutritional disorders (eg, bilirubinemia, increased creatinine), hyperglycemia, thyroid disorder, thrombocytopenia, anemia, impaired neutrophil function, capillary leak syndrome, cardiotoxicity, exacerbation of autoimmune and inflammatory disease, eosinophilia, possible antibody formation; others.

How supplied: Single-use vials—1

ALEMTUZUMAB

R

CAMPATH Genzyme

Monoclonal antibody, CD52 (recombinant, humanized). Alemtuzumab 30mg/mL; soln; for IV infusion after dilution; preservative-free.

Indications: B-cell chronic lymphocytic leukemia (B-CLL).

Adults: Premedicate with antihistamine and acetaminophen before 1st dose, and at dose escalations. Give by IV infusion over 2 hrs. Initially 3mg per day until infusion reactions are $\leq$ grade 2, then increase to 10mg per day until infusion reactions are $\leq$ grade 2, then to maintenance 30mg/day three times per week (on alternate days); duration of therapy (including escalation): 12 weeks. Do not exceed max single dose 30mg/dose

or 90mg/week. Give prophylactic antibiotics and antivirals during treatment and for at least 2 months after completion or until CD4⁺ counts resolve (whichever occurs later). Dose adjustments for neutropenia and thrombocytopenia: see literature. Retitrate if therapy interrupted for ≥ 7 days.

Children: Not recommended.

Warnings/Precautions: Discontinue dose for autoimmune or recurrent/persistent severe cytopenias (except lymphopenia). Withhold dose for severe cytopenias (except lymphopenia), grade 3 or 4 infusion reactions, serious infections, or during antiviral treatment for cytomegalovirus (CMV) infection or confirmed CMV viremia. Obtain CBCs, platelet counts weekly, assess CD4⁺ counts after treatment until recovery to ≥ 200 cells/ μ L. Monitor for infusion reactions; CMV infection (continue for 2 months after therapy ends). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid live virus vaccines (after recent therapy). May interfere with tests using antibodies. Irradiate any blood products given (GVHD may occur).

Adverse reactions: See literature; may be fatal. Infusion reactions, cytopenias (eg, neutropenia, lymphopenia, thrombocytopenia, anemia), infections (eg, CMV), GI upset, insomnia, anxiety; others.

How supplied: Single-use vials—1, 3

ALITRETINOIN

R

PANRETIN Eisai

Retinoid. Alitretinoin 0.1%; gel.

Indications: Cutaneous lesions of AIDS-related Kaposi's sarcoma (KS).

Adults: Apply twice daily to lesions (avoid mucous membranes and normal skin); do not occlude; may increase to 3-4 times daily as tolerated. Reduce frequency or suspend treatment if local toxicity occurs.

Children: Not recommended.

Warnings/Precautions: Not for use when systemic KS therapy required. Avoid sun, UV light. Flammable. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Increases DEET toxicity (avoid).

Adverse reactions: Photosensitivity, rash, pruritus, pain, exfoliative dermatitis, paresthesia, edema.

How supplied: Gel—60g

ALTRETAMINE

R

HEXALEN MGI Pharma

S-triazine derivative. Altretamine 50mg; caps.

Indications: Palliative treatment of persistent or recurrent ovarian cancer following first-line therapy with a cisplatin and/or alkylating agent-based combination.

Adults: 260mg/m² daily in four divided doses (after meals and at bedtime), for either 14 or 21 consecutive days in a 28-day cycle. Discontinue for >14 days if GI intolerance is unresponsive to treatment, WBC count <2000/mm³ or granulocyte count <1000/mm³, platelet count <75000/mm³,

or progressive neurotoxicity occurs. Restart at 200mg/m² daily. Discontinue indefinitely if neurologic symptoms fail to stabilize.

Children: Not recommended.

Contraindications: Severe myelosuppression or neurologic toxicity, except cisplatin-related neuropathy.

Warnings/Precautions: Monitor for myelosuppression (do monthly CBCs) and neurotoxicity. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Avoid pyridoxine. Severe orthostatic hypotension with MAOIs.

Adverse reactions: Nausea, vomiting, peripheral neuropathy, CNS symptoms (eg, mood disorders, ataxia, dizziness), myelosuppression, renal dysfunction, increased alkaline phosphatase.

How supplied: Caps-100

ANASTROZOLE

ARIMIDEX AstraZeneca

Aromatase inhibitor. Anastrozole 1mg; tabs.

Indications: In postmenopausal women: adjuvant treatment of hormone receptor-positive early breast cancer; first-line treatment of hormone receptor-positive or unknown locally advanced or metastatic breast cancer; advanced breast cancer with disease progression after tamoxifen therapy.

Adults: 1mg once daily. Advanced disease: continue until tumor progression.

Children: Not applicable.

Contraindications: Women who are or may become pregnant. Pregnancy (Cat.X).

Warnings/Precautions: Pre-existing ischemic heart disease. Severe hepatic impairment. Monitor bone mineral density, cholesterol. Nursing mothers: not recommended.

Interactions: Antagonized by tamoxifen, estrogens; do not give concomitantly.

Adverse reactions: Hot flashes, asthenia, arthritis, pain, arthralgia, pharyngitis, hypertension, depression, nausea, vomiting, rash, osteoporosis, fractures, back pain, insomnia, headache, peripheral edema, lymphedema, dyspnea, dizziness, paresthesia, vaginal bleeding, cough, hypercholesterolemia.

How supplied: Tabs-30

ARSENIC TRIOXIDE

TRISENOX Teva US Generics

Antineoplastic. Arsenic trioxide 1mg/mL; soln for IV inj after dilution; preservative-free.

Indications: Induction of remission and consolidation in acute promyelocytic leukemia (APL) refractory to or relapsed from retinoid and anthracycline chemotherapy, and whose APL has the t(15;17) translocation or PML/RAR-alpha gene expression.

Adults: Give by IV infusion over 1–2 hours; may extend infusion up to 4 hours if acute vasomotor

symptoms occur. Induction: 0.15mg/kg per day until bone marrow remission; max 60 doses. Consolidation treatment (begin 3–6 weeks after completion of induction therapy): 0.15mg/kg per day for 25 doses for up to 5 weeks.

Children: See literature. <5yrs: not recommended. 5–16yrs: doses of 0.15mg/kg per day have been used.

Warnings/Precautions: Renal or hepatic dysfunction. History of torsades de pointes. Preexisting QT interval prolongation. CHF. Monitor hematology, renal function, and electrolytes at least twice weekly, perform ECG at baseline then weekly (hospitalize if cardiac irregularities develop); unstable patients: monitor more frequently. Correct electrolyte imbalances before starting therapy (maintain K⁺ above 4mEq/dL and Mg⁺⁺ above 1.8mg/dL). Pregnancy: (Cat.D), nursing mothers: not recommended.

Interactions: Caution with drugs that can cause QT prolongation (discontinue these before starting therapy, if possible) or electrolyte imbalances.

Adverse reactions: Leukocytosis, GI upset, fatigue, edema, hyperglycemia, cough, rash, headache, dizziness, paresthesia, arthralgia, renal failure, electrolyte disorders (eg, hypokalemia, hypomagnesemia), abnormal LFTs; APL differentiation syndrome (eg, fever, dyspnea, weight gain, pulmonary infiltrates, pericardial effusion; give high-dose IV steroids at 1st sign), hyperleukocytosis, QT interval prolongation/heart block, atrial dysrhythmias, tachycardia, others (see literature).

How supplied: Single-use amps (10mL)-10

ASPARAGINASE

ELSPAR Lundbeck

Enzyme. Asparaginase 10,000 IU/vial; pld for IV or IM injection after reconstitution; contains mannitol; preservative-free.

Indications: Adjunct in acute lymphoblastic leukemia.

Adults and Children: Give by IV inj over at least 30 minutes or by IM inj (max 2mL/inj site). 6000 IU/m² IM or IV three times per week.

Contraindications: Pancreatitis, serious hemorrhage, or thrombosis with prior use.

Warnings/Precautions: Have resuscitation equipment available and observe for 1 hour post-dosing. Monitor blood counts, PT/INR, glucose, and hepatic function; and for pancreatitis (serum amylase, abdominal pain). Discontinue if serious allergic reactions, thrombotic events, or pancreatitis occurs. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Allergic reactions (including anaphylaxis), hyperglycemia, pancreatitis, CNS thrombosis, coagulopathy, hyperbilirubinemia, elevated transaminases.

How supplied: Single-use vial-1

ASPARAGINASE ERWINIA CHRYSANTHEMI

R

ERWINAZE Jazz

Asparagine-specific enzyme. Asparaginase *Erwinia chrysanthemi* 10,000 IU; per vial; lyophilized pld for IM inj after reconstitution.

Indications: As a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia (ALL) who have developed hypersensitivity to *E. coli*-derived asparaginase.

Adults and Children: Give by IM inj (max 2mL/inj site). To substitute for a pegaspargase dose: 25,000 IU/m² three times weekly (M/W/F) for 6 doses for each planned pegaspargase dose. To substitute for a native *E. coli* asparaginase dose: 25,000 IU/m² for each scheduled native *E. coli* asparaginase dose within a treatment.

Contraindications: History of serious pancreatitis, thrombosis, hemorrhagic events with prior L-asparaginase therapy.

Warnings/Precautions: Have resuscitation equipment available and other agents necessary to treat anaphylaxis. Discontinue if serious hypersensitivity reactions occur. Monitor for pancreatitis; discontinue if severe or hemorrhagic pancreatitis manifested by abdominal pain > 72hrs and amylase elevation $\geq 2 \times$ ULN occurs. Withhold therapy if mild pancreatitis; may resume after resolution. Monitor glucose levels at baseline and during therapy. Discontinue if thrombotic or hemorrhagic event occurs; may resume after resolution. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Serious hypersensitivity reactions including anaphylaxis, pancreatitis, abnormal transaminases, coagulation abnormalities including thrombosis and hemorrhage, nausea, vomiting, hyperglycemia.

How supplied: Vials-5

AZACITIDINE

R

VIDAZA Celgene

Cytidine analogue. Azacitidine 100mg/vial; pld for SC inj after reconstitution or IV inj after reconstitution and dilution; contains mannitol; preservative-free.

Indications: Myelodysplastic syndromes (refractory anemias, chronic myelomonocytic leukemia).

Adults: Premedicate for nausea & vomiting. Initially 75mg/m² SC (doses > 4mL divide equally into 2 syringes and inject into 2 separate sites) or IV (infuse over 10–40 minutes, must complete within 1 hour of reconstitution) daily for 7 days; repeat cycle every 4 weeks. May increase to 100mg/m² after 2 cycles if no response and no toxicity. Treat for at least 4–6 cycles. Adjust subsequent doses on blood counts and toxicities (eg, neutropenia, thrombocytopenia, decreased serum bicarbonate).

Children: Not recommended.

Contraindications: Advanced malignant hepatic tumors.

Warnings/Precautions: Renal or hepatic impairment. High tumor burden. Obtain CBC counts before each dosing cycle and as needed. Monitor serum bicarbonate and renal and hepatic function (do baseline liver chemistries and serum creatinine). Elderly. Pregnancy (Cat.D); use appropriate contraception (both men and women). Nursing mothers: not recommended.

Adverse reactions: GI upset, blood dyscrasias (esp. anemia, thrombocytopenia, neutropenia, leukopenia), fever, fatigue, inj site reactions, constipation, ecchymosis, petechiae, rigors, dyspnea, arthralgia, headache, anorexia, renal failure/tubular acidosis, hypokalemia, hepatic coma, others (see literature).

How supplied: Single-use vial-1

BCG, LIVE

R

THERACYS Sanofi Pasteur

BCG Live. Live *Bacillus Calmette and Guérin* (BCG) strain of attenuated *Mycobacterium bovis*; 81mg per vial; pld for intravesical administration after reconstitution and dilution; preservative-free.

Indications: Treatment and prophylaxis of carcinoma *in situ* (CIS) of the urinary bladder. Prophylaxis of stage Ta and/or T1 papillary tumors following transurethral resection (TUR).

Adults: Drain bladder via urethral catheter prior to instillation. Induction: Instill 1 dose intravesically once per week for 6 weeks. Maintenance: one dose at 3, 6, 12, 18, and 24 months after initial dose. Retain in bladder for up to 2 hours, then void seated. Increase fluid intake to flush bladder.

Children: Not recommended.

Contraindications: Immunosuppressed. Active TB. Febrile illness. UTI (withhold until complete resolution). Gross hematuria. Do not give within 7–14 days after biopsy, TUR, or traumatic catheterization.

Warnings/Precautions: Not for the prevention of cancer or TB. Determine PPD status prior to therapy; rule out active TB if (+). Not for stage TaG1 papillary tumors unless high tumor recurrence risk. Not for IV, IM, or SC injection. Monitor for systemic BCG reaction; may occur as a hypersensitivity reaction (eg, malaise, fever, chills) or active infection (eg, fever $\geq 101.3^{\circ}\text{F}$, or acute localized inflammation such as epididymitis, prostatitis, or orchitis persisting ≥ 2 days); if persistent fever or acute febrile illness consistent with BCG infection occurs, discontinue BCG permanently and treat with ≥ 2 antimycobacterial drugs (except pyrazinamide). Local irritative effects: do not use antimycobacterial drugs prophylactically. Pre-existing arterial aneurysm or prosthetic devices: risk of ectopic BCG infection. High-risk for HIV. Latex allergy. Small bladder. PPD seroconversion may occur with treatment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See contraindications.

Immunosuppressants, myelosuppressants, radiation, antimicrobial therapy may reduce efficacy.

Adverse reactions: Bladder irritation, inflammation (begins after 4 hrs and last up to 72 hrs), dysuria, urinary frequency, malaise, hematuria, fever, chills, cystitis, anemia, UTI, GI upset, renal toxicity, genital pain, arthralgia, incontinence, cramps, flu-like syndrome, systemic BCG infection.

How supplied: Vial-1 (w. diluent)

BCG, LIVE

TICE BCG Merck

BCG Live. *Bacillus of Calmette and Guérin* (BCG) strain of *Mycobacterium bovis* live, attenuated culture preparation; 50mg per vial; pld for intravesical administration after reconstitution and dilution; preservative-free.

Indications: Treatment and prophylaxis of carcinoma in situ (CIS) of the urinary bladder. Prophylaxis of stage Ta and/or T1 papillary tumor of the urinary bladder.

Adults: 1 vial in 50mL preservative-free saline intravesically once per week for 6 weeks (may repeat this regimen once if remission not achieved); then monthly for 6–12 months if needed. Avoid fluid at least 4 hrs before treatment and void immediately before administration. Retain in bladder for 2 hours.

Children: Not recommended.

Contraindications: Immunosuppressed. Active TB. Febrile illness. UTI. Gross hematuria. Do not give within 7 days after bladder biopsy, transurethral resection (TUR), or traumatic catheterization.

Warnings/Precautions: Not a vaccine for prevention of cancer or TB. Not for IV or SC use. Determine PPD status prior to therapy; rule out active TB if (+). Monitor for signs of systemic BCG infection: flu-like symptoms >72 hrs, fever $\geq 103^{\circ}\text{F}$, persistent LFT abnormalities; prostatitis, epididymitis, orchitis >2 days; treat with at least 2 antimycobacterial drugs (except pyrazinamide). Local irritative toxicities: do not treat with antimycobacterials. Bleeding bladder mucosa, small bladder. Disinfect fluid voided after therapy with bleach. PPD seroconversion may occur with treatment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Immunosuppressants, myelosuppressants, radiation, antimicrobial therapy may reduce efficacy.

Adverse reactions: Urine discoloration, bladder irritation, inflammation (begins after 4 hrs and last up to 72 hrs), malaise, fever, chills, flu-like syndrome, systemic BCG infection, dysuria, urinary frequency, hematuria, cystitis, urgency, nocturia, cramps, pain, incontinence, rigors, arthralgia.

How supplied: Vial-1

BENDAMUSTINE

TREANDA Teva Oncology

Alkylating agent. Bendamustine HCl 25mg, 100mg; per vial; lyophilized pld for IV infusion after reconstitution and dilution; contains mannitol; preservative-free.

Indications: Chronic lymphocytic leukemia (CLL). Indolent B-cell non-Hodgkin's lymphoma (NHL) that has progressed during or within 6 months of treatment with rituximab or a rituximab-containing regimen.

Adults: CLL: Give by IV infusion over 30 minutes. 100mg/m² on Days 1 and 2 of a 28-day cycle, up to 6 cycles. Hematologic toxicity ($\geq$ Grade 3): reduce dose to 50mg/m² on Days 1 and 2 of each cycle; if toxicity recurs, reduce dose to 25mg/m² on Days 1 and 2. Non-hematologic toxicity (clinically significant $\geq$ Grade 3): reduce dose to 50mg/m² on Days 1 and 2 of each cycle. Subsequent cycles: may consider dose re-escalation. NHL: Give by IV infusion over 60 minutes. 120mg/m² on Days 1 and 2 of a 21-day cycle, up to 8 cycles. Hematologic toxicity (Grade 4) or non-hematologic toxicity ($\geq$ Grade 3): reduce dose to 90mg/m² on Days 1 and 2 of each cycle; if toxicity recurs, reduce dose to 60mg/m² on Days 1 and 2. Both: May give allopurinol prophylactically for those at high risk of tumor lysis syndrome. Delay treatment for Grade 4 hematologic toxicity or clinically significant $\geq$ Grade 2 non-hematologic toxicity. Severe renal impairment (CrCl <40mL/min) or moderate to severe hepatic impairment: not recommended.

Children: Not recommended.

Warnings/Precautions: Myelosuppression; monitor leukocytes, platelets, hemoglobin, neutrophils closely; restart treatment based on ANC and platelet count recovery. Renal or hepatic impairment. Monitor for infection, infusion or skin reactions, tumor lysis syndrome. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: May be potentiated or antagonized by CYP1A2 inhibitors, inducers.

Adverse reactions: Lymphopenia, anemia, thrombocytopenia, leukopenia, neutropenia, pyrexia, nausea, vomiting, asthenia, fatigue, malaise, dry mouth, somnolence, cough, constipation, headache, mucosal inflammation, stomatitis, increased bilirubin, increased AST or ALT; infection, infusion reactions (discontinue if severe), tumor lysis syndrome, skin reactions (if severe or progressive, withhold dose or discontinue), other malignancies (eg, myelodysplastic syndrome, acute myeloid leukemia).

How supplied: Single-use vial (25mg/8mL, 100mg/20mL)-1

BEVACIZUMAB

AVASTIN Genentech

Angiogenesis inhibitor. Bevacizumab 100mg, 400mg; per vial; soln for IV infusion after dilution; preservative-free.

Indications: Metastatic colorectal carcinoma, in combination with 5-FU-based chemotherapy for first- or second-line treatment; or in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine oxaliplatin-based therapy for second-line treatment in patients who have progressed on a first-line Avastin-containing regimen. First-line treatment of unresectable, locally advanced, recurrent or

metastatic non-squamous, non-small cell lung cancer (NSCLC), in combination with carboplatin and paclitaxel. Glioblastoma, as a single agent for patients with progressive disease following prior therapy. Metastatic renal cell carcinoma (mRCC) in combination with interferon alfa.

Adults: Give by IV infusion after chemotherapy. Infuse 1st dose over 90 minutes; if tolerated, infuse 2nd dose over 60 minutes, and subsequent doses over 30 minutes. Metastatic colorectal carcinoma: 5mg/kg (when used with bolus-IFL) or 10mg/kg (when used with FOLFOX-4) once every 2 weeks until disease progression detected; 5mg/kg every 2 weeks or 7.5mg/kg every 3 weeks (when used with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based therapy). NSCLC: 15mg/kg once every 3 weeks with carboplatin/paclitaxel. Glioblastoma: 10mg/kg every 2 weeks. mRCC: 10mg/kg every 2 weeks with interferon alfa.

Children: Not established.

Warnings/Precautions: Do not start therapy before or for at least 28 days after surgery; allow surgical incisions to completely heal (see full labeling). History of hemoptysis of $\geq \frac{1}{2}$ teaspoon of red blood: do not administer. Discontinue if GI perforation, significant wound dehiscence, serious hemorrhage, severe arterial thromboembolic events, hypertensive crisis, nephrotic syndrome, non-GI fistula formation, or reversible posterior leukoencephalopathy syndrome occurs; suspend therapy if severe hypertension, moderate to severe proteinuria, or severe infusion reaction occurs. Cardiovascular disease. Renal or hepatic impairment. Monitor BP every 2–3 weeks. Elderly. Increases risk of ovarian failure; inform females of reproductive potential prior to starting therapy. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Epistaxis, headache, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain, exfoliative dermatitis; GI perforation, wound dehiscence/ impaired healing, necrotizing fasciitis (discontinue if occurs), hemorrhage, non-GI fistula formation, arterial thromboembolic events, hypertensive crisis, reversible posterior leukoencephalopathy syndrome, infusion reactions, ovarian failure.

How supplied: Single-use vial–1

BEXAROTENE

R_x

TARGETIN Eisai

Retinoid. Bexarotene 75mg; caps.

Indications: Cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.

Adults: Take with food. Initially 300mg/m² once daily; may increase after 8 weeks to 400mg/m² once daily if no tumor response and if well tolerated; monitor carefully. If toxicity occurs, reduce to 200mg/m² then 100mg/m² once daily, or suspend therapy.

Children: Not recommended.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: Be fully familiar with this drug's toxicity before use. Pancreatitis or risk of pancreatitis (eg, history of pancreatitis, uncontrolled hyperlipidemia, excess alcohol consumption, uncontrolled diabetes, biliary tract disease, drugs that can cause pancreatitis). Counsel patients monthly about need for contraception. Women of childbearing potential: obtain reliable negative pregnancy test within 1 week of start; repeat monthly. Start therapy on 2nd or 3rd day of normal menstrual period. Use two effective forms of contraception 1 month prior to, during, and for 1 month after therapy. Max 1 month/R_x. Men with partners who are or may become pregnant: use condoms during and for at least 1 month after therapy. Monitor lipids before treatment, weekly until stable, then every 8 weeks; try to keep triglycerides <400mg/dL; treat hyperlipidemia, or reduce or suspend bexarotene if needed. Hepatic or renal insufficiency. Monitor liver function at baseline, 1, 2, and 4 weeks after start, then (if stable) at least every 8 weeks during therapy; consider suspending or discontinuing treatment if SGOT/AST, SGPT/ALT, or bilirubin >3×ULN occurs. Monitor WBC with differential and thyroid function at baseline and during treatment; treat hypothyroidism if needed. Avoid sun and UV light. Nursing mothers: not recommended.

Interactions: Concomitant gemfibrozil: not recommended. Levels may be increased by CYP3A4 inhibitors (eg, ketoconazole, itraconazole, erythromycin, grapefruit juice). Levels may be reduced by CYP3A4 inducers (eg, rifampin, phenobarbital, phenytoin). May potentiate antihyperglycemics (eg, insulin, sulfonylureas, thiazolidinediones); monitor. May potentiate or be potentiated by protein-bound drugs. May antagonize tamoxifen, hormonal contraceptives, other CYP3A4 substrates. Limit Vit. A supplements to avoid toxicity. May increase CA125 assay values.

Adverse reactions: Lipid abnormalities, headache, hypothyroidism, asthenia, leukopenia, anemia, rash, GI disturbances, peripheral edema, dry skin, exfoliative dermatitis, alopecia, insomnia, fatigue, abnormal liver function tests, pancreatitis, pruritus, photosensitivity.

How supplied: Caps–100

BEXAROTENE

R_x

TARGETIN GEL Eisai

Retinoid. Bexarotene 1%; gel.

Indications: Cutaneous lesions in patients with CTCL (Stage IA and IB) who have refractory or persistent disease after other therapies or who have not tolerated other therapies.

Adults: Apply once every other day for the 1st week; then increase frequency at weekly intervals to once daily, then twice daily, then 3 times daily, then 4 times daily based on lesion tolerance. Usual dosing frequency: 2–4 times daily; may reduce if application site toxicity occurs. Allow gel to dry. Do not occlude.

Children: Not recommended.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: Be fully familiar with this drug's toxicity before use. Counsel patients monthly about need for contraception. Women of childbearing potential: obtain reliable negative pregnancy test within 1 week of start; repeat monthly. Start therapy on 2nd or 3rd day of normal menstrual period. Use two effective forms of contraception 1 month prior to, during, and for 1 month after therapy. Max 1 month/B. Men with partners who are or may become pregnant: use condoms during and for at least 1 month after therapy. Hepatic or renal insufficiency. Discontinue temporarily if severe irritation occurs. Avoid sun, UV light, and mucosal membranes. Nursing mothers: not recommended.

Interactions: Avoid concomitant products that contain DEET. May be potentiated by CYP3A4 inhibitors (eg, ketoconazole, itraconazole, erythromycin, grapefruit juice). Caution with gembfibrozil. Limit Vit. A supplements to avoid toxicity.

Adverse reactions: Application site reactions (eg, rash, pruritus, skin disorders, pain, contact dermatitis).

How supplied: Gel-60g

BICALUTAMIDE

R

CASODEX AstraZeneca

Antiandrogen. Bicalutamide 50mg; tabs.

Indications: In combination with luteinizing hormone-releasing hormone (LHRH) analogue in stage D₂ metastatic prostate carcinoma.

Adults: Take at the same time each day. 50mg daily. Start treatment at same time as starting LHRH analogue.

Children: Not applicable.

Contraindications: Women of childbearing potential. Pregnancy (Cat.X).

Warnings/Precautions: Moderate to severe hepatic impairment. Monitor prostate specific antigen and hepatic function (discontinue if ALT >2×ULN or if jaundice occurs). Nursing mothers.

Interactions: Monitor oral anticoagulants.

Adverse reactions: Hot flashes, gynecomastia, breast pain, diarrhea, pain, asthenia, infection, dyspnea, impotence, loss of libido, others (see literature); rare: hepatitis.

How supplied: Tabs-30, 100

BLEOMYCIN

R

BLEOMYCIN (various)

Cytotoxic glycopeptide antibiotic. Bleomycin 15units/vial, 30units/vial; lyophilized pwd for IM, IV, SC, or intrapleural administration after reconstitution.

Indications: Palliative treatment for squamous cell carcinoma (head and neck, penis, cervix, vulva), lymphomas (Hodgkin's disease, non-Hodgkin's lymphoma), testicular carcinoma (embryonal cell, choriocarcinoma, teratocarcinoma). Sclerosing agent for the treatment of malignant pleural effusion and prevention of recurrent pleural effusions.

Adults: Lymphomas: treat with ≤2 units for the first two doses, if no acute reaction occurs, follow regular dosage schedule. Squamous cell carcinoma, non-Hodgkin's lymphoma, testicular carcinoma: 0.25-0.5 units/kg IV, IM, or SC weekly or twice weekly. Hodgkin's disease: 0.25-0.5 units/kg IV, IM, or SC weekly or twice weekly; after a 50% response, a maintenance dose of 1 unit daily or 5 units weekly IV or IM should be given. Malignant pleural effusion: 60 units as a single dose bolus intrapleural injection. Renal impairment: see literature. Total doses >400 units: increased risk of pulmonary toxicity.

Children: Not recommended.

Warnings/Precautions: Renal impairment. Compromised pulmonary function. Monitor renal function. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: May be potentiated by nephrotoxic drugs.

Adverse reactions: Erythema, rash, striae, vesiculation, hyperpigmentation, tenderness of the skin, hyperkeratosis, nail changes, alopecia, pruritus, stomatitis; pneumonitis, pulmonary fibrosis, idiosyncratic reaction (hypotension, mental confusion, fever, chills, wheezing).

How supplied: Contact supplier.

BORTEZOMIB

R

VELCADE Millennium

Proteasome inhibitor. Bortezomib 3.5mg/vial; pwd for IV or SC inj after reconstitution; contains mannitol.

Indications: Multiple myeloma. Mantle cell lymphoma in patients who have received at least one prior therapy.

Adults: Give as a 3-5 second IV bolus inj or as SC inj into thigh or abdomen (rotate sites). Previously untreated multiple myeloma: Treat for nine 6-week cycles in combination with oral melphalan and oral prednisone. Cycles 1-4: 1.3mg/m² twice weekly (days 1, 4, 8, 11, 22, 25, 29, 32); Cycles 5-9: 1.3mg/m² once weekly (days 1, 8, 22, 29). Relapsed multiple myeloma or mantle cell lymphoma: Standard schedule: 1.3mg/m² twice weekly for 2 weeks (days 1, 4, 8, 11) then 10 day rest period (days 12-21); Extended therapy (if using >8 cycles): may use standard schedule, or maintenance schedule: 1.3mg/m² once weekly for 4 weeks (days 1, 8, 15, 22) then 13 day rest period (days 23-35). Allow at least 72 hours between consecutive doses. Adjust dose if toxicity develops: see literature. SC inj may be considered for patients with pre-existing or at high-risk of peripheral neuropathy. Moderate-to-severe hepatic impairment: reduce to 0.7mg/m² in 1st cycle; may consider dose increase to 1mg/m² or decrease to 0.5mg/m² in subsequent cycles based on tolerance.

Children: Not established.

Contraindications: Boron or mannitol sensitivity. Intrathecal administration.

Warnings/Precautions: Hepatic impairment. Pre-existing severe neuropathy; treat only after

careful risk-benefit assessment. Monitor for development or worsening of peripheral neuropathy; consider dose or schedule adjustment. Diabetes. History of syncope. Avoid dehydration; give fluids and electrolytes. Heart disease (monitor for CHF). Monitor CBC and platelets and for toxicities. High tumor burden (monitor for tumor lysis syndrome). Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: Concomitant strong CYP3A4 inducers (eg, rifampin): not recommended; efficacy may be reduced. Avoid St. John's Wort. Potentiated by ketoconazole, other potent CYP3A inhibitors. Increased risk of peripheral neuropathy with other agents that can cause neuropathy (eg, amiodarone, antivirals, isoniazid, metronidazole, statins, nitrofurantoin, or previous neurotoxic agents). Caution with hypotensives and hypoglycemics.

Adverse reactions: Asthenia, GI upset, peripheral neuropathy, decreased appetite, thrombocytopenia, anemia, orthostatic hypotension, pyrexia, headache, insomnia, psychiatric disorders, arthralgia, neutropenia, hypercalcemia, pain, edema, paresthesia, dysesthesia, dyspnea, cough, pruritus, dizziness, blurred vision, pneumonia, CHF, decreased LVEF, herpes reactivation, hepatotoxicity; rare: pulmonary disorders, reversible posterior leukoencephalopathy syndrome (discontinue if occurs).

How supplied: Single-dose vial-1

BRENTUXIMAB VEDOTIN

R

ADCETRIS Seattle Genetics
CD30-directed antibody-drug conjugate. Brentuximab vedotin 50mg/vial; pwd for IV infusion after reconstitution; preservative-free.

Indications: Treatment of Hodgkin lymphoma (HL) after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates. Treatment of systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen.

Adults: Give by IV infusion over 30 minutes. 1.8mg/kg every 3 weeks (if >100kg, calculate dose based on wt. of 100kg); continue until a max of 16 cycles, disease progression or unacceptable toxicity. Peripheral neuropathy: if Grade 2/3: withhold until resolve to ≤Grade 1, then restart with 1.2mg/kg; if Grade 4: discontinue therapy. Neutropenia: Grade 3/4: withhold until resolve to ≤Grade 2; may consider growth factor support; recurrent Grade 4: discontinue or consider reducing dose to 1.2mg/kg.

Children: Not established.

Contraindications: Concomitant bleomycin.

Warnings/Precautions: Risk of JC virus infection. Monitor for progressive multifocal leukoencephalopathy (PML); withhold dose if suspected and discontinue if confirmed. Monitor for neuropathy and delay, change, or discontinue dose

accordingly. Monitor for infusion-related reactions; permanently discontinue and treat if anaphylaxis occurs. Monitor CBCs prior to each dose and frequently for Grade 3 or 4 neutropenia; if develops, delay, reduce or discontinue dose. Increased risk of tumor lysis syndrome in rapidly proliferating tumor/high tumor burden patients; monitor closely. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: See Contraindications. Potentiated by strong CYP3A4 inhibitors (eg, ketoconazole); monitor. Antagonized by potent CYP3A4 inducers (eg, rifampin).

Adverse reactions: Neutropenia, peripheral sensory neuropathy, fatigue, GI upset, anemia, upper respiratory tract infection, pyrexia, rash, thrombocytopenia, cough; infusion reactions, Stevens-Johnson syndrome (discontinue if occurs), PML (may be fatal).

How supplied: Single-use vial-1

BUSULFAN

R

BUSULFEX Otsuka

Alkylating agent. Busulfan 6mg/mL; soln for IV administration after dilution.

Indications: In combination with cyclophosphamide, as a conditioning regimen prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.

Adults: See literature. Premedicate with phenytoin and antiemetics. Give by IV infusion over 2 hours. 0.8mg/kg of ideal body weight or actual body weight, whichever is lower, every 6 hours for 4 days (total of 16 doses). Obese: base dose on adjusted ideal body weight.

Children: See literature.

Warnings/Precautions: Myelosuppression. Seizure disorder. Head trauma. Renal or hepatic impairment. Obtain CBCs with differential, platelet count, liver enzymes, bilirubin during treatment and until recovery. Monitor for infection and bleeding. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Potentiated by itraconazole and acetaminophen. May be antagonized by phenytoin. Caution with potentially epileptogenic drugs.

Adverse reactions: Myelosuppression (eg, granulocytopenia, thrombocytopenia, anemia), GI upset, stomatitis, anorexia, abdominal pain, dyspepsia, fever, headache, asthenia, chills, pain, tachycardia, hypertension, edema, dyspnea, dizziness, depression, elevated creatinine, hypomagnesemia, hyperglycemia, hypokalemia, hypocalcemia, hyperbilirubinemia, insomnia, anxiety, rhinitis, rash; seizures (with higher doses), hepatic veno-occlusive disease, cardiac tamponade (in pediatric patients with thalassemia); rare: bronchopulmonary dysplasia with pulmonary fibrosis.

How supplied: Single-use vials (10mL)-8

BUSULFAN**MYLERAN** GlaxoSmithKline*Alkylating agent.* Busulfan 2mg; tabs.**Indications:** Palliative treatment of chronic myelogenous leukemia.**Adults:** Remission induction: 4–8mg/day or 60micrograms/kg or 1.8mg/m², daily. Reserve doses >4mg/day for severe cases. Reduce dose or discontinue at first sign of reduced bone marrow reserve. Discontinue before leukocyte count normalizes; see literature. Normal leukocyte counts usually achieved in 12–20 weeks. If remission <3 months, maintenance therapy of 1–3mg/day may be advisable.**Children:** Remission induction: 60micrograms/kg or 1.8mg/m², daily. Reduce dose or discontinue at first sign of reduced bone marrow reserve. Discontinue before leukocyte count normalizes. Normal leukocyte counts usually achieved in 12–20 weeks. See literature.**Warnings/Precautions:** Confirm diagnosis. Monitor hepatic and bone marrow function. Obtain CBCs and differential weekly; monitor for anemia. Previously compromised bone marrow (irradiation, chemotherapy). Seizure disorder or risk. Head trauma. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended.**Interactions:** Myelosuppression increased with other myelosuppressives. Increased pulmonary toxicity with other cytotoxic drugs. Potentiated by itraconazole, cyclophosphamide (see literature). May be antagonized by phenytoin. Hepatotoxicity possible with long-term continuous thioguanine therapy. Caution with drugs that lower seizure threshold.**Adverse reactions:** See literature. Bone marrow suppression (eg, pancytopenia, anemia, leukopenia, thrombocytopenia, aplastic anemia), pulmonary toxicity, cellular dysplasia, malignant tumors, acute leukemias, cardiac tamponade (esp. in thalassemia), hyperpigmentation, adrenal insufficiency, seizures, hepatic veno-occlusive disease, infection (eg, pneumonia, sepsis), mucositis, myasthenia gravis, gonadal suppression, rash; rare: cataracts, bronchopulmonary dysplasia (discontinue if occurs).**How supplied:** Tabs–25**CABAZITAXEL****JEVTANA** Sanofi Aventis*Taxane antimicrotubule.* Cabazitaxel 60mg/1.5mL; soln for IV infusion after dilution; contains polysorbate 80, diluent contains ethanol.**Indications:** In combination with prednisone, hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing regimen.**Adults:** Pretreat with IV antihistamine, corticosteroid, and H₂ blocker 30 min before each dose (see literature) and with antiemetic (IV or oral as needed). 25mg/m² by IV infusion over 1 hour every 3 weeks, with oral prednisone 10mg/day during treatment. Do not treat if

R

neutrophil count $\leq 1,500$ cells/mm³. Prolonged grade ≥ 3 neutropenia (>1 week), febrile neutropenia, grade ≥ 3 diarrhea: delay treatment and/or reduce dose to 20mg/m² (see literature). Discontinue if reactions persist after dosing at 20mg/m².**Children: Not recommended.****Contraindications:** Baseline neutrophil count $\leq 1,500$ cells/mm³. Allergy to polysorbate 80.**Warnings/Precautions:** Do CBC weekly in 1st cycle and before each subsequent cycle. Increased risk of neutropenia complications; consider G-CSF prophylaxis. Hepatic impairment: not recommended. Severe renal impairment (CrCl <30mL/min) or ESRD. Elderly (increased susceptibility to adverse reactions); monitor closely. Pregnancy (Cat.D; avoid). Nursing mothers: not recommended.**Interactions:** Avoid strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, atazanavir, nefazodone, nelfinavir, ritonavir, saquinavir, voriconazole) (may potentiate cabazitaxel); caution with moderate CYP3A4 inhibitors. Avoid strong CYP3A4 inducers (eg, phenytoin, carbamazepine, rifampin, phenobarbital) (may antagonize cabazitaxel). Avoid St. John's Wort.**Adverse reactions:** Bone marrow suppression (esp. neutropenia, anemia, leukopenia, thrombocytopenia), febrile neutropenia, GI upset (esp. diarrhea, may be fatal), renal failure, fatigue, constipation, asthenia, abdominal pain, hematuria, back pain, anorexia, peripheral neuropathy, pyrexia, dyspnea, dysgeusia, cough, arthralgia, alopecia, hypersensitivity reactions (eg, rash, hypotension, bronchospasm).**How supplied:** Kit (single-use vial + diluent)–1**CAPECITABINE**

R

XELODA Roche*Fluoropyrimidine.* Capecitabine (prodrug of 5-fluorouracil) 150mg, 500mg; tabs.**Indications:** Metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel when further anthracycline therapy is not indicated (eg, prior cumulative doses of 400mg/m² of doxorubicin or its equivalents). With docetaxel for metastatic breast cancer after failure of prior anthracycline-containing regimen. First-line treatment of metastatic colorectal carcinoma when fluoropyrimidine therapy alone is preferred. Adjuvant treatment of Dukes' C colon cancer after complete resection of the primary tumor when fluoropyrimidine therapy alone is preferred.**Adults:** See literature. Give cyclically (2 weeks on, 1 week off). Take with water within 30 minutes after AM & PM meals. ≥ 18 yrs: 1250mg/m² twice daily. Dukes' C colon cancer: continue for a total of 8 cycles.Combination therapy: give with docetaxel 75mg/m² IV infused over 1 hour every 3 weeks. Interrupt, adjust dose, and/or treat symptoms if toxicity occurs (eg, hyperbilirubinemia, diarrhea, nausea, vomiting, hand-and-foot syndrome, stomatitis) (see literature); do not increase dose afterwards. Renal impairment (CrCl 51–80mL/min): monitor carefully; (CrCl

30–50mL/min): reduce capecitabine dose to 75% of starting dose (ie, 950mg/m² twice daily).

Children: <18yrs: **not recommended.**

Contraindications: Severe renal impairment (CrCl <30mL/min). Dihydropyrimidine dehydrogenase deficiency. Pregnancy (Cat.D), nursing mothers: not recommended.

Warnings/Precautions: Hepatic or renal dysfunction. Coronary artery disease. Elderly (≥80years).

Interactions: Potentiated by leucovorin. Monitor warfarin, other CYP2C9 substrates, phenytoin.

Adverse reactions: Diarrhea, lymphopenia, necrotizing enterocolitis, hand-and-foot syndrome, GI upset, stomatitis, fatigue, dermatitis, anorexia, cardiotoxicity, bone marrow suppression, blood dyscrasias, hyperbilirubinemia, paresthesias, eye irritation, fever, headache, edema, dizziness, insomnia, myalgia, dehydration, nail disorder, limb pain, skin discoloration, alopecia.

Testing considerations: TS (thymidylate synthase), MSI (microsatellite instability), DPD (dihydropyrimidine dehydrogenase)

How supplied: Tabs 150mg–600mg–120

CARBOPLATIN

R

CARBOPLATIN (various)

Platinum coordination complex. Carboplatin 10mg/mL; soln for IV infusion.

Indications: Initial treatment of advanced ovarian cancer in combination with other chemotherapy. Secondary treatment of recurrent ovarian cancer after prior chemotherapy, including patients previously treated with cisplatin.

Adults: See literature. Give by IV infusion over ≥15 minutes. Combination therapy with cyclophosphamide (previously untreated): 300mg/m² on Day 1 every 4 weeks for 6 cycles. As a single agent for recurrent ovarian carcinoma: 360mg/m² on Day 1 every 4 weeks. In either case the Calvert equation may be used (Total Dose [mg] = [target area under the curve (AUC)] × [glomerular filtration rate + 25]). Use Calvert equation for elderly patients. Adjust dose for renal insufficiency and blood counts (see literature).

Children: **Not recommended.**

Contraindications: Severe bone marrow suppression. Significant bleeding. Pregnancy (Cat.D). Nursing mothers.

Warnings/Precautions: Dose-related bone marrow suppression. Elderly. Renal dysfunction. Monitor blood counts frequently; do not repeat dose until neutrophil count is >2,000 and platelets are >100,000. Anemia (transfusions may be needed). Premedicate with antiemetics; increasing infusion time or dividing total daily dose over 5 days may reduce emesis. Previous platinum-containing therapy. Loss of vision with higher than recommended doses.

Interactions: Potentiates nephrotoxicity with other nephrotoxic drugs (eg, aminoglycosides). Caution with other myelosuppressives.

Adverse reactions: Bone marrow suppression with possible infectious or hemorrhagic complications, anemia, vomiting, abdominal pain, anorexia, diarrhea, constipation, peripheral neuropathies, ototoxicity, visual disturbances, taste perversion, CNS symptoms, nephrotoxicity, hepatotoxicity, electrolyte changes, hypersensitivity reactions, injection site reactions, pain, asthenia, alopecia, malaise, hypertension; respiratory, genitourinary, mucosal, cardiovascular events; rare: hemolytic uremic syndrome.

Note: Avoid contact with aluminum (eg, needles).

How supplied: Contact supplier.

CARMUSTINE

R

BICNU Bristol-Myers Squibb

Alkylating agent. Carmustine 100mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free.

Indications: Palliative therapy as a single agent or in combination with other chemotherapeutic agents for brain tumors (glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, metastatic brain tumors), multiple myeloma (in combination with prednisone), Hodgkin's disease (as secondary therapy in patients who relapse or fail to respond to primary therapy), Non-Hodgkin's lymphomas (as secondary therapy in patients who relapse or fail to respond to primary therapy).

Adults: Pretreat with antiemetics. Give by slow IV infusion. Previously untreated patients as a single agent: Initially 150–200mg/m² every 6 weeks. May give as one single dose or divided into daily injections (eg, 75–100mg/m²) on 2 consecutive days. Adjust subsequent doses based on hematologic response (see literature). In combination therapy: adjust doses accordingly (see literature).

Children: **Not recommended.**

Contraindications: Bone marrow suppression.

Warnings/Precautions: Monitor blood counts weekly for > 6 weeks after a dose. Do not give repeat doses until platelets are >100,000/mm³ and leukocytes are 4000/mm³. Monitor liver and renal function. Perform pulmonary function tests prior to and during therapy. History of lung disease. Patients with baseline < 70% of the predicted Forced Vital Capacity or Carbon Monoxide Diffusing Capacity, and cumulative doses > 1400mg/m² increase risk of pulmonary toxicity. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended.

Adverse reactions: Delayed myelosuppression leading to infection and bleeding, pulmonary toxicity, delayed pulmonary fibrosis, secondary malignancies, nausea, vomiting, hepatotoxicity, nephrotoxicity, neuroretinitis, chest pain, headache, hypersensitivity, hypotension, tachycardia. Intensive flushing of the skin and suffusion of the conjunctiva related to rapid IV infusion.

How supplied: Single-use vial-1 (w. 3mL sterile diluent)

CETUXIMAB**ERBITUX** Bristol-Myers Squibb

Epidermal growth factor receptor blocker. Cetuximab 100mg/vial, 200mg/vial; soln for IV infusion; preservative-free.

Indications: In combination with radiation therapy for treating locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN). In combination with platinum-based therapy with 5-fluorouracil (5-FU) for first-line treatment of recurrent locoregional disease or metastatic SCCHN. As a single agent for recurrent or metastatic SCCHN after failure of prior platinum-based therapy. *K-Ras* mutation-negative (wild-type), EGFR-expressing metastatic colorectal carcinoma: for use in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for first-line treatment, or in combination with irinotecan (if refractory to irinotecan-based chemotherapy), or as a single agent (after failure of both irinotecan- and oxaliplatin-based regimens or if irinotecan-intolerant). Not recommended for use with *K-Ras* mutation-positive or *K-Ras* somatic mutations in codon 12 or 13.

Adults: Pretreat with H_1 blocker. Give by IV infusion (use filter); max rate: 10mg/min. Initial dose: 400mg/m² once over 2 hours; then 250mg/m² once weekly over 1 hour. SCCHN (combination therapy): Give initial dose 1 week prior to initiation of radiation therapy. Complete administration 1 hour prior to platinum-based therapy with 5-FU. Give subsequent weekly dose for duration of radiation therapy (6–7 weeks) or until disease progression or unacceptable toxicity. Colorectal (combination therapy): Complete administration 1 hour prior to FOLFIRI. Permanently reduce infusion rate by 50% if Grade 1 or 2 and non-serious Grade 3 infusion reaction occurs; permanently discontinue if Grade 3 or 4 serious reaction occurs. Monitor patient during and for 1 hr post-infusion. Skin toxicity: see full labeling.

Children: Not recommended.

Warnings/Precautions: Confirm *K-Ras* mutation status and EGFR expression for colorectal cancer. Discontinue if severe infusion reactions or interstitial lung disease occur. Monitor for infusion reactions, cardiopulmonary arrest, pulmonary toxicity, skin inflammation/infection; avoid sun, UV light. Additive cutaneous reactions with irradiation. Cardiovascular diseases (w. irradiation or platinum-based therapy with 5-FU). Monitor electrolytes (eg, magnesium, potassium, calcium) during and after cetuximab therapy. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Increased mucositis (Grade 3–4), radiation recall syndrome, acneiform rash, cardiac events, and electrolyte disturbances with radiation and cisplatin.

Adverse reactions: Cutaneous reactions (pruritus, nail changes), acneiform rash, headache, diarrhea, infection, asthenia, mucositis, weight loss, xerostomia, dehydration, electrolyte abnormalities; infusion reactions (may be severe: eg, bronchospasm,

R

dyspnea), interstitial lung disease, cardiopulmonary arrest, hypomagnesemia, fever, sepsis, kidney failure, pulmonary embolus; others (see full labeling).

Testing considerations: EGFR amplification analysis, *K-RAS* mutation analysis, *B-RAF* mutation analysis.

How supplied: Single-use vials–1**CHLORAMBUCIL**

R

LEUKERAN GlaxoSmithKline

Alkylating agent. Chlorambucil 2mg; tabs.

Indications: Palliative treatment of chronic lymphatic (lymphocytic) leukemia and malignant lymphomas (including lymphosarcoma, giant follicular lymphoma, and Hodgkin's disease).

Adults: See literature. 0.1–0.2mg/kg per day for 3–6 weeks. Reduce dose if leukocyte or platelet counts fall below normal values and discontinue if more severe depression occurs. Do not give full dose within 4 weeks of radio- or chemotherapy.

Children: Not recommended.

Warnings/Precautions: Compromised bone marrow function. History of seizure disorder or head trauma. Monitor blood weekly (during first 3–6 weeks, do WBC count 3–4 days after each weekly CBC). Discontinue if skin reactions occur. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Avoid live vaccines. Myelosuppressives, radiotherapy potentiates antineoplastic effect. Caution with drugs that lower seizure threshold.

Adverse reactions: Bone marrow suppression, seizures, fever, rash, hypersensitivity, urticaria, azoospermia, amenorrhea, sterility, hepato- and pulmonary toxicity, secondary malignancies, GI upset.

How supplied: Tabs–50**CISPLATIN**

R

CISPLATIN (various)

Platinum coordination complex. Cisplatin 1mg/mL; soln for IV infusion after dilution.

Indications: As a single agent, for treating transitional cell bladder cancer or for secondary therapy of metastatic ovarian tumor. Adjunctive therapy for metastatic testicular or ovarian tumor.

Adults: Give by IV infusion over 6–8 hours. Bladder: 50–70mg/m² IV per cycle once every 3–4 weeks; heavily pretreated patients: initially 50mg/m² IV per cycle every 4 weeks. Testicular: 20mg/m² IV daily for 5 days per cycle. Ovarian: 100mg/m² IV per cycle once every 4 weeks; or, (when given with cyclophosphamide): 75–100mg/m² IV per cycle once every 4 weeks. Usual max: 100mg/m² per cycle. Subsequent cycles: give as tolerated, withhold dose if serum creatinine, BUN, platelets, WBCs, or auditory acuity out of normal limits; see literature.

Children: Not recommended.

Contraindications: Renal or hearing impairment. Myelosuppression. Pregnancy (Cat.D). Nursing mothers.

Warnings/Precautions: Have epinephrine, antihistamine available. Monitor baseline and pre-

treatment renal function, electrolytes, auditory function; do periodic CBCs (weekly), liver function tests, neurologic exam. Hydrate patient before dosing. Avoid extravasation. Elderly.

Interactions: Potentiates nephrotoxicity with other nephrotoxic drugs (eg, aminoglycosides). May antagonize anticonvulsants. May be antagonized by pyridoxine.

Adverse reactions: Nephrotoxicity, neurotoxicity (eg, peripheral neuropathies), ototoxicity, myelosuppression, hemolytic anemia, marked nausea and vomiting, vascular toxicity (eg, MI, TIA), electrolyte disturbances, hyperuricemia, SIADH, hepatotoxicity, anaphylactic-like reactions, others; see literature.

Note: Avoid contact with aluminum (eg, needles).

How supplied: Contact supplier.

CLADRIBINE

LEUSTATIN Janssen Biotech

Chlorinated purine nucleoside analog. Cladribine 1mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: Active hairy cell leukemia.

Adults: Give by continuous IV infusion for 7 consecutive days. 0.09mg/kg per day.

Children: See full labeling.

Warnings/Precautions: Delay or discontinue if neurotoxicity or renal toxicity occurs. Myelosuppression. Active infection. Renal or hepatic insufficiency.

Monitor blood counts (esp. during first 4–8 weeks post-dose), renal and hepatic function. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Live attenuated vaccines: not recommended. Increased toxicity with myelosuppressive, immunosuppressive, or nephrotoxic agents.

Adverse reactions: Severe myelosuppression (eg, neutropenia, anemia, thrombocytopenia), fever, infection, fatigue, nausea, rash, headache, inj site reactions, others; neurotoxicity, nephrotoxicity, tumor lysis syndrome (rare).

How supplied: Single-use vial (10mL)–7

CLOFARABINE

CLOLAR Genzyme

Purine nucleoside antimetabolite. Clofarabine 1mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: Acute lymphoblastic leukemia (ALL) in patients 1–21 years of age after relapses from, and/or refractoriness to, at least two prior regimens.

Adults: Not established.

Children: Monitor blood pressure, cardiac, renal, and hepatic function before and during therapy. Give by IV infusion over 2 hours. 1–21yrs: 52mg/m² daily for 5 consecutive days; repeat approximately every 2–6 weeks following recovery or return to baseline organ function. Provide supportive care (eg, IV fluids, antihyperuricemics, alkalinize urine, steroids, antiemetics, diuretics, albumin) throughout treatment. Renal impairment (CrCl 30–60mL/min): reduce dose by 50%. Dose modifications: see full labeling.

Warnings/Precautions: Obtain CBCs and platelets daily during the 5 days of therapy, then 1–2 times weekly or as needed. Monitor for signs/symptoms of infection, tumor lysis syndrome, cytokine release (eg, tachypnea, hypotension); if cytokine release progresses to systemic inflammatory response syndrome (SIRS)/capillary leak syndrome and/or if organ dysfunction (grade 3 or 4 hepatic or renal toxicity) occurs, discontinue and treat; may restart at lower dose if organ function recovers and patient is stable. Ensure adequate hydration. Monitor for venous occlusive disease of the liver in patients who previously received hematopoietic stem cell transplant; discontinue if suspected. Pregnancy (Cat.D); use effective contraception. Nursing mothers: not recommended.

Interactions: Minimize exposure to drugs with known renal toxicity during treatment. Consider avoiding concomitant drugs known to induce hepatic toxicity. Caution with drugs that affect BP or cardiac function; monitor.

Adverse reactions: Nausea, vomiting, diarrhea, headache, rash, pruritus, pyrexia, fatigue, palmar-plantar erythrodysesthesia syndrome, anxiety, flushing, mucosal inflammation; bone marrow suppression (eg, febrile neutropenia, anemia, leukopenia, thrombocytopenia), infections, hyperuricemia, hypotension, cardiac events, SIRS/capillary leak syndrome.

How supplied: Single-use vial (20mL)–1, 4

CRIZOTINIB

XALKORI Pfizer

Tyrosine kinase inhibitor. Crizotinib 200mg, 250mg; caps.

Indications: Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

Adults: Swallow whole. 250mg twice daily. Dose interruption and/or dose reduction to 200mg twice daily may be required based on individual safety/tolerability, then to 250mg once daily if necessary. Dose reduction for hematologic and non-hematologic toxicities: see literature.

Children: Not established.

Warnings/Precautions: Risk of hepatotoxicity. Monitor CBCs with differential, ALT, total bilirubin monthly, and more frequently in Grade 2–4 elevations, or if fever/infection occurs; temporarily suspend, reduce dose, or permanently discontinue as indicated. Risk of severe pneumonitis: monitor for pulmonary symptoms; permanently discontinue if occurs. Congenital long QT syndrome; avoid. History of or predisposition for QTc prolongation (eg, CHF, bradyarrhythmias, electrolyte abnormalities, concomitant drugs that prolong QT interval): consider monitoring ECG, electrolytes periodically; permanently discontinue if Grade 4 QTc prolongation occurs. Test for ALK-positive NSCLC with FDA-approved test before treating. Hepatic impairment. Severe renal

impairment or ESRD. Pregnancy (Cat.D); avoid. Use adequate contraception during therapy and at least 90 days after. Nursing mothers: not recommended.

Interactions: Avoid concomitant strong CYP3A inhibitors (eg, atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone), grapefruit juice or strong CYP3A inducers (eg, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, St. John's Wort). Avoid concomitant CYP3A substrates (eg, alfentanil, cyclosporine, ergots, fentanyl) with narrow therapeutic indices. Caution with moderate CYP3A inhibitors. Dose reduction may be needed with coadministered drugs metabolized by CYP3A.

Adverse reactions: Vision disorder, GI upset, edema, constipation, Grade 3–4 events: ALT increased, neutropenia; elevated total bilirubin, pneumonitis (may be fatal), QT prolongation, hepatotoxicity (may be fatal).

How supplied: Caps–60

CYCLOPHOSPHAMIDE

R

CYCLOPHOSPHAMIDE (various)
Alkylating agent. Cyclophosphamide 25mg, 50mg; tabs.

Indications: See literature. Malignant lymphomas, multiple myeloma, leukemias, advanced mycosis fungoides, neuroblastoma, ovarian adenocarcinoma, retinoblastoma and breast carcinoma.

Adults: Initial and maintenance: 1–5mg/kg/day.

Children: See literature.

Also: Cyclophosphamide
CYTOXAN INJECTION Bristol-Myers Squibb
 Cyclophosphamide 500mg, 1g, 2g; per vial; pwd for inj after reconstitution; preservative-free.

Adults: Initially 40–50mg/kg IV in divided doses over 2–5 days; or 10–15mg/kg IV every 7–10 days; or 3–5mg/kg IV twice weekly.

Children: See literature.

Contraindications: Severe bone marrow depression.

Warnings/Precautions: Leukopenia. Thrombocytopenia. Tumor cell infiltration of bone marrow. Previous X-ray therapy or cytotoxic chemotherapy. Impaired renal or hepatic function. Infections. Adrenalectomy. General anesthesia within 10 days of therapy. Monitor hematologic profile (esp. neutrophils and platelets). Obtain urine sample (monitor for hemorrhagic cystitis); maintain adequate hydration. May interfere with wound healing. Elderly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Potentiated by phenobarbital. Potentiates other myelosuppressives, radiotherapy, succinylcholine. May potentiate doxorubicin-induced cardiotoxicity.

Adverse reactions: GI upset, alopecia, leukopenia, infections, thrombocytopenia, anemia, hemorrhagic cystitis (discontinue if occurs), renal tubular necrosis, interstitial pulmonary fibrosis, gonadal toxicity (amenorrhea, infertility), anaphylactic reactions.

How supplied: Tabs–contact supplier
 Single-use vial–1

CYTARABINE

R

CYTARABINE Bedford
Antimetabolite. Cytarabine 100mg, 500mg, 1g, 2g; per vial; lyophilized pwd for IV, intrathecal, SC inj after reconstitution.

Indications: Remission induction in acute non-lymphocytic leukemia of adults and children. Acute lymphocytic leukemia. Chronic myelocytic leukemia (blast phase). Prophylaxis and treatment of meningeal leukemia (intrathecal route).

Adults and Children: Induction therapy of acute non-lymphocytic leukemia: 100mg/m² per day by continuous IV infusion (days 1–7) or 100mg/m² IV every 12 hours (days 1–7). Acute lymphocytic leukemia and chronic myelocytic leukemia: see literature. Meningeal leukemia: Usual range: 5–75mg/m² intrathecally; may give once daily for 4 days to once every 4 days; most frequently used dose: 30mg/m² every 4 days until cerebrospinal fluid findings are normal.

Warnings/Precautions: Do not use diluent with benzyl alcohol for intrathecal administration. Pre-existing myelosuppression. Renal or hepatic impairment. Monitor blood counts, renal, hepatic function. Neonates. Pregnancy (Cat.D); avoid use. Nursing mothers.

Interactions: May antagonize gentamicin, fluorocytosine.

Adverse reactions: Myelosuppression (leukopenia, thrombocytopenia, anemia), GI upset, anorexia, abdominal pain, oral ulceration, rash, fever, hepatic dysfunction, infection, bleeding; cytarabine syndrome, hyperuricemia, pancreatitis, paralysis (rare), others.

How supplied: Vials (100mg, 200mg)–10 1g, 2g–1

CYTARABINE

R

DEPOCYT Enzon
Antimetabolite. Cytarabine 50mg/vial; liposomal suspension for intrathecal administration; preservative-free.

Indications: Intrathecal treatment of lymphomatous meningitis.

Adults: See literature. Give intrathecally over 1–5 minutes. Administer dexamethasone 4mg twice daily for 5 days with each cycle of treatment. Induction: 50mg every 14 days for 2 doses (weeks 1 and 3). Consolidation: 50mg every 14 days for 3 doses (weeks 5, 7 and 9) followed by 1 additional dose at week 13. Maintenance: 50mg every 28 days for 4 doses (weeks 17, 21, 25 and 29). Reduce dose to 25mg if neurotoxicity develops and discontinue if it persists.

Children: Not recommended.

Contraindications: Active meningeal infection.

Warnings/Precautions: Chemical arachnoiditis; reduce symptoms with dexamethasone. Previous irradiation, cytotoxic chemotherapy. Monitor blood counts and for development of neurotoxicity. Renal

and hepatic impairment. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Increased risk of neurotoxicity with concomitant cranial/spinal irradiation or other intrathecal antineoplastics.

Adverse reactions: See literature. Arachnoiditis, GI upset, headache, fever, neurological toxicity (myelopathy), hydrocephalus, elevated CSF protein and WBC, weakness, back pain, insomnia, blurred vision, anaphylactic reactions; others.

How supplied: Single-use vials (5mL)–1

DACARBAZINE

R

DTIC-DOME Bayer

Alkylating agent. Dacarbazine 200mg/vial; pwd for IV infusion after reconstitution and dilution; contains mannitol.

Indications: Metastatic malignant melanoma. Second-line therapy for Hodgkin's disease, in combination with other agents.

Adults: Give by IV infusion. Malignant melanoma: 2–4.5mg/kg/day for 10 days, may repeat every 4 weeks; or 250mg/m² daily for 5 days, may repeat every 3 weeks. Hodgkin's disease (in combination with other drugs): 150mg/m² daily for 5 days, may repeat every 4 weeks; or 375mg/m² on day 1, then repeat every 15 days.

Children: Not recommended.

Warnings/Precautions: Monitor CBCs, platelets; may need to discontinue or suspend therapy if hemopoietic toxicity occurs. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Myelosuppression (eg, leukopenia, thrombocytopenia, anemia), anorexia, nausea, vomiting, flu-like syndrome, alopecia, facial flushing/paresthesia, inj site reactions, anaphylaxis; rare: hepatic necrosis, photosensitivity reactions.

How supplied: Vials (20mL)–12

DACTINOMYCIN

R

COSMEGEN Lundbeck

Actinomycin antibiotic. Dactinomycin 500mcg/vial; lyophilized pwd for IV inj or regional perfusion after reconstitution; contains mannitol; preservative-free.

Indications: In combination with other chemotherapy and/or multi-modality treatment regimen for Wilms' tumor, childhood rhabdomyosarcoma, Ewing's sarcoma and metastatic, nonseminomatous testicular cancer. Gestational trophoblastic neoplasia. As a component of regional perfusion, for palliative and/or adjunctive treatment of locally recurrent or locoregional solid malignancies.

Adults: Give by IV infusion. Wilms' tumor, childhood rhabdomyosarcoma, Ewing's sarcoma: 15mcg/kg daily for 5 days. Metastatic nonseminomatous testicular cancer (in combination with cyclophosphamide, bleomycin, vinblastine, and cisplatin): 1000mcg/m² on Day 1. Gestational trophoblastic neoplasia: 12mcg/kg daily for 5 days as a single agent; 500mcg on Days 1 and 2 as

combination regimen with etoposide, methotrexate, folinic acid, vincristine, cyclophosphamide, and cisplatin. Regional perfusion: 50mcg/kg for lower extremity or pelvis; 35mcg/kg for upper extremity. Max 15mcg/kg/day per 2-week cycle or 400–600mcg/m²/day for five days. Use surface area to calculate dose for obese or edematous patients.

Children: See literature.

Contraindications: Current or recent chickenpox or herpes zoster.

Warnings/Precautions: Myelosuppression; monitor bone marrow and hold treatment if platelets or WBCs decrease markedly. Extremely corrosive; avoid extravasation. Avoid skin, mucous membranes, eyes. Previous irradiation (esp. within 2 months of irradiation for treatment of right-sided Wilms' tumor), cytotoxic chemotherapy. Monitor renal and hepatic function. Obese. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid live vaccines. Concomitant radiotherapy in Wilms' tumor: not recommended.

Adverse reactions: GI upset, stomatitis, bone marrow suppression (neutropenia, thrombocytopenia), liver toxicity, infusion site reactions, malaise, fatigue, alopecia, possible second primary tumors (including leukemia); for perfusion therapy: infection, impaired wound healing, superficial ulceration of gastric mucosa, edema, soft tissue damage, possible venous thrombosis.

How supplied: Vials–1

DASATINIB

R

SPRYCEL Bristol-Myers Squibb

Tyrosine kinase inhibitor. Dasatinib 20mg, 50mg, 70mg, 80mg, 100mg, 140mg; tabs.

Indications: Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib. Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.

Adults: Swallow whole. ≥18yrs: Chronic phase CML: 100mg once daily. Doses of up to 140mg once daily have been used. Accelerated phase CML, myeloid or lymphoid blast CML, Ph+ ALL: 140mg once daily. Doses of up to 180mg once daily have been used. Concomitant CYP3A4 inhibitors (see Interactions): consider reducing dose. Concomitant CYP3A4 inducers (see Interactions): consider increasing dose. See literature for dose adjustments with toxicity.

Children: <18yrs: not recommended.

Warnings/Precautions: History of QT prolongation. Proarrhythmic conditions. Cumulative high-dose anthracycline therapy. Monitor for signs/symptoms of cardiac dysfunction; treat appropriately if occurs. Hypokalemia, hypomagnesemia; correct electrolyte imbalances before starting therapy. Monitor for pleural effusions. Increased risk of

pulmonary arterial hypertension (PAH); evaluate for signs/symptoms of underlying cardiopulmonary disease before and during treatment; permanently discontinue if occurs. Obtain CBCs weekly for the first 2 months, then monthly thereafter. Hepatic impairment. Pregnancy (Cat.D; use adequate contraception); nursing mothers: not recommended.

Interactions: Avoid potent CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin, ritonavir, atazanavir, indinavir, nefazodone, nelfinavir, saquinavir, telithromycin, voriconazole), grapefruit juice. May be antagonized by CYP3A4 inducers (eg, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, phenobarbital); St. John's wort: not recommended. Separate dosing of antacids by at least 2 hours; H_2 blockers, proton pump inhibitors: not recommended. May potentiate drugs metabolized by CYP3A4 (eg, cyclosporine, fentanyl, pimozide, quinidine, sirolimus, tacrolimus, ergot alkaloids). Caution with concomitant anticoagulants or drugs that inhibit platelet function. Caution with anti-arrhythmics or other drugs that may lead to QT prolongation.

Adverse reactions: Myelosuppression (eg, severe thrombocytopenia, neutropenia, anemia), fluid retention (eg, ascites, edema, pleural and pericardial effusions), GI upset, headache, dyspnea, musculoskeletal pain, rash, fatigue, severe hemorrhage (eg, CNS, GI); QT prolongation; cardiac events (eg, cardiomyopathy, CHF, fatal MI, left ventricular dysfunction); PAH.

How supplied: Tabs 20mg, 50mg, 70mg–60 80mg, 100mg, 140mg–30

DAUNORUBICIN

R

CERUBIDINE Bedford

Anthracycline. Daunorubicin HCl 20mg/vial; lyophilized pwd for IV infusion after reconstitution; contains mannitol.

Indications: In combination with other chemotherapy for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults.

Adults: Give by IV infusion. Acute nonlymphocytic leukemia (in combination with cytosine arabinoside): <60yrs: 45mg/m² daily on days 1, 2 and 3 of the first course and on days 1, 2 of subsequent courses; ≥60yrs: 30mg/m² daily on days 1, 2 and 3 of the first course and on days 1, 2 of subsequent courses. Acute lymphocytic leukemia (in combination with vincristine, prednisone, L-asparaginase): 45mg/m² daily on days 1, 2 and 3. Hepatic or renal impairment: reduce dose (see literature).

Children: Give by IV infusion. <2yrs or BSA<0.5m²: use weight (mg/kg) to calculate dose. 25mg/m² on day 1 every week (in combination with vincristine and prednisone).

Warnings/Precautions: Treat if any systemic infections 1st. Pre-existing drug-induced bone marrow suppression. Cardiovascular disease, thoracic

irradiation, previous doxorubicin therapy (cumulative doses >550mg/m²): increased risk of cardiotoxicity. Monitor blood counts, cardiac, hepatic and renal function prior to each treatment. Renal or hepatic impairment. Hyperuricemia: monitor blood uric acid levels and give allopurinol prophylactically. Avoid extravasation. Children. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Do not use if previously received max cumulative doxorubicin dose; or if concomitant with cyclophosphamide: increased cardiotoxicity. Concomitant myelosuppressives: consider dose reduction. Increased risk of liver toxicity with hepatotoxic agents (eg, high-dose methotrexate).

Adverse reactions: Myelosuppression, cardiotoxicity, alopecia, rash, inj site reactions, GI upset, mucositis, abdominal pain, hyperuricemia; rare: anaphylaxis.

How supplied: Single-dose vials–10

DECITABINE

R

DACOGEN Eisai

Nucleoside analogue. Decitabine 50mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution.

Indications: Myelodysplastic syndromes (MDS) including previously treated and untreated, *de novo* and secondary MDS of all French-American-British subtypes and Intermediate-1, Intermediate-2, and High-risk International Prognostic Scoring System groups.

Adults: May premedicate with antiemetics. Treat for a minimum of 4 cycles; may take longer for a complete or partial response. Regimen 1: Give by continuous IV infusion over 3 hours. 15mg/m² every 8 hours for 3 days; repeat every 6 weeks. Regimen 2: Give by continuous IV infusion over 1 hour. 20mg/m² once daily for 5 days; repeat every 4 weeks. Both: dose adjustment based on hematology values: see literature. Non-hematologic toxicities (eg, serum creatinine ≥2mg/dL; SGPT, total bilirubin ≥2 × ULN; active or uncontrolled infection): do not restart until toxicity resolved.

Children: Not recommended.

Warnings/Precautions: Renal or hepatic impairment. Obtain CBC and platelet counts before each dosing cycle and as needed. Monitor hepatic function (do baseline liver chemistries and serum creatinine). Pregnancy (Cat.D); use appropriate contraception (both men and women). Nursing mothers: not recommended.

Adverse reactions: Neutropenia, thrombocytopenia, anemia, leukopenia, fatigue, pyrexia, nausea, cough, petechiae, constipation, diarrhea, hyperglycemia.

How supplied: Single-use vial–1

DEGARELIX

R

FIRMAGON Ferring

GnRH receptor antagonist. Degarelix 80mg/vial, 120mg/vial; pwd for SC inj after reconstitution.

Indications: Advanced prostate cancer.

Adults: Give by SC inj in abdomen once every 28 days; avoid waist and rib areas. Two 120mg injections once, then one 80mg inj once every 28 days.

Children: Not recommended.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: Severe renal or hepatic impairment. Congenital long QT syndrome. Electrolyte imbalances. Congestive heart failure. Monitor serum PSA. Discontinue if serious hypersensitivity reaction occurs; do not rechallenge. Nursing mothers: not recommended.

Interactions: Caution with Class IA (eg, quinidine, procainamide) or Class III (eg, amiodarone, sotalol) antiarrhythmics.

Adverse reactions: Inj site reactions (eg, pain, erythema, swelling, induration), hot flashes, increased weight, fatigue, increased transaminases, increased gamma-glutamyltransferase; QT prolongation.

How supplied: Treatment Initiation pack (120mg/vial)–2 (w. supplies)

Maintenance pack (80mg/vial)–1 (w. supplies)

DENILEUKIN DIFTITOX

R

ONTAK Eisai

Interleukin 2-diphtheria toxin fusion protein.

Denileukin diftotox 150mcg/mL; soln for IV infusion after thawing and dilution.

Indications: Persistent or recurrent cutaneous T-cell lymphoma in which malignant cells express the CD25 component of the IL-2 receptor.

Adults: Premedicate with an antihistamine or acetaminophen prior to each infusion. Give by IV infusion over 30–60 minutes. 9 or 18mcg/kg per day for 5 consecutive days every 21 days for 8 cycles.

Children: Not recommended.

Warnings/Precautions: Ensure CD25 expression before starting therapy. Have resuscitative equipment available during administration. Permanently discontinue if serious infusion reactions occur.

Monitor for signs/symptoms of capillary leak syndrome (hypotension, edema, hypoalbuminemia) and weight gain. Monitor serum albumin levels prior to each treatment course; withhold treatment if serum albumin <3g/dL. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Fever, fatigue, rigors, GI upset, headache, edema, cough, dyspnea, pruritus, rash, hypotension, back pain, myalgia, chest pain, tachycardia, hypoalbuminemia, asthenia, elevated transaminases; capillary leak syndrome (may be fatal), serious infusion reactions, visual impairment (monitor).

Testing considerations: CD25 expression

How supplied: Single-use vials (2mL)–6

DENOSUMAB

R

XGEVA Amgen

Osteoclast inhibitor (RANKL inhibitor). Denosumab 120mg/vial (70mg/mL); soln for SC inj; preservative-free.

Indications: Treatment of adults and skeletally-mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

Adults: Give by SC inj into upper arm, upper thigh, or abdomen. 120mg once every 4 weeks with additional 120mg doses on Days 8 and 15 of the 1st month of therapy.

Children: Not established (interferes with bone growth and dentition).

Warnings/Precautions: Correct hypocalcemia before starting; ensure adequate daily calcium, magnesium, and Vit.D intake, esp. in renal impairment (CrCl <30mL/min). Monitor calcium, phosphorus, magnesium levels in susceptible patients (eg, severe renal impairment, receiving dialysis). Monitor for osteonecrosis of the jaw.

Perform oral exam and preventive dentistry before and regularly during therapy. Maintain good oral hygiene. Avoid invasive dental procedures during treatment. Pregnancy (Cat.D); use highly effective contraception during therapy, and for at least 5 months after last dose. Nursing mothers: avoid (may impair mammary gland development/lactation).

Interactions: Concomitant drugs that can lower calcium levels; monitor.

Adverse reactions: Fatigue, asthenia, hypophosphatemia, nausea, dyspnea, osteonecrosis of jaw, severe hypocalcemia (may be fatal).

How supplied: Single-use vial (1.7mL)–1

DOCETAXEL

R

TAXOTERE Sanofi Aventis

Antimicrotubule agent. Docetaxel 40mg/mL; soln for IV infusion after dilution; contains polysorbate 80; diluent contains alcohol.

Indications: Locally advanced or metastatic breast cancer after failure of prior chemotherapy. In combination with doxorubicin and cyclophosphamide: adjuvant treatment of operable node (+) breast cancer. Locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of prior platinum-based chemotherapy. In combination with cisplatin: initial treatment of unresectable, locally advanced or metastatic non-small cell lung cancer without previous chemotherapy. In combination with prednisone: hormone-refractory metastatic prostate cancer. In combination with cisplatin and fluorouracil: advanced gastric adenocarcinoma without previous chemotherapy; induction treatment of locally advanced squamous cell carcinoma of the head and neck.

Adults: Give by IV infusion over 1 hour once every 3 weeks. Breast cancer: 60–100mg/m². Adjuvant in operable node (+) breast cancer (treat for 6 courses), NSCLC, prostate cancer, gastric adenocarcinoma, head and neck squamous cell carcinoma: 75mg/m². Chemotherapy-naïve NSCLC: 75mg/m². For all: premedicate with oral corticosteroid. Adjust dose based on tolerability and

effect (see literature); allow neutrophils and platelets to recover before subsequent cycles.

Children: Not recommended.

Contraindications: Neutrophil count <1500 cells/mm³.

Warnings/Precautions: Hepatic dysfunction; bilirubin $>ULN$, SGOT and/or SGPT $>1.5 \times ULN$ concomitant with alkaline phosphatase $>2.5 \times ULN$: not recommended. Monitor blood (esp CBC), liver function tests. Pre-existing effusions. Pregnancy (Cat.D; use adequate contraception); nursing mothers: not recommended.

Interactions: May affect, or be affected by, other CYP3A4 inhibitors, inducers, or substrates (eg, cyclosporine, ketoconazole, erythromycin, troleandomycin).

Adverse reactions: Neutropenia, anemia, febrile neutropenia, hypersensitivity/infusion site reactions, thrombocytopenia, neuropathy, dysgeusia, dyspnea, constipation, anorexia, nail disorders, fluid retention, asthenia, pain, GI upset, mucositis, alopecia, myalgia; cutaneous reactions (erythema, edema, desquamation), acute myeloid leukemia, death (septic and nonseptic); others.

How supplied: Single-dose vials (0.5mL, 2mL)–1 (w. diluent, supplies)

DOXORUBICIN

R

DOXORUBICIN HCl (various)

Anthracycline antibiotic. Doxorubicin HCl 10mg/vial, 20mg/vial, 50mg/vial; pwd for IV inj after reconstitution; contains lactose.

Also: Doxorubicin

R

DOXORUBICIN HCl SOLUTION

Doxorubicin HCl 2mg/mL; soln for IV inj.

Indications: Disseminated neoplasias (eg, acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin's disease, malignant lymphoma, neuroblastoma, Wilms' tumor, soft tissue and bone sarcomas; breast, ovarian, bladder, thyroid, lung, gastric carcinoma). Adjunct in breast cancer after resection.

Adults and Children: Monotherapy: usually 60–75mg/m² IV every 21 days. Combination therapy: usually 40–60mg/m² IV every 21 to 28 days. Hyperbilirubinemia, inadequate bone marrow reserves: reduce dose.

Contraindications: Severe myelosuppression (baseline neutrophils <1500 cells/mm³) or severe hepatic impairment. Cardiac disease (eg, severe myocardial insufficiency, arrhythmias). Recent MI. Previous treatment with max cumulative doses of anthracyclines, anthracenediones.

Warnings/Precautions: Pre-existing heart disease or risk thereof. Obtain baseline CBC, bilirubin, AST, creatinine, LVEF. Hepatic dysfunction. Monitor cardiac function (LVEF, ECG echocardiogram), hepatic function, CBC, uric acid levels. Avoid extravasation. Children (cardiotoxicity, impaired myocardial growth). Elderly. Pregnancy (Cat.D; use adequate contraception). Nursing mothers: not recommended.

Interactions: See Contraindications. Mediastinal irradiation, cyclophosphamide, calcium channel blockers, other anthracyclines increase risk of cardiac toxicity; limit lifetime dose to 400mg/m². Necrotizing colitis with cytarabine. May increase toxicity of cyclophosphamide, mercaptopurine. May reduce serum digoxin levels. Doxorubicin toxicity increased with high-dose IV progesterone, cyclosporine, streptozocin, and if given after paclitaxel infusion (give doxorubicin dose first). Elimination increased by phenobarbital. May decrease phenytoin levels. Recall pneumonitis with actinomycin and radiation in children.

Adverse reactions: Local necrosis if extravasation occurs, myocardial toxicity (immediate or delayed), arrhythmias, leukemia, myelosuppression, hyperuricemia, urine discoloration, alopecia, hyperpigmentation, severe GI upset/ulceration, phlebosclerosis, facial flushing, fever, urticaria, peripheral neuropathy, anaphylaxis.

How supplied: Contact supplier.

DOXORUBICIN, LIPOSOMAL

R

DOXIL Janssen Biotech

Anthracycline. Doxorubicin HCl (liposomal) 2mg/mL; dispersion for IV infusion after dilution; preservative-free.

Indications: AIDS-related Kaposi's sarcoma refractory to combination chemotherapy. Ovarian cancer refractory to platinum-based chemotherapy. Multiple myeloma, in combination with bortezomib, in patients not previously treated with bortezomib and who have received at least one prior therapy.

Adults: Give by IV infusion at initial rate of 1mg/min; may increase rate to complete infusion over 1 hour if no infusion reactions occur; may premedicate with antiemetics. Kaposi's sarcoma: 20mg/m² once every 3 weeks. Ovarian cancer: 50mg/m² once every 4 weeks; continue for at least 4 cycles as tolerated. Multiple myeloma: 30mg/m² on day 4 of each cycle following bortezomib (see literature for bortezomib dose); may treat for up to 8 cycles. Hepatic dysfunction (serum bilirubin ≥ 1.2 mg/dL), hand-foot syndrome, hematologic toxicity (esp. ANC, platelets), or stomatitis: reduce dose. Consider total anthracycline and anthracenedione doses and irradiation when calculating total cumulative dose. See literature.

Children: Not established.

Warnings/Precautions: Not substitutable on a mg/mg basis with other doxorubicin products. Cardiotoxicity, acute infusion-related reactions, myelosuppression may occur. Have resuscitative/antiallergic equipment and expertise available. Avoid extravasation. Monitor blood (esp. CBC + platelets), hepatic (esp. SGOT/SGPT, alkaline phosphatase), and cardiac function (esp. myocardial biopsy). Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: Caution with cyclosporine, phenobarbital, phenytoin, streptozocin, digoxin, myelosuppressants, others. Previous mediastinal irradiation, cyclophosphamide, other cardiotoxic drugs: monitor for cardiotoxicity and hepatotoxicity.

Adverse reactions: Asthenia, fatigue, fever, anorexia, nausea, vomiting, stomatitis, diarrhea, constipation, hand and foot syndrome, rash, neutropenia, thrombocytopenia, anemia; infusion reactions, cardiovascular events (eg, cardiomyopathy, CHF, acute LV failure), recall of skin reaction from prior radiation therapy, toxoplasmosis, urine discoloration (red/orange).

How supplied: Single-use vials (10mL, 30mL)–1

EPIDRUBICIN

R

ELLECE Pfizer

Anthraclycline. Epirubicin HCl 2mg/mL; soln for IV infusion; preservative-free.

Indications: Adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.

Adults: Give by IV infusion over 15–20 minutes. Administer in repeated 3–4 week cycles for a total of 6 cycles. Total dose may be given on Day 1 of each cycle; or divided equally and given on Days 1 and 8 of each cycle. Initially 100–120mg/m². Bone marrow dysfunction: consider lower starting dose (75–90mg/m²). Renal or hepatic impairment, dose adjustments: see full labeling.

Children: Not established.

Contraindications: Baseline neutrophil count <1500 cells/mm³. Cardiomyopathy and/or heart failure. Recent MI. Severe arrhythmias. Previous treatment with anthracyclines (max cumulative doses). Severe hepatic dysfunction.

Warnings/Precautions: Cardiovascular disease. Prior or concomitant radiotherapy to mediastinal/pericardial area. Previous anthracycline therapy. Renal or hepatic impairment. Monitor CBCs, platelets, cardiac, renal, and hepatic function before and during each treatment cycle. Consider monitoring serum uric acid, potassium, calcium, phosphate after starting therapy. Avoid extravasation. Elderly (esp. female ≥70yrs). Advise women of child-bearing potential to avoid becoming pregnant during treatment and use effective contraceptive methods. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Caution with other cardiotoxic drugs. Avoid concomitant live vaccines. Potentiated by cimetidine; stop cimetidine during therapy. Inflammatory recall reaction possible with previous radiation therapy.

Adverse reactions: Myelosuppression (leukopenia, neutropenia, anemia, thrombocytopenia), amenorrhea, lethargy, nausea, vomiting, mucositis, diarrhea, infection, conjunctivitis/keratitis, alopecia, local toxicity, rash/itch; cardiotoxicity, hyperuricemia, acute myelogenous leukemia.

How supplied: Single-use vials (25mL, 100mL)–1

ERIBULIN

R

HALAVEN Eisai

Non-taxane microtubule dynamics inhibitor. Eribulin mesylate 0.5mg/mL, soln for IV inj.

Indications: Treatment of metastatic breast cancer in patients who have previously received at least two chemotherapeutic regimens for metastatic disease. Prior therapy should have included an anthracycline and a taxane in either the adjuvant or metastatic setting.

Adults: Give by IV injection over 2–5 minutes.

1.4mg/m² on Days 1 and 8 of a 21-day cycle. Mild hepatic impairment (Child-Pugh A) or moderate renal impairment (CrCl 30–50mL/min): 1.1mg/m² on days 1 and 8 of a 21-day cycle. Moderate hepatic impairment (Child-Pugh B): 0.7mg/m² on Days 1 and 8 of a 21-day cycle. Hold dose for ANC <1000/mm³, platelets <75000/mm³, or grade 3 or 4 non-hematological toxicities. Delay or reduce dose according to toxicities; see literature. Do not re-escalate dose after it is reduced.

Children: <18yrs: not recommended.

Warnings/Precautions: Monitor CBCs; increase frequency of monitoring if grade 3 or 4 cytopenias develop, delay and reduce subsequent doses if febrile neutropenia or grade 4 neutropenia lasting >7 days develops. Monitor for peripheral neuropathy; withhold dose if grade 3 or 4 peripheral neuropathy develops until resolution to grade 2 or less. Congenital long QT syndrome: avoid. CHF, bradyarrhythmias, electrolyte abnormalities: monitor ECG for prolonged QT interval. Correct electrolyte abnormalities (K⁺, Mg²⁺) before treatment; monitor. Severe hepatic impairment (Child-Pugh C) or severe renal impairment (CrCl <30mL/min): insufficient data. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Caution with other drugs that prolong QT interval (eg, Class IA and III antiarrhythmics); monitor.

Adverse reactions: Neutropenia, anemia, asthenia/fatigue, alopecia, peripheral neuropathy, nausea, constipation, febrile neutropenia; possible QT prolongation, elevated liver enzymes.

Note: Do not mix with dextrose-containing solutions. Do not administer in same line as other drugs or fluids.

How supplied: Single-use vial (2mL)–1

ERLOTINIB

R

TARCEVA Genentech

Human epidermal growth factor receptor type 1/epidermal growth factor receptor tyrosine kinase inhibitor. Erlotinib (as HCl) 25mg, 100mg, 150mg; tabs.

Indications: Maintenance treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. Treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen.

In combination with gemcitabine: first-line treatment

of locally advanced, unresectable or metastatic pancreatic cancer.

Adults: Take on empty stomach. NSCLC: 150mg once daily. Pancreatic cancer: 100mg once daily + gemcitabine (see literature). Both: use until disease progression or unacceptable toxicity occurs. Diarrhea unresponsive to loperamide, severe skin reactions, strong CYP3A4 inhibitors (see Interactions), hepatic impairment: reduce in 50mg decrements. CYP3A4 inducers (see Interactions): consider increased dose (see literature).

Children: Not recommended.

Warnings/Precautions: Discontinue if interstitial lung disease, hepatic failure, or GI perforation occurs; interrupt or discontinue therapy in patients with dehydration at risk for renal failure, or with severe bullous, blistering or exfoliative skin conditions, or with acute/worsening ocular disorders. Hepatic impairment. Monitor liver function tests periodically; if tests worsen, consider withholding or reducing dose; interrupt or discontinue therapy if severe changes (eg, total bilirubin $>3 \times \text{ULN}$, and/or transaminases $>5 \times \text{ULN}$) occur. Monitor renal function, serum electrolytes, pulmonary function, INR, prothrombin time. History of peptic ulcers or diverticular disease. Pregnancy (Cat.D); use adequate contraception (see literature). Nursing mothers: not recommended.

Interactions: Potentiated by CYP3A4 inhibitors (eg, clarithromycin, ritonavir, ketoconazole). Plasma levels decreased by CYP3A4 inducers (eg, rifampicin, phenytoin, carbamazepine, phenobarbital, St. John's wort), proton pump inhibitors or H_2 blockers, and smoking. Antagonizes midazolam. Increased risk of GI perforation with concomitant anti-angiogenic agents, steroids, NSAIDs, taxane-based chemotherapy. Monitor for bleeding with oral anticoagulants, NSAIDs.

Adverse reactions: Rash, diarrhea, GI upset, anorexia, fatigue, elevated LFTs, unexplained pulmonary symptoms (eg, dyspnea, cough, fever; discontinue and follow-up if occurs), stomatitis, infection; rare: GI perforation (may be fatal), ocular disorders (eg, conjunctivitis, keratitis, corneal ulceration/perforation), MI/ischemia, hemolytic anemia, cerebrovascular accidents, interstitial lung disease; hepatic or renal failure and hepatorenal syndrome (may be fatal); bullous, blistering and exfoliative skin conditions (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis).

Testing considerations: K-RAS mutation analysis, EGFR amplification analysis

How supplied: Tabs-30

ESTRADIOL

R

ESTRACE Warner Chilcott

Estrogen. Estradiol 0.5mg, 1mg, 2mg+; scored tabs; + contains tartrazine.

Indications: Palliative treatment of androgen-dependent advanced prostate cancer. Palliative treatment of metastatic breast cancer in select patients (see literature).

Adults: Prostate cancer: 1-2mg 3 times daily. Breast cancer: 10mg 3 times daily for at least 3 months.

Children: Not applicable.

Contraindications: Thrombophlebitis.

Thromboembolic disorders. Cerebrovascular disorders. Abnormal undiagnosed genital bleeding. Estrogen-dependent neoplasias. Liver dysfunction or disease. Pregnancy (Cat.X).

Warnings/Precautions: Asthma (2mg tabs).

Hepatic dysfunction. Conditions aggravated by fluid retention. Cardiovascular disorders, arterial vascular disease, and risks factors (eg, hypertension, diabetes, obesity, SLE). Familial hyperlipoproteinemia. Monitor BP. Discontinue if jaundice occurs and before prolonged immobilization (eg, surgery). Nursing mothers.

Adverse reactions: See literature. GI upset, headache, hypertension, edema, hypercalcemia, gallbladder or thromboembolic disease, gynecostasia, impotence, impaired glucose tolerance.

How supplied: Tabs-100

ESTRAMUSTINE

R

EMCYT Pfizer

Estramustine phosphate sodium (prodrug of estradiol) 140mg; caps.

Indications: Palliative of metastatic, progressive prostate cancer.

Adults: Take 1 hour before or 2 hours after meals. 14mg/kg in 3 or 4 divided doses; reevaluate after 30 to 90 days. Continue as long as favorable response maintained.

Children: Not applicable.

Contraindications: Active thrombophlebitis or thromboembolic disorders (except when tumor mass caused by thromboembolic phenomenon). Allergy to estradiol, nitrogen mustard.

Warnings/Precautions: History of thrombophlebitis, thrombosis, thromboembolic disorders. Cerebro- or cardiovascular disease. Diabetes. Hypertension. Conditions aggravated by fluid retention. Renal or hepatic dysfunction. Monitor bilirubin and hepatic enzymes during and for 2 months after treatment is discontinued. Metabolic bone diseases associated with hypercalcemia. Use effective contraception.

Interactions: Absorption impaired by calcium.

Adverse reactions: Edema, dyspnea, leg cramps; nausea, diarrhea, GI upset; pruritus, dry skin, easy bruising; breast tenderness and enlargement; lethargy, emotional lability, insomnia; leucopenia; abnormal bilirubin, LDH, SGOT. Thrombosis, MI.

How supplied: Caps-100

ESTROGENS, ESTERIFIED

R

MENEST King

Estrogen. Esterified estrogens 0.3mg, 0.625mg, 1.25mg, 2.5mg; tabs.

Indications: Palliative treatment of androgen-dependent advanced prostate cancer.

Adults: 1.25-2.5mg 3 times daily.

Children: Not applicable.

Contraindications: Thrombophlebitis.

Thromboembolic disorders. Cerebrovascular or coronary artery disease. Pregnancy (Cat.X).

Warnings/Precautions: Hepatic dysfunction.

Gallbladder disease. Conditions aggravated by fluid retention. Familial hyperlipoproteinemia. Discontinue if jaundice occurs. Nursing mothers.

Adverse reactions: See literature. Migraine, depression, edema, weight changes, hypertension, GI upset, gynecomastia, impotence.

How supplied: Tabs 2.5mg–50

0.3mg, 0.625mg, 1.25mg–100

ETOPOSIDE

ETOPOSIDE (various)

Topoisomerase inhibitor. Etoposide 50mg; caps; contain parabens.

Indications: Small cell lung cancer.

Adults: Round dose to nearest 50mg increment.

Range: 70mg/m² per day for 4 days to 100mg/m² per day for 5 days. Repeat course every 3 to 4 weeks after recovery (esp myelosuppression). Renal impairment (CrCl ≤50mL/min): reduce dose (see literature). Consider dose reduction with existing myelosuppression due to previous radiation or chemotherapy.

Children: Not recommended.

Warnings/Precautions: Monitor blood (esp CBC/differential, platelets, hemoglobin) before each cycle and during therapy; renal function. Withhold dose if platelet count <50,000/mm³ or ANC <500/mm³. Hypoalbuminemia. Elderly. Pregnancy (Cat.D); nursing mothers: not recommended.

Interactions: Potentiated by cyclosporine. Additive toxicity with radiation, other cytotoxic therapies.

Adverse reactions: GI upset, mucositis, myelosuppression (esp. neutropenia, thrombocytopenia; may be fatal), alopecia, fever, infections, peripheral neurotoxicity; hypersensitivity reactions, acute leukemia (rare); others.

How supplied: Contact supplier.

ETOPOSIDE

TOPOSAR Teva US Generics

Topoisomerase inhibitor. Etoposide 20mg/mL; soln for IV infusion; contains dehydrated alcohol 33.2%, polysorbate 80.

Indications: Refractory testicular tumors after appropriate radiation, surgery, and other chemotherapy. First-line treatment of small cell lung cancer.

Adults: Give by slow IV infusion over 30–60mins. Testicular cancer: range 50–100mg/m² per day on days 1 through 5 to 100mg/m² per day on days 1, 3, and 5. Small cell lung cancer: range 35mg/m² per day for 4 days to 50mg/m² per day for 5 days. Repeat course every 3 to 4 weeks after recovery from any toxicity. Renal impairment (CrCl 15–50mL/min): reduce dose to 75%; (CrCl <15mL/min): see literature. Consider dose reduction with existing

myelosuppression due to previous radiation or chemotherapy.

Children: Not recommended.

Warnings/Precautions: Monitor for myelosuppression; obtain CBCs with differential, platelets, hemoglobin at baseline, prior to each subsequent dose, during and after therapy. Withhold dose if platelet count <50,000/mm³ or ANC <500/mm³. Renal impairment. Hypoalbuminemia. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Potentiated by cyclosporine. Additive toxicity with radiation, other cytotoxic therapies.

Adverse reactions: Hypersensitivity/infusion reactions (eg, fever/chills, hypotension, bronchospasm), GI upset, anorexia, mucositis, myelosuppression (esp neutropenia, thrombocytopenia; may be fatal), alopecia, fever, infections, peripheral neurotoxicity; rare: acute leukemia; others.

How supplied: Multi-dose vials (5mL, 25mL, 50mL)–1

ETOPOSIDE PHOSPHATE

ETOPHOS Bristol-Myers Squibb

Topoisomerase inhibitor. Etoposide (as phosphate) 100mg/vial; pwd for IV infusion after reconstitution and dilution.

Indications: Refractory testicular tumors after appropriate radiation, surgery, and other chemotherapy. Small cell lung cancer.

Adults: See literature. Give by IV infusion over 5 to 210 minutes; use doses equivalent to those used for VePesid (eg, for testicular cancer: range 50–100mg/m² per day on days 1 through 5 to 100mg/m² per day on days 1, 3, 5. For small cell lung cancer: range 35mg/m² per day for 4 days to 50mg/m² per day for 5 days). Repeat course every 3 to 4 weeks after recovery (esp myelosuppression). Toxicity unknown at doses >175mg/m² per day. Renal impairment (CrCl ≤50mL/min): reduce dose (see literature). Consider dose reduction with existing myelosuppression due to previous radiation or chemotherapy.

Children: Not recommended.

Warnings/Precautions: Monitor blood (esp. CBCs/differential, platelets, hemoglobin) before each cycle and during therapy; renal function. Withhold dose if platelet count <50,000/mm³ or ANC <500/mm³. Hypoalbuminemia. Elderly. Pregnancy (Cat.D); nursing mothers: not recommended.

Interactions: Caution with levamisole, others that inhibit phosphatase activity. May be potentiated by cyclosporine. Additive toxicity with radiation, other cytotoxic therapies.

Adverse reactions: Hypersensitivity/infusion reactions (eg, fever/chills, hypotension, bronchospasm), GI upset, mucositis, myelosuppression (esp. neutropenia, thrombocytopenia; may be fatal), asthenia, alopecia, fever, infections, peripheral neurotoxicity; rare: acute leukemia; others.

How supplied: Single-dose vials–1

Indicates medications marketed by Teva

EVEROLIMUS

R

AFINITOR Novartis*mTOR kinase inhibitor.* Everolimus 2.5mg, 5mg, 7.5mg, 10mg; tabs.

Indications: Postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ BC) in combination with exemestane after failure of treatment with letrozole or anastrozole. Progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease. Advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib. Renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery. Subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC) in patients who require therapeutic intervention but are not candidates for curative surgical resection.

Adults: Swallow whole with water or disperse tablet in 30mL of water and drink immediately. Take at the same time each day either consistently with or without food. HR+ BC, PNET, RCC, or renal angiomyolipoma with TSC: 10mg once daily. Mild hepatic impairment (Child-Pugh class A): 7.5mg daily, may reduce to 5mg if not tolerated. Moderate hepatic impairment (Child-Pugh class B), or adverse reactions: reduce to 5mg daily, may be reduced to 2.5mg if not tolerated. Severe hepatic impairment (Child-Pugh class C): max 2.5mg daily if benefits outweigh risk. Concomitant moderate CYP3A4 or P-glycoprotein inhibitors: reduce to 2.5mg once daily; may consider increasing to 5mg if tolerated. If moderate inhibitor is discontinued, allow 2–3 days washout period before increasing everolimus dose; return to dose used prior to initiating the moderate inhibitor. Concomitant strong CYP3A4 inducers: may increase from 10–20mg once daily by increments of 5mg. If strong inducer is discontinued, should return to dose used prior to initiating the strong inducer. SEGA: BSA < 0.58m²: not studied. Initially: BSA: 0.5–1.2m²: 2.5mg once daily; 1.3–2.1m²: 5mg once daily; ≥2.2m²: 7.5mg once daily. Evaluate SEGA volume approx. 3 months after starting therapy and periodically thereafter; dose adjustments may be made at 2 week intervals. Trough concentrations should be assessed every 2 weeks, dosing should be titrated to attain a concentration of 5–10ng/mL (see literature). Severe adverse reactions: temporarily reduce dose or interrupt therapy; consider alternate day dosing for patients receiving 2.5mg daily. Severe hepatic impairment: not recommended. Concomitant strong CYP3A4 inhibitors: avoid; moderate CYP3A4 and/or P-gp inhibitors: reduce dose by 50%, if CYP3A4 and/or P-gp inhibitor discontinued, return to dose used prior to initiating moderate inhibitor. Concomitant strong CYP3A4 inducers: avoid, if required, then double dose of everolimus; if discontinued, then return to dose used prior to initiating strong inducer. For all: continue as long as benefit observed or until unacceptable toxicity occurs.

Children: HR+ BC, PNET or RCC: not recommended. SEGA: <3yrs: not recommended.

Contraindications: Sirolimus, temsirolimus, rapamycin allergy.

Warnings/Precautions: Hepatic impairment (see Adult dose). Increased risk of infections; some may be severe or fatal. Pre-existing invasive fungal infections: treat before starting. Monitor CBCs, renal function, lipids, blood glucose, and for pneumonitis and infections: treat promptly if occur. Women of childbearing potential should use effective method of contraception during and up to 8 weeks after treatment. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Avoid live vaccines. Potentiated by strong CYP3A4 inhibitors, or P-glycoprotein inhibitors; avoid (eg, ketoconazole, itraconazole, clarithromycin, atazanavir, nefazodone, saquinavir, telithromycin, ritonavir, indinavir, nelfinavir, voriconazole, grapefruit juice). Caution with moderate CYP3A4 inhibitors (eg, amprenavir, fosamprenavir, aprepitant, erythromycin, fluconazole, verapamil, diltiazem) or P-glycoprotein inhibitors; reduce everolimus dose if used. Antagonized by strong CYP3A4 inducers; avoid (eg, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital, St. John's wort); increase everolimus dose if used.

Adverse reactions: Pneumonitis (reduce dose and/or manage with corticosteroids; if severe, discontinue. May restart daily dose at approx. 50% lower than previously administered), infections (discontinue if invasive systemic fungal infection develops), stomatitis (treat with non-alcoholic, non-peroxide mouthwash), GI upset, rash, fatigue, edema, fever, headache, asthenia, cough, decreased appetite; increased serum creatinine, blood glucose, lipids; decreased hemoglobin, platelets, neutrophils, serum phosphate; proteinuria, renal failure, others (see literature).

How supplied: Tabs—28 (4 blister cards × 7 tabs)

EXEMESTANE

R

AROMASIN Pfizer*Aromatase inactivator.* Exemestane 25mg; tabs.

Indications: In postmenopausal women: adjuvant treatment of estrogen-receptor positive early breast cancer after 2–3 years of tamoxifen therapy to complete a total of 5 years of hormonal therapy; advanced breast cancer with disease progression after tamoxifen therapy.

Adults: Give after a meal. 25mg once daily. Concomitant potent CYP3A4 inducer (eg, rifampicin, phenytoin): 50mg once daily. Advanced disease: continue until tumor progression is evident.

Children: Not established.

Contraindications: Pregnancy (Cat.X).

Premenopausal women.

Warnings/Precautions: Hepatic or renal insufficiency. Perform routine assessment of Vit. D levels prior to initiation; supplement if deficient. Nursing mothers.

Interactions: May be antagonized by estrogens (avoid), CYP3A4 inducers. Avoid concomitant bisphosphonates, Vit. D supplements, calcium.

Adverse reactions: Hot flashes, fatigue, arthralgia, headache, insomnia, increased sweating, nausea, increased appetite; reductions in bone mineral density.

How supplied: Tabs-30

FLOXURIDINE

R

FLOXURIDINE (various)

Antimetabolite. Floxuridine 500mg/vial; lyophilized pwd for intra-arterial infusion after reconstitution and dilution.

Indications: Palliative therapy of GI adenocarcinoma with liver metastases in select patients (see literature).

Adults: Continuous arterial infusion 0.1–0.6mg/kg per day. Hepatic artery infusion: 0.4–0.6mg/kg per day. May give until adverse reactions occur; treat as long as response continues. See literature.

Children: Not recommended.

Contraindications: Poor nutritional state.

Myelosuppression. Serious infections.

Warnings/Precautions: Hospitalize for 1st course. Hepatic or renal dysfunction. History of high-dose pelvic irradiation or alkylating therapy. Monitor blood (esp WBC, platelets). Discontinue for myocardial ischemia, stomatitis or esophagopharyngitis, WBC <3500 or rapidly falling, intractable vomiting, GI ulcer/bleeding, diarrhea, platelets <100,000, hemorrhage. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Adverse reactions: GI upset, enteritis, stomatitis, localized erythema, myelosuppression, liver dysfunction, GI bleeding/ulcer, duodenitis, gastroenteritis, glossitis, pharyngitis, intra- and extrahepatic biliary sclerosis, acalculous cholecystitis, alopecia, dermatitis, myocardial ischemia, fever, malaise; lab abnormalities (eg, anemia, leukopenia, thrombocytopenia, abnormal PT, total proteins, ESR, ALT/SGOT, bilirubin, lactic dehydrogenase); procedural complications (eg, arterial aneurysm, ischemia, thrombotic events, fibromyositis, thrombophlebitis, hepatic necrosis, abscess).

How supplied: Contact supplier.

FLUDARABINE

R

FLUDARABINE Genzyme

Antimetabolite. Fludarabine phosphate 50mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free; contains mannitol.

Indications: B-cell chronic lymphocytic leukemia (CLL) in patients who have not responded to or whose disease progressed during treatment with at least 1 alkylating-agent containing regimen.

Adults: Give by IV infusion over 30 minutes. 25mg/m² daily for 5 days every 28 days. Renal dysfunction (CrCl 30–70mL/min): reduce dose by 20%; CrCl <30mL/min: not recommended. Give for

3 cycles after the max response. Reduce or delay dose if toxicity occurs.

Children: Not recommended.

Warnings/Precautions: Myelosuppression. Evaluate and monitor for hemolysis. Monitor blood (esp CBC, platelets). Use irradiated blood products if transfusions are required. May need to prophylax for tumor lysis syndrome with large tumors. Renal insufficiency. Delay or stop therapy if neurotoxicity occurs. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Severe pulmonary toxicity with pentostatin (not recommended).

Adverse reactions: Myelosuppression (severe/cumulative), bone marrow hypoplasia, autoimmune hemolytic anemia (fatal/severe), infection, fever, chills, GI upset, malaise, fatigue, CNS effects (eg, weakness, agitation, confusion, visual disturbances, coma, peripheral neuropathy), pneumonia, pulmonary hypersensitivity (eg, dyspnea, interstitial pulmonary infiltrate), stomatitis, GI bleeding, edema, tumor lysis syndrome, rash, hemorrhagic cystitis (rare); others.

How supplied: Single-dose vials-5

FLUOROURACIL

R

FLUOROURACIL Teva US Generics

Antimetabolite. Fluorouracil 50mg/mL; soln for IV inj.

Indications: Palliative management of carcinoma of the colon, rectum, breast, stomach, and pancreas.

Adults: Give by IV inj. 12mg/kg once daily for 4 successive days; max 800mg/day. If no toxicity is observed, 6mg/kg are given on the 6th, 8th, 10th, and 12th days unless toxicity occurs. Maintenance therapy: repeat dosage of 1st course every 30 days after the last day of the previous course of treatment; or give a maintenance dose of 10–15mg/kg per week as a single dose; max: 1g/week. Poor risk patients: see literature for dose adjustments.

Children: Not recommended.

Contraindications: Poor nutritional state.

Depressed bone marrow function. Potentially serious infections.

Warnings/Precautions: Narrow margin of safety; monitor for toxicity. Consider hospitalization for 1st course. History of high-dose pelvic irradiation.

Previous use of alkylating agents. Widespread involvement of bone marrow by metastatic tumors. Renal or hepatic impairment. Discontinue if signs of toxicity appear (eg, stomatitis, esophagopharyngitis, leukopenia, intractable vomiting, diarrhea, GI ulceration or bleeding, thrombocytopenia, hemorrhage). Monitor WBCs with differential before each dose. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Potentiated by leucovorin.

Adverse reactions: Stomatitis, esophagopharyngitis, GI upset, anorexia, leukopenia, alopecia, dermatitis, hand-foot syndrome; others.

Testing considerations: TS (thymidylate synthase), MSI (microsatellite instability), DPD (dihydropyrimidine dehydrogenase)

How supplied: Single-dose vials (10mL)-10

FLUOROURACIL**CARAC** Valeant*Antimetabolite.* Fluorouracil 0.5% (0.35% in microspheres); crm.**Indications:** Multiple actinic or solar keratoses of the face and anterior scalp.**Adults:** ≥ 18 yrs: Wash and dry area. Wait 10 minutes. Apply thin film to skin where lesions appear once daily for up to 4 weeks. Do not occlude. May apply sunscreen/moisturizer 2 hours later. Wash hands after use.**Children:** < 18 yrs: **not recommended.****Contraindications:** Dihydropyrimidine dehydrogenase (DPD) deficiency. Women of childbearing potential. Pregnancy (Cat.X).**Warnings/Precautions:** Discontinue if symptoms of DPD deficiency develop (eg, abdominal pain, bloody diarrhea, vomiting, fever, chills). Ulcerated or inflamed skin. Avoid eyes, mucous membranes, exposure to sun or UV light. Nursing mothers: not recommended.**Adverse reactions:** Application site reaction (may persist 2 weeks after drug is stopped), eye irritation.**How supplied:** Crm-30g

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FLUOROURACIL**EFUDEX** Valeant*Antimetabolite.* Fluorouracil 2%, 5%; soln.**Also: Fluorouracil****EFUDEX CREAM**

Fluorouracil 5%.

Indications: Multiple actinic or solar keratoses. Superficial basal cell carcinoma when conventional therapy is impractical (5% only); see literature.**Adults:** Keratoses: Apply twice daily until erosion occurs (usually 2–4 wks). Basal cell carcinoma (5% only): Apply twice daily, usually for 3–6 weeks (obliteration may take 10–12 weeks).**Children:** **Not recommended.****Contraindications:** Dihydropyrimidine dehydrogenase (DPD) deficiency. Pregnancy (Cat.X).**Warnings/Precautions:** Apply cautiously near eyes, nose, mouth. Avoid mucous membranes, occlusion, ulcerated/inflamed skin, exposure to UV light. Wash hands after application if fingers were used. Notify patients of expected skin reaction. Biopsy unresponsive lesions. Nursing mothers: not recommended.**Adverse reactions:** Pain or burning at application site, pruritus, irritation, hyperpigmentation.**How supplied:** Soln-10mL (w. drop dispenser); Crm-25g

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FLUOROURACIL**FLUOROURACIL** (various)*Antimetabolite.* Fluorouracil 50mg/mL; soln for IV inj.**Indications:** Palliative management of carcinoma of the colon, rectum, breast, stomach, and pancreas.

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Adults: Give by IV inj. 12mg/kg once daily for 4 successive days; max 800mg/day. If no toxicity is observed, 6mg/kg are given on the 6th, 8th, 10th, and 12th days unless toxicity occurs. Maintenance therapy: repeat dosage of 1st course every 30 days after the last day of the previous course of treatment; or give a maintenance dose of 10–15mg/kg per week as a single dose; max: 1g/week. Poor risk patients: see literature for dose adjustments.**Children:** **Not recommended.****Contraindications:** Poor nutritional state.

Depressed bone marrow function. Potentially serious infections.

Warnings/Precautions: Narrow margin of safety; monitor for toxicity. Consider hospitalization for 1st course. History of high-dose pelvic irradiation. Previous use of alkylating agents. Widespread involvement of bone marrow by metastatic tumors.

Renal or hepatic impairment. Discontinue if signs of toxicity appear (eg, stomatitis, esophagopharyngitis, leukopenia, intractable vomiting, diarrhea, GI ulceration or bleeding, thrombocytopenia, hemorrhage). Monitor WBCs with differential before each dose. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Potentiated by leucovorin.**Adverse reactions:** Stomatitis, esophagopharyngitis, GI upset, anorexia, leukopenia, alopecia, dermatitis, hand-foot syndrome; others.**Testing considerations:** TS (thymidylate synthase), MSI (microsatellite instability), DPD (dihydropyrimidine dehydrogenase)**How supplied:** Contact supplier.**FLUTAMIDE****FLUTAMIDE** (various)*Antiandrogen.* Flutamide 125mg; caps.**Indications:** In combination with LHRH agonists (GnRH analogues) in locally confined stage B₂-C and stage D₂ metastatic prostate carcinoma.**Adults:** 250mg every 8 hrs.**Children:** **Not applicable.****Contraindications:** Severe hepatic impairment.ALT $\geq 2 \times$ ULN: not recommended.**Warnings/Precautions:** Monitor liver function at baseline, monthly for first 4 months, then periodically, and if liver dysfunction occurs; if ALT $> 2 \times$ ULN or jaundice occurs, discontinue and monitor closely until resolution. Monitor prostate specific antigen (PSA). Consider monitoring methemoglobin levels in patients susceptible to aniline toxicity (eg, G6PD deficiency, smokers, hemoglobin M disease). Pregnancy (Cat.D); not for use in women.**Interactions:** Monitor warfarin.**Adverse reactions:** Diarrhea, hot flashes, loss of libido, impotence, GI disturbances, gynecomastia, rash, edema, hypertension, CNS effects, blood dyscrasias, urine discoloration, liver failure.**How supplied:** Contact supplier.

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FULVESTRANT**FASLODEX** AstraZeneca

Estrogen receptor antagonist. Fulvestrant 50mg/mL; soln for IM inj.

Indications: Hormone receptor positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy. **Adults:** Give by IM inj slowly (1–2 mins/injection). 500mg (as two 5mL injections, one in each buttock) on days 1, 15, 29, then once per month thereafter. Moderate hepatic impairment: 250mg (as one 5mL injection) on days 1, 15, 29, then once per month thereafter.**Children: Not applicable.****Warnings/Precautions:** Bleeding diatheses, thrombocytopenia, or anticoagulant use. Moderate to severe hepatic impairment. Pregnancy (Cat.D; avoid); exclude pregnancy before starting. Nursing mothers: not recommended.**Adverse reactions:** Inj site pain, GI upset, bone pain, arthralgia, headache, back pain, fatigue, pain in extremity, hot flash, anorexia, asthenia, musculoskeletal pain, cough, dyspnea, constipation; increased hepatic enzymes, hypersensitivity reactions.**How supplied:** Prefilled syringe kit (2 × 5mL)–1

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conjunctivitis, stomatitis, eye symptoms (eg, amblyopia, pain, corneal erosion/ulcer, aberrant eyelash growth); rare: pancreatitis, severe skin rashes, interstitial lung disease (may be fatal).

Testing considerations: EGFR mutation analysis**How supplied:** Tabs–30**GEMCITABINE****GEMZAR** Lilly

Antimetabolite. Gemcitabine HCl 200mg, 1g; per vial; pld for IV infusion after reconstitution; contains mannitol.

Indications: Advanced ovarian cancer (in combination with carboplatin) that has relapsed at least 6 months after completion of platinum-based therapy. First-line treatment of metastatic breast cancer (in combination with paclitaxel) after failure of prior anthracycline-containing adjuvant chemotherapy, unless anthracyclines were contraindicated. First-line treatment of inoperable, locally advanced (Stage IIIA or IIIB), or metastatic (Stage IV) non-small cell lung cancer (NSCLC) (in combination with cisplatin). First-line treatment of locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) pancreatic cancer.**Adults:** Infuse over 30 minutes (increased toxicity if infusion goes beyond 60 minutes). Pancreatic cancer (as a single agent): 1000mg/m² once weekly for up to 7 weeks, followed by a week of rest; subsequent cycles: infuse once weekly for 3 consecutive weeks out of every 4 weeks. NSCLC (in combination with cisplatin): 4-week schedule: 1000mg/m² on Days 1, 8, and 15 of each 28 day cycle; or 3-week schedule: 1250mg/m² on Days 1 and 8 of each 21 day cycle. Breast cancer (in combination with paclitaxel): 1250mg/m² on Days 1 and 8 of each 21 day cycle. Ovarian cancer (in combination with carboplatin): 1000mg/m² on Days 1 and 8 of each 21 day cycle. Adjust dose based on toxicity (see literature).**Children: Not recommended.****Warnings/Precautions:** Not for use in combination with radiation therapy. Discontinue immediately if severe lung toxicity, hemolytic uremic syndrome, or capillary leak syndrome occurs. Renal or hepatic impairment. Evaluate renal and hepatic function prior to therapy, then periodically thereafter. Discontinue if severe liver injury develops. Monitor for myelosuppression; obtain CBCs, platelets prior to each dose. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended.**Interactions:** See Warnings/Precautions.

Concomitant radiation therapy: may cause severe radiation toxicity.

Adverse reactions: Myelosuppression, nausea, vomiting, elevated transaminases, proteinuria, hematuria, rash, pruritus, dyspnea, edema, flu-like symptoms, infection, alopecia, neurotoxicity, others; rare: renal or liver failure, hemolytic uremic syndrome, capillary leak syndrome.**Testing considerations:** ERCC1 overexpression for response and prognosis; RRM1**How supplied:** Single-use vials–1

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GEFITINIB**IRESSA** AstraZeneca

Tyrosine kinase inhibitor. Gefitinib 250mg; tabs.

Indications: Monotherapy in the treatment of locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel therapies in patients who are benefiting or have benefited from gefitinib therapy. See literature.**Adults:** 250mg once daily. May disperse tabs in plain water, then drink or give via NG tube. Consider interrupting if diarrhea or skin reactions (for up to 14 days) or eye symptoms occur. Concomitant potent CYP3A4 inducers (see Interactions): may increase to 500mg/day.**Children: Not recommended.****Warnings/Precautions:** Suspend if symptoms of interstitial lung disease occur (eg, dyspnea, cough, fever); discontinue if confirmed and treat. Prior chemotherapy, radiation, or pulmonary fibrosis may increase risk of interstitial lung disease. Monitor liver function; discontinue if severe changes occur. Consider suspending if eye symptoms (eg, eyelash changes) develop; remove aberrant eyelashes. Severe renal impairment. Pregnancy (Cat.D), nursing mothers: not recommended.**Interactions:** CYP3A4 inducers (eg, rifampicin, phenytoin) may decrease levels; consider increasing gefitinib dose if used with potent inducers. CYP3A4 inhibitors (eg, ketoconazole) may increase levels. May potentiate warfarin. May be antagonized by drugs that increase gastric pH (eg, H₂ blockers, proton pump inhibitors). May exacerbate neutropenia with vinorelbine.**Adverse reactions:** GI upset, rash, acne, dry skin, pruritus, asthenia, peripheral edema, dyspnea,

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GEMTUZUMAB**MYLOTARG** Pfizer

Humanized IgG4, kappa antibody, recombinant. Gemtuzumab ozogamicin 5mg/vial; pld for IV infusion after reconstitution and dilution; preservative-free.

Indications: Treatment of patients with CD33 positive acute myeloid leukemia in first relapse who are ≥ 60 yrs old and are not candidates for other chemotherapy.

Adults: Pretreat with diphenhydramine and acetaminophen; methylprednisolone may reduce infusion-related symptoms. 9mg/m² infused over 2 hours. Treat for a total of 2 doses with 14 days between each dose.

Children: Not recommended.

Contraindications: Nursing mothers.

Warnings/Precautions: Withhold treatment if dyspnea or significant hypotension occurs; monitor until resolves. Discontinue if anaphylaxis, pulmonary edema, or acute respiratory distress syndrome occurs. Symptomatic intrinsic lung disease. High peripheral blast counts (WBCs $\geq 30,000/\mu\text{L}$): consider leukoreduction or leukapheresis before administering. Hepatic or renal impairment. Monitor CBCs, platelets, electrolytes, hepatic function. Ensure adequate hydration. Product is light sensitive. Pregnancy (Cat.D): not recommended.

Adverse reactions: Infusion reactions (eg, fever, chills), GI upset, headache, dyspnea, myelosuppression, neutropenia, anemia, thrombocytopenia, leukopenia, infections, bleeding, mucositis, electrolyte imbalances, rash, hypotension, hypertension, hyperglycemia, pulmonary events, hepatotoxicity (eg, veno-occlusive disease), tumor lysis syndrome; others.

How supplied: Single-use vials-1

GOSERELIN**ZOLADEX** AstraZeneca

GnRH analogue. Goserelin (as acetate) 3.6mg; SC implant.

Also: Goserelin

ZOLADEX 3-MONTH 10.8mg

Goserelin (as acetate) 10.8mg; SC implant.

Indications: Palliative treatment of advanced breast cancer in pre- and perimenopausal women. Palliative treatment of advanced prostate carcinoma. In combination with flutamide for management of locally confined Stage T2b-T4 (Stage B2-C) prostate carcinoma.

Adults: Implant SC into anterior abdominal wall. Breast cancer: one 3.6mg implant every 28 days. Prostate cancer: one 3.6mg implant every 28 days or one 10.8mg implant every 12 weeks. Stage B2-C prostatic carcinoma (in combination with flutamide): Treat 8 weeks prior to and during radiotherapy. Initially one 3.6mg implant, followed in 28 days by

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one 10.8mg implant; or may use one 3.6mg implant every 28 days.

Children: Not applicable.

Contraindications: Pregnancy (Cat.D).

Warnings/Precautions: Males: increased risk of diabetes, MI, sudden cardiac death, stroke; monitor blood glucose and for signs/symptoms of CVD during therapy. Risk of ureteral obstruction or spinal cord compression (monitor during 1st month of therapy). Females: nondiagnosed abnormal vaginal bleeding: not recommended. Risk factors for decreased bone mineral density (eg, chronic alcohol, tobacco, anticonvulsants, corticosteroids). Premenopausal women: use nonhormonal contraception during and for 12 weeks after therapy or until menses resume. Nursing mothers: not recommended.

Interactions: May affect tests of pituitary-gonadotropic and gonadal functions.

Adverse reactions: Females: hypoestrogenism (eg, hot flashes, headache, sweating, acne, emotional lability, depression, decreased libido, vaginitis, breast atrophy, seborrhea). Males: decreased testosterone levels (eg, hot flashes, sexual dysfunction, decreased erections, gynecomastia), lower urinary tract symptoms. Both: transient worsening of symptoms (eg, bone pain), tumor flare, GI upset, edema, malaise, hyperglycemia, hypercalcemia, decreased bone mineral density.

How supplied: Implant (in syringe)-1

HISTRELIN

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VANTAS Endo

GnRH analogue. Histrelin acetate 50mg; SC implant.

Indications: Palliative treatment of advanced prostate cancer.

Adults: Insert 1 implant SC in the inner aspect of the upper arm. Remove after 12 months; may replace.

Children: Not applicable.

Contraindications: Pregnancy (Cat.X). Nursing mothers. Not for use in women or children.

Warnings/Precautions: Metastatic vertebral lesions, urinary tract obstruction (monitor closely in 1st few weeks). Avoid wetting inserted arm for 24hrs and heavy lifting or strenuous exertion for 1st week. Increased risk of developing diabetes; monitor blood glucose and HbA1c periodically; treat if occurs. Increased risk of developing MI, sudden cardiac death, stroke; monitor for signs/symptoms of cardiovascular disease. Measure serum testosterone, PSA levels periodically. Implant not visible on X-ray.

Interactions: May interfere with pituitary gonadotropic and gonadal function tests.

Adverse reactions: Hot flashes, initial worsening of signs/symptoms (eg, bone pain, urinary tract obstruction, hematuria), fatigue, local reactions, CNS or antiandrogenic effects, renal impairment, constipation; hyperglycemia, diabetes, cardiovascular disease.

How supplied: Kit-1 (w. implant and supplies)

HYDROXYUREA**HYDREA** Bristol-Myers Squibb*Substituted urea*. Hydroxyurea 500mg; caps.**Indications:** Melanoma, recurrent metastatic or inoperable ovarian carcinoma, resistant chronic myelocytic leukemia, adjunct with irradiation therapy in primary squamous cell (epidermoid) carcinomas of the head and neck, excluding the lip.**Adults:** See literature. Concomitant irradiation for carcinomas of head and neck, and intermittent therapy for solid tumors: 80mg/kg as single dose every 3rd day. Continuous therapy for solid tumors, and resistant chronic myelocytic leukemia: 20–30mg/kg/day as single dose. Renal impairment: reduce dose.**Children: Not recommended.****Contraindications:** Marked bone marrow depression.**Warnings/Precautions:** Previous irradiation therapy or chemotherapy. Correct anemia before starting. Monitor hematologic, renal, hepatic function before and during treatment. Marked renal dysfunction. Myeloproliferative disorders; discontinue if cutaneous vasculitic ulcerations develop and use alternative agents. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.**Interactions:** Avoid concomitant didanosine, with or without stavudine, or other antiretrovirals (may cause pancreatitis [monitor], fatal hepatotoxicity, peripheral neuropathy). Myelosuppressives potentiate antineoplastic effect. May antagonize antigout agents. Increased risk of vasculitic toxicities with interferon therapy. May cause falsely elevated urease, uricase, lactate dehydrogenase.**Adverse reactions:** Leukopenia, anemia, erythrocytic abnormalities, thrombocytopenia, GI upset, rash, erythema, fever, CNS effects, temporary renal impairment, acute pulmonary reactions, secondary leukemias, skin cancer.**Note:** Wear disposable gloves when handling caps or bottle.**How supplied:** Caps–100**IBRITUMOMAB****ZEVALIN** Spectrum*Radioisotope (B-lymphocyte-restricted differentiation antigen [CD20] inhibitor)*. Ibritumomab tiuxetan 3.2mg/2mL; soln for IV inj; contains albumin; preservative-free.**Indications:** B-cell non-Hodgkin's lymphoma (relapsed or refractory, low grade or follicular). Previously untreated follicular non-Hodgkin's lymphoma in patients who achieve a partial or complete response to first-line chemotherapy.**Adults:** See literature. Prepare In-111 Zevalin and Y-90 Zevalin as directed. Initiate Zevalin therapy after recovery of platelets to $\geq 150,000/\text{mm}^3$ at least 6 weeks, but no more than 12 weeks, after the last dose of first-line chemotherapy. Administered in two steps. Step 1: Single infusion of rituximab followed by a fixed

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dose of 5mCi (1.6mg total antibody dose) of In-111 Zevalin given as a 10-minute IV push. Step 2 (7–9 days after Step 1): Second rituximab infusion followed by 0.4mCi/kg of Y-90 Zevalin given as a 10-minute IV push; if platelet count $100,000\text{--}149,000/\text{cells}/\text{mm}^3$, reduce dose to 0.3 mCi/kg. Do not treat if platelets $< 100,000/\text{cells}/\text{mm}^3$. Max Y-90 Zevalin dose: 32mCi.**Children: Not recommended.****Contraindications:** Hypersensitivity to murine proteins.**Warnings/Precautions:** See literature. Use only if trained in radionuclide therapy. Do not treat patients with altered biodistribution. $\geq 25\%$ lymphoma marrow involvement and/or impaired bone marrow reserve (eg, prior myeloablative therapies, platelet count $< 100,000/\text{cells}/\text{mm}^3$, neutrophil count $< 1500/\text{cells}/\text{mm}^3$), or history of failed stem cell collection: not recommended. Monitor for cytopenias and complications (eg, febrile neutropenia, hemorrhage) for up to 3 months after treatment. Obtain CBCs, platelets weekly until levels recover. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.**Interactions:** Caution with anticoagulants, platelet aggregation inhibitors, or live viral vaccines. Separate growth factor treatment by 2 weeks before and after Zevalin therapy.**Adverse reactions:** Neutropenia, leukopenia, thrombocytopenia, anemia, infections, asthenia, musculoskeletal symptoms, GI upset, abdominal pain, fatigue, nasopharyngitis, cough, dizziness, hemorrhage, altered biodistribution; infusion reactions, severe cutaneous/mucocutaneous reactions: both may be fatal, discontinue if occurs; leukemia and myelodysplastic syndrome.**Note:** Indium-111 chloride sterile solution must be ordered separately at the time the In-111 Zevalin kit is ordered. Yttrium-90 chloride sterile solution will be shipped directly upon placement of order for Y-90 Zevalin kit.**How supplied:** In-111 Zevalin kit (ibritumomab tiuxetan 3.2mg/2mL vial + sodium acetate vial + formulation buffer vial + empty reaction vial)–1 Y-90 Zevalin kit (ibritumomab tiuxetan 3.2mg/2mL vial + sodium acetate vial + formulation buffer vial + empty reaction vial)–1**IDARUBICIN****IDAMYCIN** Pfizer*Anthracycline*. Idarubicin HCl 20mg/vial; lyophilized pwd for IV infusion after reconstitution.**Also: Idarubicin****IDAMYCIN PFS**

Idarubicin 1mg/mL; soln for IV infusion; preservative-free.

Indications: Acute myeloid leukemia.**Adults:** Give by slow IV infusion (over 10–15 minutes). 12mg/m² daily for 3 days (in combination with cytarabine). May give 2nd course if needed; if toxicity develops after 1st course, delay until resolved;

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reduce dose by 25%. Hepatic and renal impairment: consider reduce dose.

Children: Not recommended.

Warnings/Precautions: Pre-existing bone marrow suppression. Cardiovascular disease. Thoracic irradiation. Previous anthracycline therapy at high cumulative doses. Renal or hepatic impairment. Monitor CBCs, cardiac, renal and hepatic function prior to and during treatment. Avoid extravasation. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Adverse reactions: Myelosuppression, GI upset, mucositis, abdominal pain, alopecia, rash, inj site reactions, hepatotoxicity, renal toxicity, cardiotoxicity (eg, CHF, arrhythmias, chest pain, MI, asymptomatic declines in LVEF), hyperuricemia.

How supplied: Single-dose vials-1

PFS: Single-dose vials (5mL, 10mL, 20mL)-1

IFOSFAMIDE

IFEX Bristol-Myers Squibb

Alkylating agent. Ifosfamide 1g, 3g; per vial; pwd for IV infusion after reconstitution.

Also: Ifosfamide w. Mesna

IFEX w. MESNEX COMBINATION PACK

Alkylating agent + uroprotectant.

Ifosfamide 1g, 3g; per vial; pwd for IV infusion after reconstitution, + mesna 1g/vial.

Indications: Third-line adjunctive treatment of germ cell testicular cancer.

Adults: Give by slow IV infusion over at least 30 minutes. 1.2g/m² per day for 5 consecutive days; repeat every 3 weeks or after hematologic recovery (platelets $\geq 100,000$ /microliter, WBC ≥ 4000 /microliter).

Children: Not recommended.

Contraindications: Severe bone marrow depression.

Warnings/Precautions: Discontinue if neurologic effects (eg, somnolence, confusion, hallucinations) occur. Do urinalysis before each dose, postpone dose if hematuria occurs. Give mesna and at least 2L fluids daily. Do hematologic profile before each dose; discontinue if WBCs <2000 /microliter or platelets $<50,000$ /microliter. May interfere with wound healing. Impaired hepatic, renal, or hematopoietic function. Prior radiation therapy or other cytotoxic agents. Ensure adequate hydration. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Increased risk of myelosuppression with other chemotherapy agents.

Adverse reactions: Alopecia, GI upset, hematuria, CNS toxicity, infection, renal or liver dysfunction, phlebitis, fever, urotoxicity (eg, hemorrhagic cystitis), leukopenia, thrombocytopenia.

How supplied: Ifex single-dose vials-1

Combination Pack w. Mesnex:

Ifex 5 $\times$ 1g single-dose vials + Mesnex 3 $\times$ 1g multidose vials

Ifex 10 $\times$ 1g single-dose vials + Mesnex 10 $\times$ 1g multidose vials

Ifex 2 $\times$ 3g single-dose vials + Mesnex 6 $\times$ 1g multidose vials

IMATINIB

GLEEVEC Novartis

Signal transduction inhibitor. Imatinib (as mesylate) 100mg, 400mg; tabs.

Indications: Philadelphia-chromosome (+) chronic myeloid leukemia (CML): in newly-diagnosed adults and children in chronic phase; in patients in blast crisis, accelerated phase, or chronic phase after failure of interferon-alpha therapy. Adults with relapsed or refractory Ph (+) acute lymphoblastic leukemia (ALL). Children with newly diagnosed Ph+ ALL in combination with chemotherapy. Adults with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene rearrangements. Adults with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown. Adults with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFR α fusion kinase and for patients with HES and/or CEL who are FIP1L1-PDGFR α fusion kinase negative or unknown. Adults with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP). Kit (CD117) (+) unresectable and/or metastatic malignant GI stromal tumors (GIST). Adjuvant treatment of adults following complete gross resection of Kit (CD117) (+) GIST.

Adults: Take with food and water. May disperse tab in water or apple juice and take promptly. ≥ 18 yrs: Chronic phase CML: 400mg once daily. Accelerated phase or blast crisis: 600mg once daily. Relapsed/refractory Ph+ ALL: 600mg once daily. MDS/MPD: 400mg once daily. ASM without D816V c-Kit mutation or status unknown: 400mg once daily. ASM associated with eosinophilia: initially 100mg once daily; may increase to 400mg once daily if insufficient response. HES/CEL: 400mg once daily. HES/CEL w. FIP1L1-PDGFR α fusion kinase: initially 100mg once daily; may increase to 400mg once daily if insufficient response. DFSP: 400mg twice daily. GIST: 400mg once daily; up to 800mg daily (given as 400mg twice daily) may be considered if clinically indicated. Adjuvant GIST treatment: 400mg once daily; 36 months of treatment recommended (see full labeling). If severe non-hematologic reactions develop: interrupt dose; resume at a lower dose in hepatic dysfunction. Severe hepatic impairment: reduce dose by 25%. Renal or hematologic reactions: see full labeling. Potent CYP3A4 inducers (eg, rifampin): increase imatinib dose by at least 50%.

Children: Take with food and water in 1 or 2 divided doses; may disperse tab in water or apple juice and take promptly. <1 yrs: not recommended. ≥ 1 yrs: Newly diagnosed Ph+CML: 340mg/m² per day (max 600mg). Newly diagnosed Ph+ALL: 340mg/m² per day (max 600mg); give with chemotherapy. If severe non-hematologic reactions develop: interrupt dose; resume at a lower dose in hepatic dysfunction. Renal or hematologic reactions: see full labeling. Potent

CYP3A4 inducers (eg, phenytoin): increase imatinib dose by at least 50%; monitor closely.

Warnings/Precautions: Hepatic or renal impairment. Immunosuppressed. Monitor weight and for fluid retention regularly; CBCs weekly for 1st month, bi-weekly for 2nd month, then periodically (eg, every 2-3 months); liver function at baseline then monthly or as needed. Monitor for tumor lysis syndrome; correct clinically significant dehydration and treat high uric acid levels before initiating therapy. Monitor growth in children. Cardiovascular disease. Elderly. Avoid pregnancy (Cat.D); nursing mothers: not recommended; see full labeling.

Interactions: Potentiated by CYP3A4 inhibitors (eg, azole antifungals, macrolides). Antagonized by CYP3A4 inducers (eg, dexamethasone, phenytoin, phenobarbital, carbamazepine, St. John's wort, rifampin). May potentiate drugs metabolized by CYP3A4 (eg, acetaminophen, benzodiazepines, dihydropyridine calcium channel blockers, cyclosporine, pimozide, statins), CYP2D6, or CYP2C9 (use heparin instead of warfarin).

Adverse reactions: GI disturbances, edema (may be severe), bleeding, muscle cramps, fever, pain, rash (may be severe; eg, erythema multiforme, Stevens-Johnson syndrome), fatigue, dizziness, blurred vision, somnolence, headache, cough, arthralgia/myalgia, dyspnea, hypokalemia, night sweats, anorexia, pruritus, neutropenia, thrombocytopenia, weight gain, renal or hepatotoxicity, immunosuppression, hypothyroidism in thyroidectomy patients undergoing levothyroxine replacement (monitor TSH levels); rare: severe CHF, left ventricular dysfunction.

Testing considerations: BCR-Abl t(9;22) in Ph⁺ CML patients

How supplied: 100mg-90400mg-30

INTERFERON ALFA-2B

INTRON A Merck

Interferon alfa-2b, recombinant; 10million, 18million, or 50million IU per vial; pld; for inj after reconstitution/dilution; preservative-free.

Also: Interferon alfa-2b

INTRON A SOLUTION

Interferon alfa-2b, recombinant; 10million IU, 18million IU, 25million IU; per vial; for inj; contains m-cresol.

Also: Interferon alfa-2b

INTRON A SOLUTION MULTIDOSE PENS

Interferon alfa-2b, recombinant; 18million IU, 30million IU, 60million IU; per pen; for SC inj; contains m-cresol.

Indications: AIDS-related Kaposi's sarcoma. Hairy cell leukemia. Initial treatment of clinically aggressive follicular Non-Hodgkin's lymphoma in conjunction with anthracycline-containing combination chemotherapy. Malignant melanoma.

Adults: Use appropriate preparation and route: see literature. Use SC route if platelets <50,000/mm³. Kaposi's sarcoma: 30million IU/m² IM or SC three times weekly; continue until rapid disease progression or maximal response achieved after 16 wks; reduce dose by 1/2 or suspend therapy if severe adverse reactions occur; discontinue if persists. Leukemia, lymphoma, melanoma: see literature.

Children: Not recommended.

Contraindications: Hepatitis: decompensated liver disease. Autoimmune disorders.

Warnings/Precautions: May cause or exacerbate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, or infectious disorders: monitor closely, discontinue if they worsen. Severe psychiatric disorders (esp. depression). Cardiovascular or pulmonary disease. Severe myelosuppression. Uncontrolled thyroid abnormalities. Diabetes. Coagulation disorders. Maintain adequate hydration. Monitor blood, thyroid, visual and liver function before and during therapy; EKG in cardiovascular disease and cancer patients. Psoriasis. Renal dysfunction. Transplant recipients. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with myelosuppressives, and drugs that can exacerbate depression. May potentiate theophylline (may double its levels).

Adverse reactions: Flu-like symptoms (fever, headache, myalgia, fatigue); hepatic, hematologic, respiratory, skin, genitourinary system, CNS, cardiovascular, endocrine (esp thyroid), GI, or visual disorders; colitis, hypertriglyceridemia, pancreatitis, infections, injection site reactions; others (see literature).

How supplied: Pld (w, diluent): 10million, 18million, 50million IU/vial-1; Soln (vials): 10million IU/vial-6 (kit w. supplies); Soln (multidose vials): 18million, 25million IU/vial-1; Soln (multidose pens, 6 doses/pen): 3million IU/0.2mL, 5million IU/0.2mL, 10million IU/0.2mL-1

IRINOTECAN

CAMPTOSAR Pfizer

Topoisomerase 1 inhibitor. Irinotecan HCl 20mg/mL; soln for IV infusion after dilution.

Indications: Metastatic colorectal cancer, as 1st line therapy with 5-FU and leucovorin, or as monotherapy if disease recurs or progresses after fluorouracil-based therapy.

Adults: See literature. Give by IV infusion over 90 minutes. Combination therapy: 125mg/m² on days 1, 8, 15, 22; or, 180mg/m² on days 1, 15, 29; both: give every 6 weeks. Monotherapy: 125mg/m² on days 1, 8, 15, 22, then 2-week rest; or, 350mg/m² once every 3 weeks. Elderly (≥65 years), pelvic or abdominal radiotherapy, performance status of 2, increased bilirubin, homozygous UGT1A1*28 allele, or toxicity: reduce initial dose. May pretreat with antiemetics and/or atropine.

Children: See literature.

Contraindications: During or within 2 weeks of St. John's wort, or 1 week of ketoconazole.

Warnings/Precautions: Not for use as part of 5-FU/LV "Mayo Clinic" regimen except in certain circumstances (see literature). Renal or hepatic impairment. Dialysis: not recommended. Diabetes. Gilbert's syndrome or abnormal glucuronidation. Monitor blood counts; suspend if neutropenic fever or ANC $<1000/\text{mm}^3$ occurs. If late diarrhea occurs, may treat with loperamide; suspend until bowel function normalizes. Avoid extravasation. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid live vaccines. Concomitant irradiation: not recommended. Antagonized by CYP3A4 inducers (eg, phenytoin, phenobarbital, carbamazepine, rifampin, St. John's wort). Hyperglycemia, lymphocytopenia increased with dexamethasone. Increased risk of renal toxicity with diuretics (esp. in dehydration). May affect neuromuscular blocking agents. May be potentiated by atazanavir.

Adverse reactions: GI upset, myelosuppression, fever, infection, asthenia, renal or hepatic dysfunction, dyspnea, dizziness, somnolence, hypotension, thromboembolic events, rash, alopecia, hand-and-foot syndrome, edema, cholinergic effects, flushing, ileus, local or hypersensitivity reactions.

Testing considerations: UGT1A1 mutation analysis

How supplied: Single-dose vial (2mL, 5mL)–1

IXABEPILONE

IXEMPRA Bristol-Myers Squibb

Epothilone microtubule inhibitor. Ixabepilone 15mg/vial, 45mg/vial; pwd for IV infusion after constitution and dilution; diluent contains alcohol, polyoxyethylated castor oil.

Indications: Metastatic or locally advanced breast cancer: In combination with capecitabine after failure of an anthracycline and a taxane; and as monotherapy after failure of an anthracycline, a taxane, and capecitabine.

Adults: Pretreat with both H_1 and H_2 blockers 1hr before infusion; and with steroid if previous hypersensitivity reaction occurred. $40\text{mg}/\text{m}^2$ by IV infusion over 3hrs, once every 3wks. Use max body surface area (BSA) of 2.2m^2 to calculate dose if $\text{BSA} > 2.2\text{m}^2$. Moderate hepatic impairment (as monotherapy): initially $20\text{mg}/\text{m}^2$ per dose; max $30\text{mg}/\text{m}^2$ per dose (see literature). Neuropathy, myelosuppression, concomitant strong CYP3A4 inhibitors: reduce dose. Concomitant strong CYP3A4 inducers: consider gradual dose increases. See literature.

Children: Not recommended.

Contraindications: Baseline neutrophils $<1500\text{cells}/\text{mm}^3$ or platelets $<100,000\text{cells}/\text{mm}^3$. AST or ALT $>2.5\times\text{ULN}$ or bilirubin $>1\times\text{ULN}$ (in combination with capecitabine).

Warnings/Precautions: Monitor CBC and liver function at baseline, then periodically. Hepatic impairment (ALT or AST $>10\times\text{ULN}$ or bilirubin $>3\times\text{ULN}$: not recommended; ALT or AST $>5\times\text{ULN}$: limited data, use caution). Diabetes. Neuropathy. Cardiac disease (discontinue if cardiac ischemia or cardiac dysfunction occurs). Monitor for signs/symptoms of neuropathy, neutropenia. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Potentiated by strong CYP3A4 inhibitors (eg, azole antifungals, protease inhibitors, certain macrolides, nefazodone, grapefruit juice); avoid. Caution with mild or moderate CYP3A4 inhibitors; consider alternative agents. Antagonized by strong CYP3A4 inducers (eg, phenytoin, carbamazepine, rifampin, rifabutin, dexamethasone, phenobarbital); avoid. Avoid St. John's wort.

Adverse reactions: Peripheral sensory neuropathy, fatigue, asthenia, myalgia, arthralgia, alopecia, GI upset, stomatitis, mucositis, musculoskeletal pain, palmar-plantar erythrodysesthesia syndrome, anorexia, abdominal pain, nail disorder, constipation; myelosuppression (neutropenia, leukopenia, anemia, thrombocytopenia); hypersensitivity reactions; others.

How supplied: Kit–1 vial (w. diluent)

LAPATINIB

TYKERB GlaxoSmithKline

Tyrosine kinase inhibitor. Lapatinib 250mg; tabs.

Indications: In combination with capecitabine, for the treatment of patients with advanced or metastatic breast cancer whose tumors overexpress HER2 and who have received prior therapy including an anthracycline, a taxane, and trastuzumab. In combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses HER2 for whom hormonal therapy is indicated.

Adults: Take 1 hour before or 1 hour after a meal (capecitabine should be taken with food or within 30min after food). HER2 metastatic breast cancer: 1250mg (5 tabs) once daily on Days 1–21 continuously in combination with capecitabine $2000\text{mg}/\text{m}^2/\text{day}$ (administered orally in 2 doses approx. 12 hours apart) on Days 1–14 in a repeating 21 day cycle; continue until disease progression or unacceptable toxicity occurs. After recovery from left ventricular ejection fraction (LVEF) decrease: $1000\text{mg}/\text{day}$. Severe hepatic dysfunction (Child-Pugh Class C): $750\text{mg}/\text{day}$ (no clinical data for this dose adjustment). Concomitant potent CYP3A4 inducers: may titrate up to $4500\text{mg}/\text{day}$ (no clinical data for this dose adjustment). Hormone receptor positive, HER2 positive metastatic breast cancer: 1500mg (6 tabs) once daily continuously in combination with letrozole 2.5mg once daily. After recovery from LVEF decrease: $1250\text{mg}/\text{day}$. Severe hepatic dysfunction: $1000\text{mg}/\text{day}$ (no clinical data for this dose adjustment). Concomitant potent CYP3A4 inducers: may titrate up to $5500\text{mg}/\text{day}$ (no clinical data for

this dose adjustment). For both: Concomitant potent CYP3A4 inhibitors: 500mg/day (no clinical data for this dose adjustment). Discontinue if $\geq$ grade 2 NCI CTC toxicity occurs; may restart at 1250mg/day if toxicity improves to grade 1; if recurs, may restart at 1000mg/day (with capecitabine); 1250mg/day (w. letrozole).

Children: Not recommended.

Warnings/Precautions: Confirm normal LVEF before starting. Discontinue if $\geq$ grade 2 decrease in LVEF occurs, or if LVEF falls below institution's lower limit of normal; may restart after at least 2 weeks at reduced dose if asymptomatic and LVEF recovers. Conditions that impair left ventricular function, or risk factors for QT prolongation (eg, hypokalemia, hypomagnesemia, congenital long QT syndrome, concomitant antiarrhythmics, cumulative high dose anthracyclines); correct electrolyte disturbances before starting. Monitor for interstitial lung disease or pneumonitis; discontinue if pulmonary symptoms $\geq$ grade 3 (NCI CTCAE). Monitor liver function tests before, every 4–6 weeks during therapy and as indicated; discontinue if hepatotoxicity occurs; do not retreat. Severe hepatic impairment: consider dose reduction. Pretreat for diarrhea with antimotility drugs. Monitor ECG. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: Avoid potent CYP3A4 inhibitors (eg, ketoconazole), grapefruit; reduce dose if unavoidable. Avoid potent CYP3A4 inducers (eg, carbamazepine); slowly titrate dose up if unavoidable. May affect drugs that are affected by p-glycoprotein, CYP2C8.

Adverse reactions: Diarrhea (may be severe); nausea, vomiting, hand/foot syndrome, rash, fatigue; decreased LVEF, QT prolongation, interstitial lung disease, pneumonitis, hepatotoxicity (may be fatal).

Testing considerations: HER2 protein overexpression

How supplied: Tabs–150

LENALIDOMIDE

R

REVLIMID Celgene

Immunomodulator. Lenalidomide 2.5mg, 5mg, 10mg, 15mg, 20mg, 25mg; caps.

Indications: In combination with dexamethasone for treatment of patients with multiple myeloma (MM) who have received at least one prior therapy. Treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

Adults: Do not break, chew, or open caps. Swallow whole with water. $\geq$ 18yrs: initially 25mg once daily on Days 1–21 of each 28-day cycle. Renal impairment: Moderate (CrCL 30–60mL/min): 10mg per day. Severe (CrCL $<$ 30mL/min without dialysis): 15mg every 48 hrs. ESRD (CrCL $<$ 30mL/min with dialysis): 5mg once daily; administer after dialysis (on dialysis days). Dose adjustments if thrombocytopenia or neutropenia develops: see full labeling.

Children: $<$ 18yrs: not established.

Contraindications: Pregnancy (Cat.X). Women who may become pregnant.

Warnings/Precautions: Must register patient in RevAssist program; patient must understand toxicity with fetal exposure. Counsel patient on need for contraception; female: use 2 forms of contraception 1 month before, during, and 1 month after therapy; male: use condom during and 1 month after therapy; obtain 2 negative pregnancy tests (one within 10–14 days, and then another within 24 hours prior to starting therapy), repeat at least weekly for 1st month then every 4 weeks; get informed consent. Monitor for signs/symptoms of thromboembolic events. For MM: obtain CBCs every 2 weeks for first 3 months, then monthly. For MCL: obtain CBCs weekly for the first cycle, every 2 weeks during cycles 2–4, and then monthly thereafter. Renal impairment (monitor). Monitor for tumor lysis syndrome in those with high tumor burden. Monitor liver enzymes; discontinue if elevation occurs. Monitor for second primary malignancies. Maximum 1 month per R. Nursing mothers: not recommended.

Interactions: Monitor digoxin. Concomitant warfarin; monitor PT, INR. May increase risk of thrombosis with erythropoietic agents or estrogen containing therapies.

Adverse reactions: Birth defects, thrombocytopenia, neutropenia, GI upset, pruritus, rash, fatigue, arthralgia, pyrexia, back pain, cough, dizziness, headache, dyspnea, blurred vision, muscle cramp; thrombosis/embolism, allergic reactions (discontinue if occurs; do not resume), tumor flare reaction (monitor; esp. in treating MCL), hepatotoxicity.

Note: Available only through RevAssist program.

Report any suspected fetal exposure to the FDA at (800) FDA-1088 and Celgene at (888) 423-5436.

How supplied: Caps 2.5mg, 5mg, 10mg–28, 100 15mg, 20mg, 25mg–21, 100

LETROZOLE

R

FEMARA Novartis

Aromatase inhibitor. Letrozole 2.5mg; tabs.

Indications: In postmenopausal women: Adjuvant treatment of hormone receptor positive early breast cancer; Extended adjuvant treatment of early breast cancer after 5 years of adjuvant tamoxifen therapy; First-line treatment of hormone receptor positive or unknown, locally advanced or metastatic breast cancer; Treatment of advanced breast cancer with disease progression following antiestrogen therapy.

Adults: 2.5mg once daily. Continue until tumor progression is evident. Adjuvant or extended adjuvant therapy: treat for at least 24 months (see literature). Severe hepatic impairment or cirrhosis: 2.5mg every other day.

Children: Not applicable.

Contraindications: Women of premenopausal endocrine status. Pregnancy (Cat.X).

Warnings/Precautions: Severe renal or hepatic impairment. Monitor bone mineral density, serum cholesterol. Nursing mothers.

Adverse reactions: Pain (bone, musculoskeletal, and others), hot flashes, arthralgia, flushing, asthenia, edema, headache, dizziness, hypercholesterolemia, sweating increased, GI upset, fatigue, dyspnea, cough, insomnia, hypertension, alopecia, anorexia, weight changes, hypercalcemia, pleural effusion, vertigo; thromboembolic or cardio- or cerebrovascular events (rare).
How supplied: Tabs-30

LEUCOVORIN

LEUCOVORIN Teva US Generics
Folic acid derivative. Leucovorin calcium 100mg/vial, 350mg/vial; lyophilized pld for IV or IM inj after reconstitution; preservative-free.

Indications: Palliative treatment of advanced colorectal cancer in combination with 5-fluorouracil.

Adults: Max IV infusion rate: 160mg/min. 200mg/m² by slow IV inj over a minimum of 3 minutes, followed by 5-fluorouracil (370mg/m²); or 20mg/m² IV followed by 5-fluorouracil (425mg/m²); both regimens: daily for 5 days, may be repeated at 4-week intervals for 2 courses and then repeated at 4-5 week intervals (if completely recovered from toxic effects of previous course).

Children: See literature.

Contraindications: Pernicious anemia and other megaloblastic anemias due to Vit. B₁₂ deficiency.

Warnings/Precautions: Do not administer intrathecally. CNS metastases. Monitor CBCs with differential, platelets, electrolytes, liver function tests prior to each treatment, then periodically. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates toxicity of 5-fluorouracil; use lower 5-fluorouracil dose. May antagonize phenobarbital, phenytoin, and primidone. Caution with trimethoprim-sulfamethoxazole.

Adverse reactions: Leukopenia, thrombocytopenia, infection, GI upset, stomatitis, constipation, lethargy, malaise, fatigue, alopecia, dermatitis, anorexia; seizures, syncope.

How supplied: Single-use vials-1

LEUPROLIDE

ELIGARD 7.5MG 1-MONTH Sanofi Aventis
GnRH analogue. Leuprolide acetate 7.5mg per inj; ext-rel susp; for SC inj.

Also: Leuprolide

ELIGARD 22.5MG 3-MONTH
 Leuprolide acetate 22.5mg per inj; ext-rel susp; for SC inj.

Also: Leuprolide

ELIGARD 30MG 4-MONTH
 Leuprolide acetate 30mg per inj; ext-rel susp; for SC inj.

Also: Leuprolide

ELIGARD 45MG 6-MONTH
 Leuprolide acetate 45mg per inj; ext-rel susp; for SC inj.

Indications: Palliative treatment of advanced prostate cancer.

Adults: Allow product to reach room temperature before using; inject within 30 minutes of mixing. Use correct formulation. 7.5mg SC once per month; or 22.5mg SC once every 3 months; or 30mg SC once every 4 months; or 45mg SC once every 6 months. Rotate inj site.

Children: Not established.

Contraindications: Women. Pregnancy (Cat.X).

Warnings/Precautions: May worsen metastatic vertebral lesions and/or urinary tract obstruction; monitor closely during first few weeks. Increased risk of diabetes, MI, sudden cardiac death, stroke; monitor blood glucose, HbA1c, and for signs/symptoms of CVD during therapy. Monitor serum testosterone, PSA periodically.

Adverse reactions: Malaise, fatigue, hot flashes/sweats, testicular atrophy, gynecomastia, local reactions, asthenia, pain, spinal cord compression, decreased bone density; transient worsening of signs/symptoms (eg, bone pain, neuropathy, hematuria, bladder outlet obstruction); rare: pituitary apoplexy.

How supplied: Single-use kit-1

LEUPROLIDE

LUPRON DEPOT 7.5MG AbbVie
GnRH analogue. Leuprolide acetate 7.5mg; depot susp for IM inj.

Indications: Palliative treatment of advanced prostatic carcinoma.

Adults: 7.5mg IM once a month. Rotate inj site.

Children: Not applicable.

Also: Leuprolide

LUPRON DEPOT-3 MONTH 22.5MG
 Leuprolide acetate 22.5mg; depot susp for IM inj.

Adults: 22.5mg IM inj every 3 months (84 days). Do not split doses.

Children: Not applicable.

Also: Leuprolide

LUPRON DEPOT-4 MONTH 30MG
 Leuprolide acetate 30mg; depot susp for IM inj; preservative-free.

Adults: 30mg as single IM inj every 4 months (16 weeks). Do not split doses.

Children: Not applicable.

Also: Leuprolide

LUPRON DEPOT-6 MONTH 45MG
 Leuprolide acetate 45mg; depot susp for IM inj.
Adults: 45mg as single IM inj every 6 months (24 weeks). Do not split doses.

Children: Not applicable.

Contraindications: Women. Pregnancy (Cat.X).

Warnings/Precautions: Metastatic vertebral lesions. Urinary obstruction. Monitor serum testosterone, PSA, acid phosphatase. Increased risk of diabetes, MI, sudden cardiac death, stroke; monitor blood glucose, HbA1c, and for

signs/symptoms of CVD during therapy. Risk of QT prolongation: long-term androgen deprivation therapy, congenital long QT syndrome, electrolyte abnormalities, or CHF, and concomitant Class IA or III antiarrhythmics. Instruct patient on correct self administration.

Interactions: Concomitant Class IA (eg, quinidine, procainamide) or Class III (eg, amiodarone, sotalol) antiarrhythmics may prolong the QT interval.

Adverse reactions: Hot flashes/sweats, inj site reaction, initial worsening of signs/symptoms (eg, bone pain, urinary tract obstruction, hematuria), edema, GI upset, pain, cardiovascular events, CNS and antiandrogenic effects, asthenia, spinal cord compression; hyperglycemia, anaphylactoid, photosensitivity.

How supplied: Depot kit-1 (prefilled dual-chamber syringe w. supplies)

LEVELEUCOVORIN

FUSILEV Spectrum

Folate analogue. Leveleucovorin (as calcium pentahydrate) 50mg/vial; pld for IV inj after reconstitution; contains mannitol 50mg/vial; 175mg/17.5mL; soln for IV inj; preservative-free.

Indications: Palliative treatment of advanced metastatic colorectal cancer in combination with 5-fluorouracil (5-FU).

Adults: Administer leveleucovorin and 5-FU separately to avoid precipitate formation. Regimen 1: give leveleucovorin at 100mg/m² by slow IV inj over a minimum of 3 minutes, followed by 5-FU at 370mg/m² by IV inj. Regimen 2: give leveleucovorin at 10mg/m² by IV inj, followed by 5-FU at 425mg/m² by IV inj. Both: Treat daily for 5 days. Five-day treatment course may be repeated at 4 week (28 days) intervals for 2 courses, and then repeated at 4–5 week (28–35 days) intervals provided that patient recovered completely from toxic effects from prior treatment course. Dose adjustments for subsequent treatment course: see literature.

Children: Not recommended.

Warnings/Precautions: Not for treating pernicious anemia and megaloblastic anemia. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates 5-fluorouracil toxicity. Antagonizes TMP/SMZ. Antagonizes anticonvulsants (eg, phenobarbital, primidone, phenytoin). May be affected by drugs that affect MTX elimination.

Adverse reactions: Stomatitis, nausea, diarrhea.

How supplied: Single-use vial (pld, soln)–1

LOMUSTINE

CEENU Bristol-Myers Squibb

Alkylating agent. Lomustine 10mg, 40mg, 100mg; caps.

Indications: Primary and metastatic brain tumors, in patients who have already received appropriate surgery and radiotherapy. Secondary therapy for Hodgkin's disease in combination with other approved

drugs in patients who relapse while being treated or who fail primary therapy.

Adults and Children: Pretreat with antiemetics and give on empty stomach. Give one dose every 6 weeks. Previously untreated (as a single agent): 130mg/m². Compromised bone marrow function: 100mg/m². Combination with other myelosuppressive drugs: adjust doses accordingly. Subsequent doses: adjust according to hematologic response (see literature).

Warnings/Precautions: Monitor blood counts weekly for ≥ 6 weeks after a dose; repeat courses should not be given before 6 weeks (delayed hematologic toxicity) or until platelets are $>100,000/\text{mm}^3$ or leukocytes $>4000/\text{mm}^3$. Monitor liver and renal function. Perform pulmonary function tests prior to and frequently during therapy; increased risk of pulmonary toxicity in patients with baseline $<70\%$ of the predicted Forced Vital Capacity or Carbon Monoxide Diffusing Capacity. Pregnancy (Cat.D). Nursing mothers: not recommended.

Adverse reactions: Delayed or cumulative myelosuppression (thrombocytopenia, leukopenia) leading to infection or bleeding, pulmonary toxicity, delayed pulmonary fibrosis, secondary malignancies, liver and renal dysfunction, nausea, vomiting, stomatitis, alopecia, optic atrophy, visual disturbances, disorientation, lethargy, ataxia, dysarthria.

Note: Wear gloves when handling capsules.

How supplied: Caps–20

Dose pack (100mg–2 caps, 40mg–2 caps, 10mg–2 caps)–1

MECHLORETHAMINE

MUSTARGEN Lundbeck

Nitrogen mustard. Mechlorethamine HCl 10mg/vial; pld for IV or intracavitary inj after reconstitution.

Indications: Palliative treatment of Hodgkin's disease (stages III and IV), lymphosarcoma, chronic myelocytic or chronic lymphocytic leukemia, polycythemia vera, mycosis fungoides, bronchogenic carcinoma. Palliative treatment of metastatic carcinoma resulting in effusion.

Adults: By IV infusion, per therapeutic course: 0.4mg/kg (lean body weight) as single dose or in divided doses of 0.1–0.2mg/kg per day. See literature for intracavitary (eg, intrapleural) administration. Do not exceed recommended dose. Repeat course only after hematologic recovery (eg, every 3 weeks).

Children: See literature.

Contraindications: Infectious diseases.

Warnings/Precautions: Drug is highly toxic; verify potential benefits outweigh risks; avoid inadvertent contact with powder or vapor. Do not use if foci of acute and chronic suppurative inflammation are present. Ensure adequate hydration. Avoid extravasation. Chronic lymphatic leukemia. Bone marrow suppression. Previous X-ray, cytotoxic

chemotherapy. Infection. Hemorrhagic tendency. Monitor renal, hepatic and bone marrow function. Elderly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Adverse reactions: Bone marrow suppression, hyperheparinemia, GI upset (may be severe), anorexia, weakness, thrombosis, thrombophlebitis, hypersensitivity, jaundice, alopecia, vertigo, auditory disturbances, hemolytic anemia, skin reactions, infection, amyloidosis, hyperuricemia, gonad damage.

How supplied: Vials-4

MEGESTROL

R

MEGACE Bristol-Myers Squibb
Progestin. Megestrol acetate 20mg, 40mg; scored tabs.

Indications: Palliative treatment of advanced breast or endometrial carcinoma.

Adults: Breast carcinoma: 40mg 4 times daily. Endometrial carcinoma: 40–320mg daily in divided doses.

Children: Not applicable.

Warnings/Precautions: History of thromboembolic disease. Diabetes. Monitor for adrenal insufficiency. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: May increase insulin requirements. Decreases indinavir levels.

Adverse reactions: Weight gain, thromboembolic events, heart failure, GI upset, edema, breakthrough menstrual bleeding, dyspnea, tumor flare, hyperglycemia, alopecia, hypertension, carpal tunnel syndrome, mood changes, hot flashes, malaise, asthenia, lethargy, sweating, rash.

How supplied: Tabs-100

MELPHALAN

R

ALKERAN GlaxoSmithKline
Nitrogen mustard derivative. Melphalan 2mg; scored tabs.

Indications: Palliative treatment for multiple myeloma and non-resectable epithelial ovarian cancer.

Adults: Multiple myeloma: 6mg once daily for 2–3 weeks; stop for up to 4 weeks, maintenance 2mg per day. Ovarian cancer: 0.2mg/kg per day for 5 days; repeat course every 4–5 weeks. Both: continue treatment as hematological recovery permits (esp. WBCs and platelets); for other regimens: see literature.

Children: Not recommended.

Also: Melphalan

ALKERAN FOR INJECTION

R

Melphalan HCl 50mg/vial; pld for IV infusion after reconstitution and dilution.

Indications: Palliative treatment of multiple myeloma when oral therapy is not appropriate.

Adults: Give by IV infusion over 15–20 minutes. 16mg/m² every 2 weeks for a total of 4 doses, then at 4-week intervals. Continue treatment as

hematological recovery permits. Renal insufficiency (BUN ≥ 30mg/dL): consider reducing dose by 50%.

Children: Not recommended.

Contraindications: Prior resistance to melphalan.

Warnings/Precautions: Prior irradiation or chemotherapy. Bone marrow suppression. Azotemia. Monitor platelets, hemoglobin, WBC and differential at start of therapy and prior to each course; discontinue if WBC < 3,000cells/μL or platelets < 100,000cells/μL. Moderate to severe renal impairment. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Radiotherapy potentiates antineoplastic effect. For IV: caution with cyclosporine, cisplatin, BCNU, nalidixic acid.

Adverse reactions: Bone marrow suppression, GI upset, hepatic dysfunction, anemia, blood dyscrasias, secondary malignancies (eg, nonlymphocytic leukemia), rash, alopecia, pulmonary fibrosis, interstitial pneumonitis, gonadal toxicity (amenorrhea, infertility); hypersensitivity reactions, cardiac arrest (rare).

How supplied: Tabs-50
Single-use vial-1 (w. diluent)

MERCAPTOPYRINE

R

MERCAPTOPYRINE (various)

Antimetabolite. Mercaptopurine (6-MP) 50mg; scored tabs.

Indications: Maintenance therapy of acute lymphatic leukemia as part of a combination regimen.

Adults and Children: 1.5–2.5mg/kg per day as a single dose. Concomitant allopurinol: reduce dose of mercaptopurine to 1/3–1/4 of the usual dose. TPMT-deficient, renal or hepatic impairment: reduce dose, see literature.

Contraindications: Prior resistance to mercaptopurine.

Warnings/Precautions: Not effective in CNS leukemia, acute myelogenous leukemia, chronic lymphocytic leukemia, the lymphomas (including Hodgkin's disease), or solid tumors. Renal impairment. Monitor liver function tests weekly at start of therapy, then monthly thereafter; discontinue if hepatotoxicity occurs. Pre-existing liver disease (monitor more frequently). Obtain CBCs with differential, hemoglobin, hematocrit, platelets; discontinue if severe bone marrow suppression occurs. Thiopurine-S-methyltransferase (TPMT) deficient: increased risk of myelosuppression, consider genotypic/phenotypic testing. Pregnancy (Cat.D); esp. 1st trimester, nursing mothers: not recommended.

Interactions: Increased risk of bone marrow suppression with allopurinol, aminosalicilate derivatives (eg, olsalazine, mesalazine, sulphasalazine), trimethoprim-sulfamethoxazole. Antagonizes warfarin. Caution with concomitant hepatotoxic agents.

Adverse reactions: Myelosuppression, hyperuricemia/hyperuricosuria, GI upset,

intestinal ulceration, rash, hyperpigmentation, alopecia, oligospermia; hepatotoxicity, infection, immunosuppression.

How supplied: Tabs-60

METHOTREXATE

TREXALL Teva US Generics

Folic acid antagonist. Methotrexate sodium 5mg, 7.5mg, 10mg, 15mg; scored tabs.

Also: Methotrexate

METHOTREXATE INJECTION (various)

Methotrexate 25mg/mL; soln for IV, IM, intra-arterial, or intrathecal administration after dilution; preservative-free.

Also: Methotrexate

METHOTREXATE FOR INJECTION (various)

Methotrexate 1gram/vial; pld for IV, IM, intra-arterial, or intrathecal administration after dilution; preservative-free.

Indications: Gestational choriocarcinoma.

Chorioadenoma destruens. Hydatidiform mole.

Prophylaxis and treatment of meningeal leukemia.

Breast cancer. Epidermoid cancers of the head and neck.

Advanced mycosis fungoides (cutaneous T cell lymphoma). Lung cancer (squamous cell and small cell types).

Advanced non-Hodgkin's lymphomas.

Non-metastatic osteosarcoma in patients who have undergone surgical resection or amputation for the primary tumor (high-dose therapy with leucovorin rescue).

Adults: See literature. Tablet form is often preferred when low doses are being administered. Choriocarcinoma and similar trophoblastic diseases:

15–30mg orally or by IM inj daily for 5 days; usually repeated 3–5 times as required with a rest period of ≥ 1 week between courses. Leukemia: Induction:

$3.3\text{mg}/\text{m}^2 + \text{prednisone}$, given daily; maintenance:

give twice weekly either orally or by IM inj for a total

weekly dose of $30\text{mg}/\text{m}^2$; or $2.5\text{mg}/\text{kg}$ IV every 14

days. Meningeal leukemia (treatment): $12\text{mg}/\text{m}^2$

intrathecally (max 15mg) at intervals of 2–5 days;

see literature for prophylaxis treatment. Burkitt's

tumor (stage I–II): $10\text{--}25\text{mg}$ per day orally for 4–8

days. Lymphosarcomas (stage III): $0.625\text{--}2.5\text{mg}/\text{kg}$

daily. Mycosis fungoides (cutaneous T cell lymphoma):

$5\text{--}50\text{mg}$ once weekly. Osteosarcoma: initially $12\text{g}/\text{m}^2$

IV infusion over 4 hours; may be increased to

$15\text{g}/\text{m}^2$; see literature for leucovorin rescue dosing

with high-dose methotrexate.

Children: See literature.

Contraindications: Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Be fully familiar with this drug's toxicity before use. Discontinue if malignant lymphomas occur. Obtain baseline and monitor CBCs with differential, platelet counts, chest X-ray, and hepatic, renal and pulmonary function. During therapy monitor hematology monthly, renal and hepatic function every 1–2 months, more often

if increasing dose or predisposed to toxicity (eg, dehydration). Discontinue immediately if blood counts drop significantly. Rule out pregnancy in women of childbearing potential; use effective contraception during therapy and for at least 1 ovulatory cycle afterwards for women and for at least 3 months afterwards for men. Interrupt therapy if vomiting, diarrhea, stomatitis, or pulmonary symptoms occur. Hepatic or renal impairment. Obesity. Diabetes. Peptic ulcer. Ulcerative colitis. Infection. Dehydration. Folate deficiency. Ascites, pleural effusions: evacuate fluid, monitor for toxicity and reduce dose or discontinue if needed. Elderly (use low doses and monitor closely). Debilitated.

Interactions: Avoid live virus vaccines. Toxicity

increased by NSAIDs, salicylates, phenytoin, sulfonyleureas, sulfonamides, probenecid, folic acid antagonists. May be potentiated by penicillins (monitor), tetracyclines, chloramphenicol, non-absorbable broad spectrum antibiotics. May be antagonized by folic acid. May potentiate theophylline, mercaptopurine. Increased risk of soft tissue necrosis and osteonecrosis with radiotherapy. Caution with other hepatotoxic drugs (eg, azathioprine, retinoids, sulfasalazine) and nephrotoxic agents (eg, cisplatin).

Adverse reactions: Ulcerative stomatitis, leukopenia, nausea, GI upset, malaise, fatigue, chills, fever, dizziness, infection, myelosuppression, hepatotoxicity, renal toxicity, CNS toxicity, seizures (esp in children); interstitial pneumonitis, tumor lysis syndrome, skin reactions (may be fatal; eg, toxic epidermal necrolysis, Stevens-Johnson syndrome).

How supplied: Tabs-30

Soln (2mL, 4mL, 8mL, 10mL)–10 (single-use vials)

Pwd (1 gram)–1 (single-use vial)

METHOXSALEN

UVADEX Therakos

Photoactive agent. Methoxsalen 20mcg/mL; sterile soln.

Indications: Extracorporeal administration with the UVAR Photopheresis System in the palliative treatment of skin manifestations of cutaneous T-cell lymphoma that is unresponsive to other forms of treatment.

Adults: Consult UVAR Photopheresis System Operator's Manual before administering. Give on two consecutive days every 4 weeks for minimum of 7 treatment cycles (6 months). 200mcg per photopheresis treatment. Accelerated treatment schedule: see literature.

Children: Not recommended.

Contraindications: Idiosyncratic reactions to psoralen compounds. History of light sensitive disease. Lupus erythematosus. Porphyria cutanea tarda. Erythropoietic protoporphyria. Variegated porphyria. Xeroderma pigmentosum. Albinism. Aphakia.

Warnings/Precautions: Exposure to sun or UV light may cause actinic degeneration, skin burning, cataracts; wear UVA-absorbing, wrap-around sunglasses and cover exposed skin (or use sunblock:

SPF ≥ 15) for 24hrs after treatment. Basal cell carcinomas (monitor and treat if occur). Pregnancy (Cat.D); nursing mothers: not recommended.

Interactions: Increased photosensitivity with anthralin, coal tar, griseofulvin, phenothiazines, nalidixic acid, halogenated salicylanilides, sulfonamides, tetracyclines, thiazides, organic staining dyes.

Adverse reactions: Hypotension secondary to changes in extracorporeal volume.

How supplied: Vials (10mL)–12

MITOMYCIN

R

MITOMYCIN (various)

Cytotoxic antibiotic. Mitomycin 5mg/vial, 20mg/vial, 40mg/vial; pwd for IV infusion after reconstitution and dilution; contains mannitol.

Indications: Disseminated adenocarcinoma of the stomach or pancreas.

Adults: Give by IV infusion. 20mg/m² as a single dose every 6–8 weeks. Discontinue if disease progresses after two courses. Myelosuppression: see literature for dose adjustments.

Children: Not recommended.

Contraindications: Thrombocytopenia. Coagulation disorders. Bleeding tendencies.

Warnings/Precautions: Renal toxicity; serum creatinine > 1.7 mg: not recommended. Monitor platelets, WBCs, differential, hemoglobin repeatedly during and for at least 8 weeks after therapy. Avoid extravasation. Monitor fluid balance and avoid overhydration. Pregnancy, nursing mothers: not recommended.

Interactions: Caution with vinca alkaloids, other chemotherapy.

Adverse reactions: Thrombocytopenia, leukopenia (cumulative myelosuppression); inj site reactions (eg, cellulitis), stomatitis, alopecia, renal toxicity, pulmonary toxicity (eg, pulmonary infiltrates); discontinue if occurs; hemolytic uremic syndrome, CHF, fever, anorexia, nausea, vomiting.

How supplied: Contact supplier.

MITOTANE

R

LYSODREN Bristol-Myers Squibb

Adrenal cytotoxic agent. Mitotane 500mg; tabs; scored.

Indications: Inoperable adrenal cortical carcinoma.

Adults: 2–6g/day in divided doses (3–4 times/day). Doses may be increased incrementally to 9–10g/day. Max: 18–19g/day. Continue as long as clinical benefit observed.

Children: Not recommended.

Warnings/Precautions: Discontinue temporarily following shock or severe trauma. Hepatic disease. Remove any tumor tissues from metastatic masses prior to therapy to minimize possible infarction and hemorrhage. Long-term administration of high doses: assess behavioral and neurological function. May need concomitant steroid replacement. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Monitor oral anticoagulants. Caution with other drugs susceptible to hepatic enzyme induction.

Adverse reactions: GI upset, lethargy, somnolence, dizziness, vertigo, rash.

How supplied: Tabs–100

MITOXANTRONE

R

NOVANTRONE OSI

Anthracenedione. Mitoxantrone 2mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: Treatment of pain in advanced hormone-refractory prostate cancer in combination with corticosteroids. Acute nonlymphocytic leukemia (ANLL) in combination with other approved drugs.

Adults: Give by IV infusion. Prostate cancer:

12–14mg/m² every 21 days. ANLL (see literature for cytarabine dose): Induction therapy: 12mg/m² daily on days 1–3 + cytarabine on days 1–7; if 2nd induction course needed, give for 2 days + cytarabine for 5 days using same daily dosage levels. Consolidation therapy: 12mg/m² on days 1–2 + cytarabine on days 1–5 for 2 courses (1st course given 6 weeks after the final induction course and the 2nd course given 4 weeks after the 1st course).

Children: Not recommended.

Warnings/Precautions: Myelosuppression; do not administer if baseline neutrophil count < 1500 cell/mm³, except in ANLL. Hepatic impairment. Monitor CBCs, platelets, liver function tests prior to each course. Monitor for signs of infection. Cardiovascular disease. Monitor LVEF before initial dose. Prior or concomitant radiotherapy to mediastinal/pericardial area. Previous anthracycline therapy. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Caution with concomitant cardiotoxic drugs.

Adverse reactions: Myelosuppression, GI upset, infection, fever, alopecia, dyspnea, hypersensitivity reactions, bluish-green urine, sclera discoloration, hyperuricemia; cardiotoxicity (eg, CHF), secondary acute myelogenous leukemia.

How supplied: Multidose-vial (5mL, 10mL)–1

NELARABINE

R

ARRANON GlaxoSmithKline

Nucleoside analogue. Nelarabine 250mg/vial; soln for IV infusion.

Indications: T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) that is unresponsive or has relapsed after ≥ 2 chemotherapy regimens.

Adults and Children: Contact manufacturer. From the pediatric trial: Patients ≤ 21 yrs: 650mg/m² by IV infusion over 1 hour daily for 5 consecutive days; repeat every 21 days. From the adult trial: Patients 16–65yrs: 1500mg/m² by IV infusion over 2 hours on days 1, 3, and 5; repeat every 21 days. The recommended duration of treatment has not

been clearly established. Treatment was generally continued until there was evidence of disease progression, the patient experienced unacceptable toxicity, the patient became a candidate for bone marrow transplant, or the patient no longer continued to benefit from treatment. See literature.

Warnings/Precautions: Discontinue if $\geq$ Grade 2 neurotoxicity occurs; may delay dosing if other toxicities occur (eg, hematologic toxicity). Prior or concurrent intrathecal chemotherapy or craniospinal irradiation (increased risk of neurotoxicity). Renal or hepatic impairment. Obtain CBCs, platelet counts. Monitor for signs/symptoms of infection, tumor lysis syndrome. Ensure adequate hydration. Elderly. Pregnancy (Cat.D); use effective contraception. Nursing mothers: not recommended.

Interactions: Avoid live vaccines. Concomitant adenosine deaminase inhibitors (eg, pentostatin): not recommended.

Adverse reactions: Hematologic disorders (eg, anemia, neutropenia, thrombocytopenia), headache, GI upset, constipation, fatigue, somnolence, dizziness, peripheral neuropathy, seizures, respiratory disorders, pyrexia; increased transaminase levels, bilirubin; decreased potassium, albumin.

How supplied: Vials-6

NILOTINIB

R

TASIGNA Novartis
Kinase inhibitor. Nilotinib (as HCl monohydrate)
150mg, 200mg; caps; contains lactose.

Indications: Newly diagnosed adults with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Chronic and accelerated phase Ph+ CML in adults resistant or intolerant to imatinib.

Adults: Take on an empty stomach. Swallow whole. Newly diagnosed Ph+ CML: 300mg every 12 hours. Hepatic impairment (mild, moderate, severe): initially 200mg twice daily, followed by dose increase to 300mg twice daily if tolerated. Resistant or intolerant Ph+ CML: 400mg every 12 hours. Hepatic impairment (mild or moderate): initially 300mg twice daily, followed by dose increase to 400mg twice daily if tolerated; severe: initially 200mg twice daily, followed by sequential dose increase to 300mg twice daily, and then 400mg twice daily if tolerated. See literature for dose adjustments for QT prolongation, hematological and non-hematological toxicities, concomitant strong CYP3A4 inhibitors and inducers.

Children: Not recommended.

Contraindications: Hypokalemia. Hypomagnesemia. Long QT syndrome.

Warnings/Precautions: Prolongs QT interval, sudden deaths have been reported; correct electrolyte abnormalities (hypokalemia, hypomagnesemia) before starting; monitor. Monitor ECG at baseline, after 7 days, then periodically and after dose changes. Hereditary galactose

intolerance, severe lactase deficiency, glucose-galactose malabsorption: not recommended. Hepatic impairment. History of pancreatitis. Uncontrolled cardiovascular or renal disease. Monitor for myelosuppression; withhold or reduce dose if occurs; perform CBCs every 2 weeks for 1st 2 months then once monthly. Monitor serum lipase, liver function. Total gastrectomy (monitor frequently); consider dose increase or alternative therapy. Tumor lysis syndrome possible; maintain adequate hydration, correct uric acid levels prior to initiating therapy. Pregnancy (Cat.D) (use adequate contraception), nursing mothers: not recommended.

Interactions: Avoid concomitant food, antiarrhythmics, or other drugs that can cause QT prolongation. Avoid strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole), grapefruit. Avoid strong CYP3A4 inducers (eg, dexamethasone, phenytoin, carbamazepine, rifampin, phenobarbital), St. John's wort; adjust nilotinib dose if unavoidable. May affect, or be affected by, other drugs metabolized by CYP3A4, 2B6, 2C8, 2C9, 2D6, UGT1A1, p-glycoprotein. Caution with drugs that affect gastric pH (eg, proton pump inhibitors, H₂ blockers).

Adverse reactions: Rash, pruritus, GI upset, fatigue, headache, constipation, reversible myelosuppression (thrombocytopenia, neutropenia, anemia), pneumonia, febrile neutropenia, leukopenia, intracranial hemorrhage, elevated serum lipase, pyrexia, electrolyte disturbances (hypophosphatemia, hypo- and hyperkalemia, hypocalcemia, hyponatremia); QT prolongation, arrhythmias, sudden death, hepatotoxicity.

Testing considerations: BCR-Abl t(9;22)

How supplied: Caps-28

NILUTAMIDE

R

NILANDRON Covis
Antiandrogen. Nilutamide 150mg; tabs.

Indications: Metastatic prostate cancer (Stage D₂), as an adjunct to surgical castration.

Adults: 300mg once daily for 30 days then 150mg once daily, starting day of or day after surgical castration.

Children: Not applicable.

Contraindications: Severe hepatic impairment or respiratory insufficiency.

Warnings/Precautions: Obtain baseline liver and pulmonary function tests and chest X-ray. Monitor for interstitial pneumonitis; discontinue if occurs. Monitor liver function for first 4 months then periodically; discontinue if ALT $>$ 2 $\times$ ULN or jaundice occurs. May discolor urine or sclera. Pregnancy (Cat.C): not for use in women. Nursing mothers.

Interactions: Monitor drugs metabolized by CYP450 (eg, Vit. K antagonists, theophylline, phenytoin); may need to adjust dose. May cause alcohol intolerance.

Adverse reactions: Hot flushes, impaired night vision, GI upset, increased liver enzymes, constipation, dizziness, abnormal vision, hypertension, hepatitis, interstitial pneumonitis.

How supplied: Tabs-30

OFATUMUMAB

R

ARZERRA GlaxoSmithKline

Cytolytic monoclonal antibody (CD20-directed).
Ofatumumab 20mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: Chronic lymphocytic leukemia (CLL) refractory to fludarabine and alemtuzumab.

Adults: Premedicate with acetaminophen (oral), antihistamine (oral or IV), corticosteroid (IV); see literature. Give by IV infusion (use in-line filter; rate varies with dose and during infusion). Initially 300mg once, then 1 week later 2000mg weekly for 7 doses, then 4 weeks later 2000mg every 4 weeks for 4 doses.

Children: Not recommended.

Warnings/Precautions: Monitor CBC, platelets, and for neurological changes. Pre-screen for hepatitis B in high-risk patients; discontinue if viral hepatitis emerges. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid vaccination with live viral vaccines.

Adverse reactions: Neutropenia, thrombocytopenia, anemia, pneumonia, pyrexia, cough, fatigue, dyspnea, rash, GI upset, bronchitis, upper respiratory tract infections; infusion reactions (eg, bronchospasm; laryngeal, pulmonary, or angioedema; flushing, hyper- or hypotension, syncope, cardiac ischemia, back or abdominal pain, fever, urticaria) (interrupt infusion and monitor; do not restart if grade 4 reaction occurs), progressive multifocal leukoencephalopathy (discontinue if occurs and monitor), intestinal obstruction, infections (eg, sepsis).

How supplied: Single-use vial (5mL)-3, 10

OMACETAXINE MEPEUSCINATE

R

SYNRIBO Teva Oncology

Protein synthesis inhibitor. Omacetaxine mepesuccinate 3.5mg/vial; lyophilized powder for SC injection after reconstitution; contains mannitol; preservative-free.

Indications: Treatment of adult patients with chronic or accelerated phase chronic myeloid leukemia (CML) with resistance and/or intolerance to two or more tyrosine kinase inhibitors (TKI).

Adults: Induction: 1.25mg/m² by SC injection twice daily for 14 consecutive days every 28 days, over a 28-day cycle. Repeat cycles every 28 days until hematologic response achieved. Maintenance: 1.25mg/m² by SC injection twice daily for 7 consecutive days every 28 days, over a 28-day cycle, as long as clinically beneficial. Dose adjustments and modifications: see full labeling.

Children: Not established.

Warnings/Precautions: Risk of myelosuppression (thrombocytopenia, neutropenia, anemia),

hemorrhage (cerebral, GI). Monitor CBCs with platelets weekly during induction, initial maintenance cycles, and every 2 weeks during later cycles.

Monitor glucose levels (esp. in diabetics). Avoid in poorly controlled diabetes until glycemic control is established. Elderly. Pregnancy (Cat.D); avoid. Nursing mothers: not recommended.

Interactions: Avoid concomitant anticoagulants, aspirin, NSAIDs if platelets <50,000/microliters; may increase risk of bleeding.

Adverse reactions: Thrombocytopenia, anemia, neutropenia, diarrhea, nausea, fatigue, asthenia, injection site reaction, pyrexia, infection, lymphopenia; bleeding, hyperglycemia.

How supplied: Single-use vial-1

OXALIPLATIN

R

ELOXATIN Sanofi Aventis

Alkylating agent (organoplatinum complex). Oxaliplatin 5mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: Adjuvant treatment for Stage III colon cancer in patients who have undergone complete resection of the primary tumor (in combination with infusional 5-FU/LV). Treatment of advanced colorectal cancer (in combination with infusional 5-FU/LV).

Adults: See literature. Premedicate with antiemetics. Give by IV infusion every two weeks for a total of 6 months (eg, 12 cycles). Day 1: 85mg/m² + leucovorin, followed by 5-FU. Day 2: Leucovorin followed by 5-FU. Severe renal impairment: initially 65mg/m². Neuropathy, other toxicities: see literature for dose adjustments.

Children: Not recommended.

Warnings/Precautions: Have epinephrine, corticosteroids, antihistamines available during infusion. Discontinue if interstitial lung disease or pulmonary fibrosis suspected. Monitor for neuropathy; reduce dose or discontinue if needed. Renal impairment. Monitor WBCs with differential, hemoglobin, platelets, blood chemistries (including ALT, AST, bilirubin, creatinine) before each treatment. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Caution with concomitant nephrotoxic agents. Monitor oral anticoagulants.

Adverse reactions: Peripheral sensory neuropathy, neutropenia, thrombocytopenia, anemia, GI upset, increased liver enzymes, emesis, fatigue, stomatitis; hypersensitivity reactions (monitor), pulmonary fibrosis (may be fatal), hepatotoxicity.

Testing considerations: ERCC1 overexpression

How supplied: Single-use vials (50mg, 100mg, 200mg)-1

PACLITAXEL

R

TAXOL Bristol-Myers Squibb

Antimicrotubule agent. Paclitaxel 6mg/mL; soln for IV infusion after dilution; contains Cremophor EL (polyoxyethylated castor oil), dehydrated alcohol.

Indications: First-line therapy (in combination with cisplatin) and subsequent therapy for advanced carcinoma of the ovary. Adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. Breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. First-line treatment of non-small cell lung cancer in combination with cisplatin in patients who are not candidates for potentially curative surgery and/or radiation therapy. Second-line treatment of AIDS-related Kaposi's sarcoma.

Adults: See literature. Premedicate with corticosteroids, diphenhydramine, H_2 antagonists. Previously untreated ovarian cancer: 175mg/m² IV over 3 hours + cisplatin every 3 weeks; or 135mg/m² IV over 24 hours + cisplatin every 3 weeks. Previously treated ovarian cancer: 135mg/m² or 175mg/m² IV over 3 hours every 3 weeks. Breast cancer (node-positive): 175mg/m² IV over 3 hours every 3 weeks for 4 courses administered sequentially to doxorubicin-containing combination chemotherapy. Breast cancer (after failure of initial chemotherapy for metastatic disease or relapse): 175mg/m² IV over 3 hours every 3 weeks. Non-small cell lung cancer: 135mg/m² IV over 24 hours + cisplatin every 3 weeks. AIDS-related Kaposi's sarcoma: 135mg/m² IV over 3 hours every 3 weeks; or 100mg/m² IV over 3 hours every 2 weeks. Hepatic impairment or neutropenia: see literature for dose modifications. Do not treat if neutrophil count <1,500cells/mm³ (<1,000cells/mm³ with Kaposi's sarcoma) or platelets <100,000cells/mm³.

Children: Not recommended.

Contraindications: Solid tumors: baseline neutrophil count <1,500cells/mm³. AIDS-related Kaposi's sarcoma: baseline neutrophil count <1,000cells/mm³.

Warnings/Precautions: Do frequent peripheral blood cell counts. Hepatic dysfunction. Conduction abnormalities: monitor cardiac function. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: May potentiate or be potentiated by CYP2C8 or CYP3A4 substrates, inducers and/or inhibitors. Potentiated by cisplatin. May potentiate doxorubicin.

Adverse reactions: Bone marrow suppression (eg, neutropenia, leukopenia, thrombocytopenia, anemia), inj site reactions, infections, hypotension, bradycardia, hypersensitivity reactions (if severe, do not rechallenge), peripheral neuropathy, myalgia, arthralgia, GI upset, mucositis, alopecia, abnormal ECG, elevated liver enzymes.

How supplied: Multidose vial (5mL, 16.7mL, 50mL)–1

PACLITAXEL, PROTEIN-BOUND R

ABRAXANE Abraxis

Taxane antimicrotubule. Paclitaxel [bound to albumin (human)] 100mg/vial; pwd for IV infusion after reconstitution; solvent-free.

Indications: Treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy (prior therapy should have included an anthracycline unless clinically contraindicated). First-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC), in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.

Adults: Do not treat if neutrophil count <1,500 cells/mm³ or platelets <100,000 cells/mm³. Breast cancer: 260mg/m² by IV infusion over 30 minutes every 3 weeks. If severe neutropenia (neutrophil <500 cells/mm³ for ≥1week) or severe sensory neuropathy occurs: reduce subsequent doses to 220mg/m²; reduce to 180mg/m² if severe neutropenia or sensory neuropathy recurs. If grade 3 sensory neuropathy occurs, suspend use until resolution to grade 1 or 2; reduce subsequent doses. NSCLC (w/carboplatin): 100mg/m² IV over 30 minutes on Days 1, 8, and 15 of each 21-day cycle. Dose reductions for hematologic and neurologic adverse reactions, hepatic impairment: see literature. Avoid extravasation.

Children: Not recommended.

Contraindications: Baseline neutrophil count <1,500 cells/mm³. Prior severe hypersensitivity reaction (do not rechallenge).

Warnings/Precautions: Do not substitute for, or with, other paclitaxel products (due to formulation differences). Do frequent peripheral blood cell counts. Hepatic or renal dysfunction. Contains human albumin; remote risk of viral transmission. Use appropriate contraception (men and women). Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: May potentiate or be potentiated by CYP2C8 and/or CYP3A4 inducers (eg, rifampin, carbamazepine, phenytoin, efavirenz, nevirapine) and/or inhibitors (eg, ketoconazole, other imidazole antifungals, erythromycin, fluoxetine, gemfibrozil, cimetidine, ritonavir, saquinavir, indinavir, nelfinavir).

Adverse reactions: Bone marrow suppression (eg, neutropenia, anemia), infections, alopecia, sensory neuropathy, peripheral neuropathy, GI upset, mucositis, fatigue/asthenia, myalgia/arthralgia, abnormal ECG; alkaline phosphatase or AST elevation; dyspnea, edema, hypotension, rash (may be serious); rare: thrombotic events.

How supplied: Single-use vial–1

PAMIDRONATE R

PAMIDRONATE DISODIUM INJECTION (various)

Bisphosphonate. Pamidronate disodium 30mg, 90mg; per vial; pwd for IV infusion after reconstitution; contains mannitol.

Indications: Hypercalcemia of malignancy. Paget's disease. Osteolytic bone metastases of breast cancer. Osteolytic lesions of multiple myeloma.

Adults: Give by IV infusion. Hypercalcemia of malignancy: Assure adequate hydration; give as a single dose infused over 2–24hrs; moderate disease

(albumin-corrected serum calcium 12–13.5mg/dL): 60–90mg; severe disease (albumin-corrected serum calcium >13.5mg/dL): 90mg; allow at least 7 days before retreatment. **Paget's disease:** 30mg daily infused over 4hrs on 3 consecutive days for a total of 90mg. Osteolytic bone lesions of multiple myeloma: 90mg infused over 4hrs once monthly. Osteolytic bone metastases: 90mg infused over 2hrs every 3–4wks. Max single dose: 90mg.

Children: Not recommended.

Warnings/Precautions: Severe renal impairment in patients with bone metastases: not recommended. Renal or hepatic insufficiency. Check serum creatinine before each dose: withhold until serum creatinine is within 10% of baseline if serum creatinine increases 0.5mg/dL from normal pre-treatment levels, or by 1mg/dL from an abnormal pre-treatment level. Monitor electrolytes (esp. calcium, magnesium, phosphate, potassium), CBC/differential, hematocrit/hemoglobin. Pre-existing blood disorders (eg, anemia, leukopenia, thrombocytopenia); monitor closely for first 2 weeks after treatment. Avoid dental surgery (do preventative dental work before therapy). Evaluate if thigh or groin pain develops and consider discontinuing if atypical femur fracture is suspected. Pregnancy (Cat.D): not recommended. Nursing mothers.

Interactions: Caution with other nephrotoxic drugs (eg, thalidomide).

Adverse reactions: Infusion-site reactions, fever, headache, dizziness, paresthesia, increased sweating, GI upset, anemia, fatigue, musculoskeletal pain (may be severe), electrolyte disturbances, hypertension, dyspnea, renal toxicity; jaw osteonecrosis, atypical subtrochanteric and diaphyseal femoral fractures.

How supplied: Contact supplier.

PANITUMUMAB

VECTIBIX Amgen

Human epidermal growth factor receptor (EGFR) inhibitor. Panitumumab 20mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: EGFR-expressing, metastatic colorectal carcinoma (mCRC) with disease progression on or following fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy regimens.

Adults: 6mg/kg by IV infusion over 60 minutes once every 14 days until disease progression detected. Doses >1000mg: infuse over 90 minutes. Infusion reactions or dermatologic toxicity: see full labeling.

Children: Not established.

Warnings/Precautions: Not for use in KRAS mutation-positive mCRC or for whom KRAS mCRC status is unknown. Test for EGFR protein expression. Not to be used with combination chemotherapy; severe diarrhea, dehydration leading to acute renal failure possible. Withhold or discontinue therapy if severe dermatologic toxicities occur; monitor for infection. Discontinue if severe infusion reactions develop. Permanently discontinue therapy if interstitial lung

disease, pneumonitis, or lung infiltrates develop. Limit sun exposure. Monitor electrolytes (eg, magnesium, calcium) during and for 8 weeks after completing therapy. Monitor for ocular toxicities (eg, keratitis); interrupt or discontinue if occur. May impair fertility in women; use effective contraception during treatment and for 6 months following last dose. Pregnancy (Cat.C). Nursing mothers: not recommended; discontinue during therapy and for 2 months after last dose.

Interactions: Concomitant chemotherapy (eg, irinotecan, bolus or infusional 5-fluorouracil, oxaliplatin, leucovorin): not recommended.

Adverse reactions: Skin rash, paronychia, hypomagnesemia, nausea, diarrhea, abdominal pain, constipation, fatigue, photosensitivity; dermatologic toxicities with possible infection (may be fatal), infusion reactions; may need to permanently discontinue: see full labeling), pulmonary fibrosis, keratitis, immunogenicity.

Testing considerations: EGFR amplification analysis, K-RAS mutation analysis, B-RAF mutation analysis

How supplied: Single-use vial (5mL, 10mL, 20mL)–1

PAZOPANIB

VOTRIENT GlaxoSmithKline

Kinase inhibitor. Pazopanib 200mg; tabs.

Indications: Advanced renal cell carcinoma. Advanced soft tissue sarcoma in patients who have received prior chemotherapy.

Adults: Take on an empty stomach. Swallow whole. 800mg once daily. Dose adjustments: see full labeling. Hepatic impairment: moderate: 200mg once daily; severe: not recommended. Concomitant strong CYP3A4 inhibitors (eg, ketoconazole, ritonavir, clarithromycin): avoid; if warranted, reduce dose of pazopanib to 400mg; may reduce further if toxicity occurs. Concomitant strong CYP3A4 inducers (eg, rifampin): avoid.

Children: Not established (increased toxicity in developing organs).

Warnings/Precautions: Not indicated for use in combination with other cancer agents. Not for treatment of adipocytic soft tissue sarcoma or gastrointestinal stromal tumors. Risk of severe and fatal hepatotoxicity. Monitor liver tests before starting and at least once every 4 weeks for at least the first 4 months of treatment, then periodically. If ALT between 3×ULN and 8×ULN continue therapy with weekly monitoring until ALT returns to Grade 1 or baseline. If ALT >8×ULN interrupt therapy until ALT returns to Grade 1 or baseline; may consider reintroducing at a reduced dose, measure liver tests weekly for 8 weeks; if ALT >3×ULN recurs, permanently discontinue. Permanently discontinue if ALT >3×ULN and bilirubin >2×ULN. Gilbert's syndrome (see full labeling). History of QT prolongation. Cardiac dysfunction risk: evaluate LVEF at baseline and periodically; monitor for CHF. Monitor ECG, electrolytes (eg, calcium, magnesium, potassium), thyroid. History

of hemoptysis, cerebral, or clinically significant GI hemorrhage in the past 6 months: not recommended. Risk of arterial thrombotic events (within previous 6 months: not recommended). Monitor for VTE, PE, infection, proteinuria (reduce dose if 24-hour urine protein ≥ 3 g). Discontinue if severe and persistent hypertension (despite antihypertensives and dose reduction) or if repeat episodes of proteinuria (despite dose reductions) occur. Stop therapy at least 7 days before surgery; discontinue in patients with wound dehiscence. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: See Adult dosing: Potentiated by strong CYP3A4 inhibitors, grapefruit juice. Antagonized by strong CYP3A4 inducers. Concomitant drugs with narrow therapeutic windows metabolized by CYP3A4, CYP2D6, or CYP2C8: not recommended. Increased risk of ALT elevations with concomitant simvastatin; caution and monitor closely; follow dosing guidelines or consider alternatives to pazopanib, or discontinuing simvastatin if develops. Caution with concomitant drugs that prolong QT interval (eg, antiarrhythmics).

Adverse reactions: Diarrhea, hypertension, hair color changes, nausea, anorexia, vomiting, fatigue, decreased weight, decreased appetite, tumor pain, musculoskeletal pain, headache, dysgeusia, dyspnea, skin hypopigmentation; hepatotoxicity, QT prolongation, hemorrhagic events, arterial thrombotic events (eg, MI, angina, ischemic stroke, TIA), venous thrombotic events (eg, VTE, PE), GI perforation or fistula, impaired wound healing, hypothyroidism, proteinuria, infection, reversible posterior leukoencephalopathy syndrome (discontinue if occurs).

How supplied: Tabs—120

PEGASPARGASE

ONCASPAR Enzon

Enzyme. Pegaspargase 750 IU/mL; soln for IV or IM inj; preservative-free.

Indications: First-line acute lymphoblastic leukemia (including patients with asparaginase hypersensitivity).

Adults and Children: Give by IV inj over 1–2 hours or by IM inj (max 2mL/inj site). 2500 IU/m² no more frequently than every 14 days.

Contraindications: History of pancreatitis, serious hemorrhage, or thrombosis with prior L-asparaginase therapy.

Warnings/Precautions: Have resuscitation equipment available and observe patient for 1 hour post-dose. Monitor coagulation parameters. Discontinue if serious allergic reactions, thrombotic events, or pancreatitis occurs. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Allergic reactions (including anaphylaxis), hyperglycemia, pancreatitis, CNS thrombosis, coagulopathy, hyperbilirubinemia, elevated transaminases.

How supplied: Single-use vial (5mL)—1

PEMETREXED

ALIMTA Lilly

Antifolate. Pemetrexed 100mg/vial, 500mg/vial; pwd for IV inj after reconstitution and dilution; preservative-free.

Indications: Locally advanced or metastatic nonsquamous non-small cell lung cancer: in combination with cisplatin as initial treatment, or as maintenance in patients whose disease has not progressed after 4 cycles of platinum-based 1st-line chemotherapy; or as a single agent after prior chemotherapy. Malignant pleural mesothelioma (MPM): in combination with cisplatin in patients whose disease is either unresectable or who are otherwise not candidates for curative surgery.

Adults: See full labeling. 500mg/m² by IV infusion over 10 minutes on Day 1 of each 21-day cycle. Adjust dose if toxicity (esp. myelosuppression) develops. Combination therapy: Give cisplatin beginning 30 minutes after pemetrexed infusion. Supplement with oral folic acid and intramuscular vitamin B₁₂ prior to initiating pemetrexed and continue during treatment. Pretreat with corticosteroid the day before, the day of, and day after pemetrexed.

Children: Not recommended.

Warnings/Precautions: See literature. Renal impairment (CrCl <45mL/min): not recommended. Discontinue if Grade 3 or 4 neurotoxicity occurs, or if any Grade 3 or 4 toxicity occurs after two dose reductions. Do not start a treatment cycle unless ANC is ≥ 1500 cells/mm³, platelets $\geq 100,000$ cells/mm³ and CrCl ≥ 45 mL/min. Hepatic impairment. Monitor CBCs, platelets, renal and hepatic function. Clinically significant third space fluid: consider draining effusion first. Pregnancy (Cat.D); avoid, use effective contraception. Nursing mothers: not recommended.

Interactions: May be potentiated by nephrotoxic agents, drugs eliminated by renal tubular secretion (eg, probenecid). Concomitant NSAIDs: use caution in patients with mild to moderate renal insufficiency (esp. ibuprofen).

Adverse reactions: Fatigue, GI upset, anorexia, stomatitis, pharyngitis, constipation, fever, infection with neutropenia, rash, desquamation, neutropenia, leukopenia, anemia, thrombocytopenia, elevated creatinine, chest pain, neuropathy; rare: renal failure.

Testing considerations: TS (thymidylate synthase) expression for response and toxicity

How supplied: Single-use vial—1

PENTOSTATIN

PENTOSTATIN Bedford

Antimetabolite. Pentostatin 10mg/vial; lyophilized pwd for IV inj after reconstitution; contains mannitol.

Indications: Active hairy cell leukemia.

Adults: Ensure adequate hydration. Give as IV bolus or infuse over 20–30 minutes after dilution. 4mg/m² every other week. Reevaluate after 6 months; discontinue if complete or partial response

not achieved; max duration of therapy 12 months. Withhold dose if ANC <200 cells/mm³; may resume when resolved.

Children: Not recommended.

Warnings/Precautions: Active infections; treat prior to initiating therapy. Withhold or discontinue therapy if severe rash or neurotoxicity develops. Renal impairment. Monitor and obtain CBCs, liver, and renal function before and during therapy. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Concomitant fludarabine: not recommended. Potentiates vidarabine. Acute pulmonary toxicity and hypotension with carmustine, etoposide, and high dose cyclophosphamide (see literature).

Adverse reactions: GI upset, fever, rash, fatigue, leukopenia, pruritus, cough, myalgia, chills, headache, abdominal pain, anorexia, asthenia, stomatitis, rhinitis, dyspnea, anemia, pain, sweating, infections, thrombocytopenia.

How supplied: Single-dose vials—1

PORFIMER

R

PHOTOFRIN Aptalis

Photosensitizing agent. Porfimer (as sodium) 75mg/vial; pwd for IV inj after reconstitution; preservative-free.

Indications: Palliation of patients with completely obstructing esophageal cancer or partially obstructing esophageal cancer who cannot be satisfactorily treated with Nd:YAG laser therapy. Reduction of obstruction and palliation in patients with completely or partially obstructing endobronchial non-small-cell lung cancer (NSCLC). Treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy is not indicated. Ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

Adults: See literature. Give by slow IV inj over 3–5 minutes. 2mg/kg then illumination with laser light 40–50 hours following injection. Esophageal, endobronchial cancer: 2nd course may be given at a minimum of 30 days after initial therapy; max 3 courses (separated by ≥ 30 days). Ablation of high-grade dysplasia in Barrett's esophagus: 2nd course may be given at a minimum of 90 days after initial therapy; max 3 courses (separated by ≥ 90 days).

Children: Not recommended.

Contraindications: Porphyrria. Existing tracheoesophageal or bronchoesophageal fistula. Tumors eroding into a major blood vessel. Emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion. Esophageal or gastric varices. Esophageal ulcers >1 cm in diameter.

Warnings/Precautions: Avoid direct sunlight or bright indoor light; wear dark sunglasses when outdoors. Increased risk of fatal massive hemoptysis with large, centrally located tumors, cavitating tumors, extensive tumor extrinsic to the bronchus. Caution with endobronchial tumors in locations where

treatment-induced inflammation could obstruct airway. Avoid extravasation. Pregnancy (Cat.C; use adequate contraception), nursing mothers: not recommended.

Interactions: Increased risk of photosensitivity reactions with other photosensitizing agents (eg, tetracyclines, sulfonamides, phenothiazines, sulfonylurea hypoglycemic agents, thiazide diuretics, griseofulvin, fluoroquinolones). May be antagonized by dimethyl sulfoxide, β -carotene, ethanol, formate, mannitol, allopurinol, calcium channel blockers, prostaglandin synthesis inhibitors, drugs that decreased clotting, vasoconstriction or platelet aggregation (eg, thromboxane A₂ inhibitors), glucocorticoid hormones. Separate radiotherapy by 2–4 weeks.

Adverse reactions: Photosensitivity reactions (eg, erythema, swelling, itching, burning sensation, feeling hot, blisters), fluid imbalance, chest pain, fever, pain, abdominal pain, GI upset, constipation, mucositis, ocular sensitivity, dyspnea, pleural effusion, anemia, fistula formation, fatal massive hemoptysis, others.

How supplied: Vial—1

PRALATREXATE

R

FOLOTYN Allos

Folate analogue inhibitor. Pralatrexate 20mg/mL; soln for IV inj; preservative-free.

Indications: Relapsed or refractory peripheral T-cell lymphoma.

Adults: Prior to administration: mucositis should be $\leq$ Grade 1, platelets should be $\geq 100,000/\mu\text{L}$ for first dose and $\geq 50,000/\mu\text{L}$ for subsequent doses, absolute neutrophil count should be $\geq 1000/\mu\text{L}$. Give by IV push over 3–5min. 30mg/m² once weekly for 6 weeks in 7-week cycles; may reduce to 20mg/m² or interrupt treatment to manage toxicity (see literature for adjustment criteria). Continue until disease progression or unacceptable toxicity develops. Supplement with vitamin B₁₂ (1mg IM every 8–10 weeks, starting within 10 weeks before first Folutyn dose) and folic acid (1–1.25mg orally daily, beginning 10 days before starting Folutyn and for 30 days after stopping).

Children: Not recommended.

Warnings/Precautions: End stage renal disease (including dialysis): avoid, unless benefit justifies potential risk for toxicity. Adjust dose to manage toxicities (eg, hematological, mucositis, hepatic impairment); see literature. Monitor CBC and for mucositis weekly. Monitor serum chemistry, renal and hepatic function before the 1st and 4th dose per cycle. Monitor for dermatological reactions; withhold dose or discontinue if severe. Renal or hepatic impairment. Pregnancy (Cat.D) (may cause fetal harm), nursing mothers: not recommended.

Interactions: May be potentiated by probenecid, NSAIDs, trimethoprim/sulfamethoxazole, other renally-excreted drugs.

Adverse reactions: Mucositis, thrombocytopenia, neutropenia, anemia, abnormal liver function tests, nausea, fatigue, pyrexia, dehydration, sepsis, dyspnea;

dermatological reactions (eg, skin exfoliation, ulceration, toxic epidermal necrolysis), tumor lysis syndrome.

How supplied: Single-use vials (1mL, 2mL)–1

PROCARBAZINE

R

MATULANE Sigma-Tau

Alkylating agent. Procarbazine (as HCl) 50mg; caps.

Indications: Stage III and IV Hodgkin's disease as part of the MOPP (nitrogen mustard, vincristine, procarbazine, prednisone) regimen.

Adults: Initially 2–4mg/kg per day for the first week, then 4–6mg/kg per day until max response is obtained or until WBCs $<4,000\text{cells}/\text{mm}^3$ or platelets $<100,000\text{cells}/\text{mm}^3$. Maintain at 1–2mg/kg per day once max response attained. In MOPP regimen: 100mg/m² daily for 14 days.

Children: Individualize. Initially 50mg/m² per day for the first week, then 100mg/m² per day until max response is obtained or leukopenia or thrombocytopenia occurs. Maintain at 50mg/m² per day once max response attained.

Contraindications: Inadequate marrow reserve.

Warnings/Precautions: Discontinue if CNS effects (eg, paresthesias, neuropathies, confusion), leukopenia, thrombocytopenia, hypersensitivity reactions, stomatitis, diarrhea, hemorrhage or bleeding tendencies occur. Hepatic or renal impairment. Obtain baseline CBCs with differential, hemoglobin, hematocrit, reticulocytes, platelets prior to therapy, then monitor at least every 3–4 days. Do renal and hepatic function tests before starting therapy, then repeated weekly. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid sympathomimetics, tricyclic antidepressants (eg, amitriptyline, imipramine), foods with high tyramine content (eg, wine, yogurt, ripe cheese, bananas). CNS depression with barbiturates, antihistamines, narcotics, hypotensive agents, phenothiazines. Disulfiram-like reactions with alcohol. Separate radiation or other myelosuppressives by at least 1 month (allow for bone marrow recovery).

Adverse reactions: Leukopenia, anemia, thrombopenia, GI upset, bleeding tendencies, CNS effects, dysphagia, anorexia, abdominal pain, hypotension, tachycardia, syncope, cough, alopecia, dermatitis, pain, others.

How supplied: Caps–100

RALOXIFENE

R

EVISTA Lilly

Selective estrogen receptor modulator (SERM).

Raloxifene HCl 60mg; tabs.

Indications: Reduction in risk of invasive breast cancer in postmenopausal women: with osteoporosis and/or at high risk for invasive breast cancer.

Adults: 60mg once daily.

Children: Not recommended.

Contraindications: Active or history of venous thromboembolic events. Nursing mothers. Pregnancy (Cat.X). Women who may become pregnant.

Warnings/Precautions: Not for use in premenopausal women. Concomitant systemic estrogen therapy: not recommended. Discontinue 72 hours before, and during prolonged immobilization; resume when fully ambulatory. Coronary heart disease or risk of coronary event (increased risk of death due to stroke). Hepatic dysfunction. Moderate to severe renal impairment.

Interactions: May antagonize warfarin; monitor. Avoid concomitant cholestyramine, other anion exchange resins. Caution with other highly protein-bound drugs (eg, diazepam, diazoxide, lidocaine).

Adverse reactions: Hot flashes, leg cramps, peripheral edema, flu syndrome, arthralgia, sweating; rare: venous thromboembolic events.

How supplied: Tabs–30, 100, 2000

RITUXIMAB

R

RITUXAN Genentech

B-lymphocyte-restricted differentiation antigen (CD20) inhibitor. Rituximab 10mg/mL; soln for IV infusion; preservative-free.

Indications: Relapsed or refractory, low-grade or follicular, CD20(+) , B-cell non-Hodgkin's lymphoma (NHL). Previously untreated follicular, CD20(+), B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as single-agent maintenance therapy. Non-progressing (including stable disease), low-grade, CD20(+), B-cell NHL as a single agent after first-line CVP chemotherapy. Previously untreated diffuse large B-cell, CD20(+) NHL (DLBCL) in combination with CHOP or other anthracycline-based chemotherapy regimens. CD20(+) chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide.

Adults: Give by IV infusion. Premedicate with an antihistamine and acetaminophen prior to each infusion. First infusion: initially at a rate of 50mg/hr; may increase infusion rate in 50mg/hr increments every 30 minutes. Subsequent infusions: initially at a rate of 100mg/hr; may increase infusion rate in 100mg/hr increments every 30 minutes. Both: max 400mg/hr if infusion reactions do not occur. Previously untreated follicular NHL and DLBCL patients: if no Grade 3 or 4 infusion related adverse events during Cycle 1, a 90-minute infusion may be given in Cycle 2 with a glucocorticoid-containing chemotherapy regimen (see full labeling). NHL: 375mg/m² once weekly for 4 or 8 doses. Retreatment therapy: 375mg/m² once weekly for 4 doses. Previously untreated, follicular, CD20(+), B-cell NHL: 375mg/m² on day 1 of each cycle of CVP chemotherapy for up to 8 doses. In patients with complete or partial response, initiate Rituxan maintenance 8 weeks following completion of Rituxan in combination with chemotherapy. Administer Rituxan as a single-agent every 8 weeks for 12 doses. Low-grade, CD20(+), B-cell NHL: 375mg/m² once weekly

for 4 doses every 6 months for up to 16 doses. Diffuse large B-cell NHL: 375mg/m² on day 1 of each cycle for up to 8 infusions. CLL: 375mg/m² the day prior to FC chemotherapy, then 500mg/m² on day 1 of cycles 2–6 (every 28 days). Give PCP and antihypertensive viral prophylaxis during and up to 12 months after CLL therapy. As a component of Zevalin regimen: see full labeling.

Children: Not recommended.

Warnings/Precautions: Severe, active infections: not recommended. Discontinue if severe infusion or mucocutaneous reactions occur (eg, hypoxia, pulmonary infiltrates, acute respiratory distress syndrome, MI, ventricular fibrillation, cardiogenic shock, Stevens-Johnson syndrome, toxic epidermal necrolysis). Tumor lysis syndrome (esp. with high tumor burden); monitor for renal toxicity, fluid balance, electrolyte abnormalities (correct if occurs). Monitor for new-onset neurologic manifestations; discontinue if progressive multifocal leukoencephalopathy (PML) develops. Pre-existing cardiovascular disease; monitor during and after treatment. Hepatitis B reactivation with fulminant hepatitis may occur; monitor for signs of active HBV infection, discontinue if occurs. Monitor CBCs, platelet counts during treatment, then periodically. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Live virus vaccines: not recommended. Renal toxicity with cisplatin.

Adverse reactions: Fever, chills, rigors, nausea, pruritus, angioedema, asthenia, hypotension, headache, bronchospasm, throat irritation, rhinitis, urticaria, rash, vomiting, myalgia, dizziness, hypertension, cough, flushing, chest tightness; myelosuppression (eg, lymphopenia, neutropenia, leukopenia, anemia, thrombocytopenia), infusion reactions (may be fatal), mucocutaneous reactions (may be fatal), progressive multifocal leukoencephalopathy, viral infections (discontinue if serious), tumor lysis syndrome, renal toxicity, bowel obstruction/perforation, hepatitis B reactivation with fulminant hepatitis, cardiac arrhythmias (discontinue if serious).

Testing considerations: FCGR3A genotype testing

How supplied: Single-use vial (10mL, 50mL)–1

ROMIDEPSIN

R

ISTODAX Celgene

Histone deacetylase inhibitor. Romidepsin 10mg/vial; pvd for IV infusion after reconstitution and dilution; contains povidone.

Indications: Cutaneous T-cell lymphoma in patients who have received at least one prior systemic therapy.

Adults: ≥18yrs: Give by IV infusion over 4hrs. 14mg/m² on days 1, 8, and 15 of a 28-day cycle; repeat cycle every 28 days; continue as tolerated and as beneficial. May interrupt, reduce dose to 10mg/m², or discontinue based on toxicities (see literature).

Children: <18yrs: not recommended.

Warnings/Precautions: Correct electrolyte imbalances (esp. K⁺, Mg⁺⁺) before starting. Monitor ECG and electrolytes in congenital long QT syndrome, significant cardiovascular disease. Moderate to severe hepatic impairment. End-stage renal disease. Monitor CBC with differential. Pregnancy (Cat.D); may cause fetal harm). Nursing mothers: not recommended.

Interactions: May interfere with hormonal (estrogen) contraceptives. Caution with other drugs that can cause QT prolongation (monitor). Monitor PT/INR with warfarin. Potentiated by drugs that inhibit P-glycoprotein and CYP3A4; avoid concomitant strong CYP3A4 inhibitors (eg, azole antifungals, protease inhibitors, clarithromycin, nefazodone). Caution with moderate CYP3A4 inhibitors. Antagonized by strong CYP3A4 inducers (eg, carbamazepine, phenytoin, phenobarbital, rifampin; avoid). Concomitant St. John's Wort: not recommended.

Adverse reactions: GI upset, fatigue, infections, anorexia, anemia, thrombocytopenia, ECG T-wave changes, neutropenia, lymphopenia.

How supplied: Kit-1 (single-use vial + diluent and supplies)

RUXOLITINIB

R

JAKAFI Incyte

Kinase inhibitor. Ruxolitinib 5mg, 10mg, 15mg, 20mg, 25mg; tabs.

Indications: Treatment of intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis and post-essential thrombocythemia myelofibrosis.

Adults: Doses may be given by NG tube if unable to swallow tabs. Platelets >200×10⁹/L: initially 20mg twice daily. Platelets 100–200×10⁹/L: initially 15mg twice daily. Platelets 50–<100×10⁹/L: initially 5mg twice daily. May increase doses by 5mg twice daily to a max of 25mg twice daily; do not increase during the first 4wks of therapy and not more frequently than every 2wks. Discontinue treatment after 6mos if no reduction in spleen size or symptom improvement. Interrupt treatment if platelets <50×10⁹/L. May restart after recovery of platelets (see full labeling for max allowable restarting doses). Consider dose reductions if platelets decrease but remain ≥50×10⁹/L (see full labeling). Dose modifications for patients starting treatment with platelets 50–<100×10⁹/L: see full labeling. Concomitant strong CYP3A4 inhibitors: initially 10mg twice daily if platelets ≥100×10⁹/L; if platelets <100×10⁹/L: avoid. Moderate or severe renal impairment (CrCl 15–59mL/min) and platelets between 100–150×10⁹/L: initially 10mg twice daily. ESRD (CrCl <15mL/min) on dialysis with platelets between 100–200×10⁹/L: 15mg after dialysis session; if with platelets >200×10⁹/L: 20mg after dialysis session. ESRD not requiring dialysis, moderate or severe renal impairment with platelets <100×10⁹/L: avoid. Hepatic impairment with

platelets between $100\text{--}150 \times 10^9/\text{L}$: initially 10mg twice daily; if platelets $<100 \times 10^9/\text{L}$: avoid.

Children: Not established.

Warnings/Precautions: Monitor for thrombocytopenia, anemia, neutropenia; withhold or reduce dose if occur. Obtain CBC and platelets before initiating therapy, every 2–4 weeks until doses are stabilized, and then as clinically indicated. Risk of serious bacterial, mycobacterial, fungal, and viral infections; evaluate and treat if signs/symptoms occur. Confirm resolution of active infections before starting. Renal or hepatic impairment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by strong CYP3A4 inhibitors (eg, boceprevir, clarithromycin, cobicistat, grapefruit juice, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole) and mild or moderate CYP3A4 inhibitors (eg, erythromycin). Antagonized by CYP3A4 inducers (eg, rifampin).

Adverse reactions: Thrombocytopenia, anemia, neutropenia, bruising, dizziness, headache, UTIs, weight gain, flatulence, progressive multifocal leukoencephalopathy (discontinue if occurs), herpes zoster.

How supplied: Tabs–60

SIPULEUCEL-T

PROVENGE Dendreon

Autologous cellular immunotherapy. Sipuleucel-T (autologous CD54+ cells activated with PAP-GM-CSF); minimum 50 million cells/dose; suspension for IV infusion.

Indications: Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer.

Adults: Autologous use only. Obtain product release from manufacturer, match patient identity on product and Cell Product Disposition form, check expiration date and time on product before infusing. Premedicate 30 minutes before infusion with acetaminophen and antihistamine. Give three doses at 2-week intervals. For each dose: give entire contents of bag by IV infusion over 60 minutes; do not use filter; do not use if clumps do not disperse with gentle mixing. Observe patient for at least 30 minutes after infusion. May interrupt or slow infusion if acute transfusion reaction occurs; do not restart if product at room temp for >3 hours.

Children: Not applicable.

Warnings/Precautions: Cardiac or pulmonary conditions. Each dose requires a standard leukapheresis procedure about 3 days before infusion. If scheduled infusion is missed, do an additional leukapheresis procedure if treatment course is to be continued. Risk of disease transmission. Pregnancy, lactation: not applicable.

Interactions: May be antagonized by concomitant chemotherapy or immunosuppressive therapy.

Adverse reactions: Infusion reactions (eg, chills, fever, respiratory events, GI upset, hypertension, tachycardia), fatigue, back pain, joint ache, headache.

Note: If product sterility tests indicate microbial contamination, manufacturer will contact physician (tests are incomplete at time of infusion).

How supplied: Patient-specific bag (250mL)–1

SORAFENIB

NEXAVAR Bayer and Onyx

Multikinase inhibitor. Sorafenib 200mg; tabs.

Indications: Advanced renal cell carcinoma.

Unresectable hepatocellular carcinoma.

Adults: Take on an empty stomach, 400mg twice daily. If toxicity occurs, may reduce dose to 400mg once daily; if further dose reduction required, may reduce dose to 400mg every other day (see full labeling). Concomitant strong CYP3A4 inducers: consider increasing dose, monitor for toxicity.

Children: Not established.

Contraindications: Concomitant carboplatin/paclitaxel in patients with squamous cell lung cancer.

Warnings/Precautions: Severe hepatic impairment (Child-Pugh C) or on dialysis. Avoid in congenital long QT syndrome. Monitor patients with CHF, bradyarrhythmias, drugs known to prolong the QT interval, electrolyte abnormalities. Discontinue if severe dermatologic toxicity, hypertension, GI perforation, hemorrhage, cardiac ischemia, MI occurs. Suspend therapy before major surgery. Monitor BP weekly during the first 6 weeks and thereafter. Monitor hepatic function regularly; discontinue if transaminases significantly elevated. Use effective contraception during and for 2 weeks after stopping treatment. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: See Contraindications. Avoid strong CYP3A4 inducers (eg, St. John's Wort, dexamethasone, phenytoin, carbamazepine, rifabutin, rifampin, phenobarbital) and neomycin; may decrease sorafenib levels. May potentiate warfarin (monitor PT& INR), docetaxel, doxorubicin, irinotecan, other drugs metabolized by UGT1A1 pathway, or substrates of CYP2B6 and CYP2C8. Concomitant Class Ia and III antiarrhythmics; may prolong QT interval.

Adverse reactions: Dermatologic toxicity (rash, hand-foot skin reaction, alopecia, pruritus, dry skin, Stevens-Johnson syndrome, toxic epidermal necrolysis), hypertension, fatigue, weight loss, GI upset, abdominal pain, anorexia, neuropathy, hemorrhage, dyspnea, cough; drug-induced hepatitis, QT prolongation.

How supplied: Tabs–120

STREPTOZOCIN

ZANOSAR Teva US Generics

Anthracycline (nitrosourea). Streptozocin 1g/vial; pld for IV inj or infusion after reconstitution/dilution; preservative-free.

Indications: Symptomatic or progressive metastatic pancreatic islet cell cancer.

Adults: 1g/m² IV once weekly for 2 weeks; may repeat weekly; max 1.5g/m² per dose. Or, 500mg/m² IV daily for 5 days every 6 weeks until max benefit or toxicity.

Children: Not recommended.

Warnings/Precautions: Renal dysfunction or disease. Monitor renal function (eg, urinalysis, BUN, creatinine, electrolytes) before, weekly during, and for 4 weeks after therapy; discontinue or reduce dose if significant renal toxicity occurs (see literature). Obtain CBCs, liver function tests weekly. Avoid extravasation. Ensure adequate hydration. Elderly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Avoid concomitant nephrotoxic agents. Additive toxicity with other cytotoxic drugs. Severe bone marrow toxicity with doxorubicin. Phenytoin may reduce cytotoxicity.

Adverse reactions: GI upset (may be severe); hematological, hepatic and renal (cumulative and dose-related; may be fatal) toxicity; glucose intolerance, nephrogenic diabetes insipidus, inj site reactions, CNS effects (eg, confusion, lethargy, depression).

How supplied: Single-use vial-1

SUNITINIB

SUTENT Pfizer

Multikinase inhibitor. Sunitinib (as malate) 12.5mg, 25mg, 50mg; caps.

Indications: Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate. Advanced renal cell carcinoma (RCC). Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

Adults: GIST and RCC: 50mg once daily for 4 weeks, then 2 weeks off (see full labeling). pNET: 37.5mg once daily continuously without a scheduled off-treatment period. All: may adjust dose in increments or decrements of 12.5mg. Concomitant strong CYP3A4 inhibitors (see Interactions): GIST and RCC: may reduce dose to 37.5mg daily; pNET: may reduce dose to 25mg daily. Concomitant strong CYP3A4 inducers (see Interactions): GIST and RCC: may increase to max 87.5mg daily; pNET: may increase to max 62.5mg daily.

Children: Not recommended.

Warnings/Precautions: Hepatotoxicity; may be severe or fatal. Monitor liver function tests before starting, during each cycle of treatment and as clinically needed; interrupt if Grade 3 or 4 hepatic adverse events occur and discontinue if no resolution; if severe liver function changes or signs/symptoms of failure, do not restart. Cardiovascular disease: monitor LVEF; interrupt or reduce dose if LVEF <50% and >20% below baseline; discontinue if CHF occurs. History of QT prolongation or proarrhythmic conditions (eg, bradycardia, electrolyte disturbances); perform periodic ECG, monitor electrolytes. Monitor BP. Suspend therapy if severe

hypertension, seizures, or pancreatitis develops. Obtain CBCs, platelets, serum chemistries at start of each cycle. Concomitant exposure to risk factors (eg, IV bisphosphonates therapy or dental disease) may increase the risk of osteonecrosis of the jaw; avoid or consider preventive dentistry prior to treatment. Risk of tumor lysis syndrome: monitor closely in RCC and GIST patients with high tumor burden. Thyroid dysfunction. Undergoing major surgery. Stress (monitor for adrenal insufficiency). Renal or hepatic impairment. Pregnancy (Cat.D; avoid). Nursing mothers: not recommended.

Interactions: May be potentiated by strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole); grapefruit. May be antagonized by CYP3A4 inducers (eg, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital); St. John's wort: not recommended.

Adverse reactions: Fatigue, asthenia, fever, GI upset, mucositis/stomatitis, dyspepsia, abdominal pain, constipation, hypertension, peripheral edema, rash, hand-foot syndrome, skin discoloration, dry skin, hair color changes, altered taste, headache, back pain, arthralgia, extremity pain, cough, dyspnea, anorexia, bleeding; hepatotoxicity, left ventricular dysfunction, QT prolongation, hemorrhage, hypertension, osteonecrosis of the jaw, tumor lysis syndrome, thyroid dysfunction, others (see full labeling).

How supplied: Caps-28

TAMOXIFEN

TAMOXIFEN (various)

Antiestrogen. Tamoxifen (as citrate) 10mg, 20mg; tabs.

Indications: Treatment of metastatic breast cancer in men and women. Axillary node-positive breast cancer in postmenopausal women after surgery + irradiation. Axillary node-negative breast cancer in women after surgery + irradiation. Reduction in risk of invasive breast cancer in women with ductal carcinoma in situ (DCIS) after surgery + radiation. Reduction in breast cancer incidence in high-risk women.

Adults: Treatment: 20–40mg/day; give doses >20mg in divided doses (AM and PM). Reduction of incidence in high-risk women or DCIS: 20mg once daily for 5 years.

Children: McCune-Albright Syndrome, precocious puberty: see literature.

Contraindications: For risk reduction: concomitant coumarin anticoagulants, history of deep vein thrombosis or pulmonary embolism, planned pregnancy. Pregnancy (Cat.D). Nursing mothers.

Warnings/Precautions: See literature. Do gynecological exam at least annually. DCIS and risk reduction: consider increased risk of uterine cancer (endometrial adenocarcinoma, uterine sarcoma) and

thrombotic events. Women with advanced disease: discontinue if severe hypercalcemia occurs. Monitor blood, lipids, liver function, for thromboembolism symptoms (eg, leg swelling, unexplained shortness of breath), and for uterine changes/cancer (eg, pelvic pain or pressure); promptly investigate any abnormal vaginal bleeding. Breast cancer treatment: history of thromboembolic events. Premenopausal: use effective non-hormonal contraception during and within 2 months of discontinuing therapy; begin therapy during menses or, if irregular menses, obtain (–) B-hCG pregnancy test first.

Interactions: May potentiate oral anticoagulants (see Contraindications). Antagonizes anastrozole (avoid concomitant use); letrozole. Plasma levels reduced by CYP3A4 inducers (eg, rifampin). Cytotoxic drugs increase risk of thrombotic events. Potentiated by bromocriptine.

Adverse reactions: Hot flashes, vaginal discharge, altered menses, rash, headache, nausea, cough, edema, fatigue, abdominal cramps, bone and tumor pain (in advanced disease), local disease flare, hypercalcemia, thrombotic events, ovarian cysts, uterine fibroids or cancer (endometrial adenocarcinoma, uterine sarcoma), endometrial or visual changes, jaundice, hypertriglyceridemia, blood dyscrasias, hair loss.

How supplied: Contact supplier.

TEMOZOLOMIDE

B

TEMODAR Merck

Alkylating agent. Temozolomide 5mg, 20mg, 100mg, 140mg, 180mg, 250mg; caps.

Indications: Newly diagnosed glioblastoma multiforme. Refractory anaplastic astrocytoma.

Adults: See literature for monitoring and dose adjustment guidelines. Swallow whole with water; take on empty stomach at bedtime to reduce nausea, pretreat with antiemetics. Glioma: Concomitant phase, for newly diagnosed: 75mg/m² daily for 42 days with focal radiotherapy; Maintenance phase, cycle 1: 150mg/m² once daily for 5 consecutive days, then 23 days off; for cycles 2 through 6: increase to 200mg/m² once daily for 5 consecutive days if tolerated, then 23 days off. Anaplastic astrocytoma: 150mg/m² once daily for 5 consecutive days per 28-day treatment cycle; increase dose in subsequent cycles to 200mg/m² if tolerated; continue until disease progression, discontinue if minimum dose not tolerated.

Children: Not recommended.

Contraindications: Hypersensitivity to dacarbazine.

Warnings/Precautions: Myelosuppression (higher risk in women or elderly, esp. in 1st cycle). Do not begin therapy unless hematology (ANC and platelets) is acceptable. Do CBC on day 22 of each cycle or within 48 hours of that day; repeat weekly until recovery if ANC or platelets fall below acceptable limits. Glioblastoma: monitor for and provide

prophylaxis against *P. carinii* pneumonia (PCP). Severe renal or hepatic impairment. Avoid inhalation, and skin/mucous membrane contact, of capsule contents. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended. See literature.

Interactions: Valproic acid may increase temozolomide levels.

Adverse reactions: Nausea, vomiting, anorexia, constipation, headache, other GI or CNS effects, alopecia, fatigue, convulsions, hemiparesis, fever, edema; myelosuppression (may be dose-limiting; see literature); others.

How supplied: Caps 5mg, 20mg, 100mg, 140mg 180mg–5, 14 250mg–5

TEMSIROLIMUS

B

TORISEL Pfizer

mTOR kinase inhibitor. Temsirolimus 25mg/mL; ethanolic soln for IV infusion after two dilutions (first w. supplied diluent); contains alcohol, polysorbate 80.

Indications: Advanced renal cell carcinoma.

Adults: 25mg once weekly. Infuse IV over 30–60min, using an infusion pump. Continue until disease progression or unacceptable toxicity occurs. Premedicate with IV antihistamine (eg, diphenhydramine). Hold dose if ANC <1000/mm³, platelets <75000/mm³, or NCI CTCAE ≥grade 3 adverse reaction occurs; may restart at a dose reduced by 5mg/week (no lower than 15mg/wk) if adverse reactions resolve to ≤grade 2. See Interactions.

Children: Not recommended.

Warnings/Precautions: Sirolimus or related allergy. Hepatic insufficiency. Perioperative period (may interfere with wound healing). CNS tumors. Monitor CBCs weekly and chemistry panels every 2 weeks, blood glucose, lipids, renal function, and for worsening respiratory or GI symptoms (eg, acute abdomen, blood in stool). Elderly. Pregnancy (Cat.D) (avoid pregnancy during and for 3 months after therapy, male patients should use appropriate contraception), nursing mothers: not recommended.

Interactions: Avoid strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin, voriconazole, grapefruit juice); if used, consider reducing temsirolimus dose to 12.5mg/week (allow 1 week after discontinuing CYP3A4 inhibitor before readjusting temsirolimus dose). Avoid strong CYP3A4 inducers (eg, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital, St. John's Wort); if used, consider increasing temsirolimus dose to 50mg/week. Avoid live vaccines, close contact with vaccinees. Additive toxicity with sunitinib (rash, gout/cellulitis), anticoagulants (intracerebral bleeding).

Adverse reactions: Rash, asthenia, mucositis, nausea, edema, anorexia, infection, pain, anemia,

hyperglycemia, hyperlipemia, hypertriglyceridemia, elevated alkaline phosphatase, elevated serum creatinine, lymphopenia, hypophosphatemia, thrombocytopenia, elevated AST, leukopenia; hypersensitivity/infusion reactions (anaphylaxis, dyspnea, flushing, chest pain), immunosuppression, interstitial lung disease, bowel perforation, acute renal failure, abnormal wound healing; others (see literature).

How supplied: Kit (vial + diluent)–1

TENIPOSIDE

VUMON Bristol-Myers Squibb

Topoisomerase inhibitor. Teniposide 10mg/mL; soln for IV infusion after dilution; contains benzyl alcohol, Cremophor EL (polyoxyethylated castor oil), dehydrated alcohol.

Indications: Refractory childhood acute lymphoblastic leukemia.

Adults and Children: See literature. Give as slow IV infusion (at least 30–60 minutes). Patients failing induction therapy with a cytarabine-containing regimen: 165mg/m² + cytarabine twice weekly for 8 to 9 doses. Refractory to vincristine/prednisone-containing regimen: 250mg/m² + vincristine weekly for 4 to 8 weeks + oral prednisone for 28 days.

Warnings/Precautions: Severe myelosuppression. Monitor for hypersensitivity reactions following infusion; have epinephrine available. Risk of hypotension with rapid IV administration. Hepatic dysfunction. Monitor and obtain CBCs with differential, hemoglobin, platelets, renal and hepatic functions before, during, and after therapy. Down syndrome (use reduced dose). Monitor children with hypoalbuminemia. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Potentiated by tolbutamid. Potentiated by tolbutamide, sodium salicylate, and sulfamethizole. Concomitant vincristine sulfate may cause neuropathy. Concomitant antiemetics in patients given high doses of teniposide may increase risk of CNS depression, hypotension.

Adverse reactions: Myelosuppression (leukopenia, neutropenia, thrombocytopenia, anemia), mucositis, GI upset, infection, alopecia, bleeding, rash, fever, hypotension, CNS depression, hypersensitivity reactions (may be fatal).

How supplied: Ampules (5mL)–1

THALIDOMIDE

THALOMID Celgene

Immunomodulator. Thalidomide 50mg, 100mg, 150mg, 200mg; caps.

Indications: Newly diagnosed multiple myeloma in combination with dexamethasone. Treatment, suppression and prevention of cutaneous manifestations of erythema nodosum leprosum (ENL).

Adults: Take at bedtime, at least 1 hour after evening meal. Multiple myeloma: 200mg once daily in

combination with dexamethasone in 28-day treatment cycles. ENL: initially 100–300mg/day; <50kg: start with lower dose; continue until signs/symptoms of active reaction have subsided (usually at least 2 weeks), then taper off in 50mg decrements every 2–4 weeks. Severe ENL: may start at higher doses; max 400mg/day. Moderate to severe neuritis with severe ENL: give concomitant corticosteroids (see literature).

Children: Not recommended.

Contraindications: Pregnancy (Cat.X). Nursing mothers. Women who may become pregnant.

Warnings/Precautions: Must register patient in STEPS program; patient must understand toxicity with fetal exposure. Counsel patient on need for contraception; female: use 2 forms of contraception 1 month before, during, and 1 month after therapy; male: use condom during and 1 month after therapy; obtain negative pregnancy test within 24 hours prior to starting treatment; repeat at least weekly for 1st month then every 4 weeks; get informed consent. Monitor for signs/symptoms of thromboembolic events, neuropathy, bradycardia, orthostatic hypotension. Discontinue if pregnancy or severe skin rash occurs. History of seizure. Avoid contact with non-intact capsule or powder content. Maximum 1 month per R.

Interactions: Increased sedative effect with barbiturates, alcohol, chlorpromazine, reserpine. Caution with drugs associated with peripheral neuropathy. Avoid drugs (eg, rifampin, carbamazepine, St. John's wort) that decrease effectiveness of hormonal contraceptives.

Adverse reactions: Birth defects, skin rash (eg, Stevens-Johnson Syndrome, toxic epidermal necrolysis), bradycardia, peripheral neuropathy, seizures, drowsiness, dizziness, orthostatic hypotension, neutropenia, increased HIV viral load, constipation, confusion, hypocalcemia, edema, dyspnea, thrombosis/embolism.

Note: Available only through STEPS program. Suspected fetal exposure must be reported to the FDA at (800) FDA-1088 and Celgene at (888) 423-5436.

How supplied: Caps–28

THIOGUANINE

TABLOID GlaxoSmithKline

Antimetabolite. Thioguanine 40mg; tabs; scored.

Indications: Remission induction and remission consolidation treatment of acute nonlymphocytic leukemias. Treatment of the chronic phase of chronic myelogenous leukemia (see literature).

Adults and Children: See literature. Initially, 2mg/kg per day. If, after 4 weeks, with no improvement, no leukocyte or platelet depression, may increase to 3mg/kg per day. Total daily dose may be given at one time.

Contraindications: Allergy to mercaptopurine.

Warnings/Precautions: Not recommended for maintenance therapy or long-term continuous

treatments; increased risk of liver toxicity (discontinue if occurs). Pre-existing liver disease. Monitor liver function tests weekly at start of therapy, then monthly thereafter. Thiopurine methyltransferase (TPMT) enzyme deficiency (may need to reduce dose to avoid severe bone marrow suppression); consider testing for TPMT deficiency. Obtain hemoglobin, hematocrit, WBCs with differential, platelets frequently during therapy. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Avoid live vaccines (if immunocompromised). Caution with drugs that inhibit TPMT (eg, olsalazine, mesalazine, or sulphasalazine).

Adverse reactions: Myelosuppression, hyperuricemia, GI upset, anorexia, stomatitis, hepatotoxicity, elevated liver enzymes, jaundice (discontinue if occurs).

How supplied: Tabs—25

THIOTEPA

R

THIOTEPA (various)

Alkylating agent. Thiotepea 15mg; per vial; lyophilized pld for IV, intravesical, or intracavitary administration after reconstitution.

Indications: Superficial papillary carcinoma of the urinary bladder. Adenocarcinomas of the breast and ovary. Intracavitary effusion due to neoplasm of serosal cavities.

Adults: Bladder cancer: avoid fluids 8–12 hrs prior to treatment. 60mg once weekly for 4 weeks; may repeat up to a total of 3 courses. Retain in bladder for 2 hours. IV administration: 0.3–0.4mg/kg IV once every 1–4 weeks. Intracavitary administration: 0.6–0.8mg/kg through same tube used to remove fluid from cavity.

Children: Not recommended.

Contraindications: Renal, hepatic, or bone marrow dysfunction; if need outweighs risk, may be used in low dosage with close monitoring.

Warnings/Precautions: Bone marrow suppression; monitor blood and platelets weekly during and for at least 3 weeks after therapy. Discontinue if WBC $\leq 3000/\text{mm}^3$ or platelets $\leq 150,000/\text{mm}^3$. Monitor renal and hepatic function. Use effective contraception if patient or partner is of childbearing potential. Elderly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Increased toxicity with concomitant or sequential alkylating agents (nitrogen mustards, cyclophosphamide), radiation, myelosuppressants. Prolonged apnea with succinylcholine.

Adverse reactions: Myelosuppression, fatigue, febrile or allergic reactions, inj site reactions, urinary retention, dysuria, GI disturbances, anorexia, alopecia, dizziness, headache, drowsiness, blurred vision, amenorrhea, interferes with spermatogenesis. Intravesical administration: rare: chemical or hemorrhagic cystitis.

How supplied: Contact supplier.

THYROTROPIN ALFA

R

THYROGEN Genzyme

Thyroid stimulating hormone (recombinant).

Thyrotropin alfa 1.1mg/vial; lyophilized pld for IM inj after reconstitution; contains mannitol.

Indications: Adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer. Adjunctive treatment for radioiodine ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of metastatic thyroid cancer.

Adults: ≥ 16 yrs: Give by IM inj into the buttock. 0.9mg, followed by a second 0.9mg injection 24 hours later. For radioiodine imaging or remnant ablation, give radioiodine 24 hours after the final Thyrogen injection.

Children: < 16 yrs: not established.

Warnings/Precautions: See literature. Reports of death in patients who are not thyroidectomized or with distant metastatic thyroid cancer within 24hrs after administration. Heart disease, extensive metastatic disease, or other serious underlying illnesses; increased risk of Thyrogen-induced hyperthyroidism, consider hospitalization for administration and post-administration observation. Caution patients regarding possible neurologic symptoms. Consider pretreatment with glucocorticoids in those whose tumor expansion may compromise vital anatomic structures (eg, trachea, CNS, lung metastases). Thyroglobulin (Tg) antibodies may render Tg levels uninterpretable; consider further evaluation with thyroid hormone withdrawal scan. Previous bovine TSH treatment. Residual thyroid tissue. End-stage renal disease. Elderly (increased risk of cardiac effects). Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Nausea, headache, fatigue, influenza-like symptoms; death (in non-thyroidectomized or with distant metastatic thyroid cancer), stroke and other neurologic events, sudden rapid tumor enlargement in distant metastatic thyroid cancer.

How supplied: 2-vial kit—2 vials of Thyrogen; 4-vial kit—2 vials of Thyrogen + 2 vials of diluent

TOPOTECAN

R

HYCAMTIN GlaxoSmithKline

Topoisomerase inhibitor. Topotecan (as HCl) 4mg/vial; pld for IV infusion after reconstitution and dilution; contains mannitol; preservative-free.

Indications: Metastatic carcinoma of the ovary after failure of initial or subsequent chemotherapy. Small cell lung cancer sensitive disease after failure of 1st line chemotherapy. Stage IV-B, recurrent or persistent carcinoma of the cervix in combination with cisplatin.

Adults: Confirm baseline neutrophils $>1,500\text{cells/mm}^3$ and platelets $>100,000\text{cells/mm}^3$ prior to 1st course of therapy. Give by IV infusion over 30 minutes. Ovarian cancer, small cell lung cancer: 1.5mg/m² daily for 5 consecutive days starting on Day 1 of a 21-day cycle. Cervical cancer: 0.75mg/m² on Days 1, 2, and 3; followed by cisplatin. Dose adjustments, renal impairment: see literature.

Children: Not recommended.

Also: Topotecan

HYCAMTIN CAPSULES

Topotecan (as HCl) 0.25mg, 1mg; caps.

Indications: Relapsed small cell lung cancer with prior complete or partial response and at least 45 days from the end of 1st line chemotherapy.

Adults: Confirm baseline neutrophils $>1,500\text{cells/mm}^3$ and platelets $>100,000\text{cells/mm}^3$ prior to 1st course of therapy. Swallow whole. 2.3mg/m²/day once daily for 5 consecutive days; repeat every 21 days. Dose adjustments, renal impairment: see literature.

Children: Not recommended.

Contraindications: Severe bone marrow depression. Pregnancy (Cat.D). Nursing mothers.

Warnings/Precautions: Monitor peripheral blood cell counts during therapy; hold subsequent doses until neutrophils $>1,000\text{cells/mm}^3$, platelets $>100,000\text{cells/mm}^3$, and hemoglobin $\geq 9\text{g/dL}$. History of interstitial lung disease, pulmonary fibrosis, lung cancer, thoracic exposure to radiation, use of pneumotoxic drugs and/or colony stimulating factors: increased risk of interstitial lung disease; monitor, discontinue if occurs. Moderate to severe renal impairment. Caps: severe diarrhea; may need to reduce dose. IV: avoid extravasation. Elderly.

Interactions: Myelosuppression potentiated with platinum agents. IV: Neutropenia potentiated by G-CSF. Caps: Avoid concomitant P-glycoprotein inhibitors (eg, cyclosporine A, elacridar, ketoconazole, ritonavir, saquinavir).

Adverse reactions: See literature. Neutropenia, leukopenia, thrombocytopenia, anemia, GI upset, anorexia, abdominal pain, stomatitis, headache, dyspnea, cough, pyrexia, alopecia, fatigue; infection, sepsis, interstitial lung disease, neutropenic colitis (may be fatal).

How supplied: Single-use vials-1, 5 Caps-10

TOREMIFENE

FARESTON Gtx

Nonsteroidal antiestrogen. Toremifene (as citrate) 60mg; tabs.

Indications: Metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.

Adults: 60mg once daily. Continue until disease progression is observed.

Children: Not applicable.

Warnings/Precautions: History of thromboembolic disease: not recommended. Bone

metastases; monitor for hypercalcemia during first weeks of treatment, discontinue if severe. Pre-existing endometrial hyperplasia; long-term therapy not recommended. Leukopenia, thrombocytopenia; obtain leukocyte and platelet counts. Monitor CBCs, calcium levels, liver function tests periodically. Pregnancy (Cat.D). Nursing mothers.

Interactions: Caution with drugs that decrease renal calcium excretions (eg, thiazide diuretics). Monitor anticoagulants (eg, warfarin). Potentiated by CYP3A4 inhibitors (eg, ketoconazole, erythromycin, other macrolides). Antagonized by CYP3A4 inducers (eg, phenobarbital, phenytoin, carbamazepine).

Adverse reactions: Hot flashes, sweating, GI upset, vaginal discharge, dizziness, edema, vaginal bleeding; hypercalcemia, tumor flare, endometrial hyperplasia; rare: leukopenia, thrombocytopenia.

How supplied: Tabs-30, 100

TOSITUMOMAB + IODINE I 131 R TOSITUMOMAB

BEXXAR GlaxoSmithKline

Radionuclide (B-lymphocyte-restricted differentiation antigen [CD20] inhibitor). Tositumomab 35mg/vial, 225mg/vial; soln; Iodine I¹³¹ tositumomab 0.61mCi/mL, 5.6mCi/mL soln; both for IV infusion after dilution; preservative-free.

Indications: Non-Hodgkin's lymphoma (CD20 antigen-expressing relapsed or refractory, low grade, follicular, transformed, or rituximab-refractory).

Adults: See literature. Pretreat with acetaminophen 650mg and oral diphenhydramine 50mg and thyroid blockers; continue thyroid blockers 2 weeks after therapeutic dose. Give by IV infusion. Dosimetric step: Tositumomab 450mg over 1hr, then Iodine I¹³¹ tositumomab (containing 5mCi I¹³¹ and 35mg tositumomab) over 20 minutes. Therapeutic step (7-14 days after dosimetric step if biodistribution acceptable): tositumomab 450mg over 1hr, then calculated therapeutic dose of Iodine I¹³¹ tositumomab over 20 minutes. Reduce infusion rate by 50% if infusion toxicity occurs; stop if severe; may continue at 50% rate if severe symptoms resolve.

Children: Not recommended.

Contraindications: Hypersensitivity to murine proteins. Pregnancy (Cat.X).

Warnings/Precautions: Use only by physicians trained in radionuclide therapy. Handle and dispose of properly. See literature on patient contact restrictions. Not for initial treatment. $>25\%$ lymphoma marrow involvement and/or impaired bone marrow reserve, platelet count $<100,000\text{cells/mm}^3$, neutrophil count $<1500\text{cells/mm}^3$, or intolerant to thyroid blockers: not recommended. High tumor burden. Splenomegaly. Renal impairment. Screen for human anti-mouse antibodies (increases anaphylaxis risk). Obtain CBCs and platelet counts before and for up to 12 weeks after therapy. Monitor TSH (before and annually), serum creatinine (before). Use adequate

contraception during and for 12 months after therapy. Elderly. Nursing mothers: not recommended.

Interactions: Concomitant other forms of irradiation or chemotherapy: not recommended. Caution with live viral vaccines, anticoagulants, platelet aggregation inhibitors.

Adverse reactions: Thrombocytopenia, neutropenia, anemia, headache, asthenia, fever, chills, pain, GI upset, cough, pneumonia, pleural effusion, dehydration, rash, infection, hemorrhage, hypersensitivity reactions (may be fatal), myelodysplastic syndrome, secondary malignancies, antibody formation.

Note: For technical questions call (877) 423-9927.

How supplied: Dosimetric pack (tositumomab 2 × 225mg/vial + 1 × 35mg/vial and iodine I¹³¹ tositumomab 1 × 20mL single-use vial)–1 Therapeutic pack (tositumomab 2 × 225mg/vial + 1 × 35mg/vial and iodine I¹³¹ tositumomab 1 or 2 × 20mL single-use vial)–1

TRASTUZUMAB

R

HERCEPTIN Genentech

Human epidermal growth factor receptor (HER2) inhibitor. Trastuzumab 440mg/vial; lyophilized pwd for IV infusion after reconstitution and dilution; preservative-free.

Indications: HER2-overexpressing metastatic breast cancer as a single agent in patients who have received one or more chemotherapy regimens; or in combination with paclitaxel in patients who have not received chemotherapy. Adjuvant treatment in HER2-overexpressing, node-positive or node-negative breast cancer (as a single agent following multi-modality anthracycline based therapy; in combination with doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; or in combination with docetaxel and carboplatin). HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma, in combination with cisplatin and capecitabine or 5-fluorouracil, in patients who have not received prior treatment.

Adults: Give as IV infusion. Metastatic breast cancer: Initially 4mg/kg over 90 minutes, followed by 2mg/kg over 30 minutes weekly; administer until tumor progression. Adjuvant treatment (administer trastuzumab weekly for 52 weeks); In combination therapy: with doxorubicin and cyclophosphamide, followed by either paclitaxel or docetaxel; or with docetaxel/carboplatin: initially 4mg/kg over 90 minutes, followed by 2mg/kg over 30 minutes once weekly for the 1st 12 weeks (concurrently w. paclitaxel or docetaxel) or 1st 18 weeks (concurrently w. docetaxel/carboplatin). One week after the last trastuzumab weekly dose, give trastuzumab 6mg/kg over 30–90 minutes every 3 weeks. Following multi-modality anthracycline based therapy: initially 8mg/kg over 90 minutes, then 6mg/kg over 30–90 minutes every 3 weeks. Metastatic gastric cancer:

initially 8mg/kg over 90 minutes, followed by 6mg/kg over 30–90 minutes every 3 weeks until disease progression. Infusion reactions or cardiomyopathy: see literature.

Children: Not recommended.

Warnings/Precautions: Increased risk of cardiomyopathy. Conduct cardiac assessment (eg, history, physical exam, LVEF) at baseline, every 3 months during and after therapy; repeat LVEF at 4 week intervals if dose is withheld due to significant left ventricular cardiac dysfunction. Interrupt therapy if dyspnea or significant hypotension occurs; consider discontinuing permanently if severe infusion reactions, CHF, pulmonary toxicity, or significant left ventricular myocardial dysfunction develops. Symptomatic intrinsic lung disease. Extensive tumor involvement of the lungs. Test for HER2 protein overexpression and HER2 gene amplification using FDA-approved tests for specific tumor type (breast or gastric/gastroesophageal adenocarcinoma). Elderly. Pregnancy (Cat.D); use adequate contraception during and at least 6 months after therapy. Nursing mothers: not recommended.

Interactions: Increased cardiomyopathy with anthracycline-containing chemotherapy. Increased toxicity with other myelosuppressives. Potentiated by paclitaxel.

Adverse reactions: Fever, GI upset, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, myalgia, thrombosis/embolism; severe infusion reactions, febrile neutropenia/exacerbation of chemotherapy-induced neutropenia, pulmonary toxicity (eg, interstitial pneumonitis), cardiomyopathy (eg, left ventricular myocardial dysfunction); pregnant women (2nd & 3rd trimesters): possible oligohydramnios (monitor); gastric cancer also: stomatitis, weight loss, upper respiratory tract infections, thrombocytopenia, mucosal inflammation, nasopharyngitis, dysgeusia.

Note: Enroll pregnant women with breast cancer who are using trastuzumab in the Cancer and Childbirth Registry (800) 690-6720.

Testing considerations: HER2 protein overexpression

How supplied: Vial–1 (w. diluent)

TRETINOIN

R

VESANOID Roche

Retinoid. Tretinoin 10mg; soft gelatin caps; contain parabens.

Indications: Induction of remission in patients with acute promyelocytic leukemia (APL), French-American-British (FAB) classification M3 (including the M3 variant), characterized by the presence of the t(15;17) translocation and/or the presence of the PML/RAR α gene who are refractory to, or who have relapsed from, anthracycline chemotherapy, or for whom anthracycline-based chemotherapy is contraindicated.

Adults: Use only for induction of remission.

45mg/m² per day in two divided doses until complete

remission is documented. Discontinue 30 days after complete remission or after 90 days of treatment, whichever occurs first.

Children: See literature.

Warnings/Precautions: Confirm APL diagnosis. Monitor for Retinoic Acid-APL (RA-APL) syndrome, leukocytosis, pseudotumor cerebri, or respiratory compromise. Consider temporarily interrupting therapy if moderate to severe RA-APL syndrome develops. Monitor blood counts, coagulation profile, lipids, liver function; consider temporary withdrawal if tests $>5 \times \text{ULN}$. Pregnancy (Cat.D); obtain negative pregnancy test 1 week before starting treatment, counsel patient about need to use 2 effective methods of contraception during, and 1 month after therapy. Nursing mothers: not recommended.

Interactions: Do not administer with Vitamin A. May be potentiated or antagonized by CYP450 enzyme inducers or inhibitors. Caution with antifibrinolytic agents; and other agents known to cause pseudotumor cerebri/intracranial hypertension.

Adverse reactions: Headache, fever, skin/mucous membrane dryness, bone pain, GI upset, rash, mucositis, pruritus, increased sweating, visual disturbances, alopecia; RA-APL syndrome, leukocytosis, pseudotumor cerebri, hypercholesterolemia/hypertriglyceridemia, others.

How supplied: Caps-100

TRIPTORELIN

R

TRELSTAR Actavis

GnRH analogue. Triptorelin pamoate 3.75mg, 11.25mg, 22.5mg; pwd for IM inj after reconstitution; contains mannitol.

Indications: Palliative treatment of advanced prostate cancer.

Adults: Give by IM inj in buttock. 3.75mg every 4 weeks, or 11.25mg every 12 weeks, or 22.5mg every 24 weeks.

Children: Not established.

Contraindications: Women. Pregnancy (Cat.X).

Warnings/Precautions: Must administer under physician supervision. Discontinue if hypersensitivity occurs. Initial transient increase in serum testosterone may result in worsening of symptoms. Spinal cord compression. Renal or hepatic impairment. Metastatic vertebral lesions. Upper or lower urinary tract obstruction. Increased risk of diabetes, MI, sudden cardiac death, stroke; monitor blood glucose and for signs/symptoms of CVD during therapy.

Interactions: Avoid hyperprolactinemic drugs.

Adverse reactions: Inj site reactions, hot flushes, skeletal pain, fatigue, hypertension, headache, dizziness, diarrhea, vomiting, leg edema, insomnia, impotence, emotional lability, anemia, pruritus, urinary retention, UTI, erectile dysfunction, testicular atrophy; hyperglycemia.

How supplied: Single-dose vial-1

Mixject system-1 (vial + vial adapter + prefilled syringe)

VALRUBICIN

R

VALSTAR Endo

Anthracycline. Valrubicin 40mg/mL; soln for intravesical instillation after dilution; contains 50% polyoxyl castor oil/50% dehydrated alcohol; preservative-free.

Indications: Intravesical therapy of BCG-refractory carcinoma *in situ* (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

Adults: Drain bladder before instillation. 800mg given intravesically via urethral catheter once weekly for 6 weeks. Retain drug for 2 hours before voiding, then void.

Children: Not recommended.

Contraindications: Concurrent UTI. Small bladder capacity (eg, unable to tolerate a 75mL instillation).

Warnings/Precautions: Monitor for disease recurrence or progression with cystoscopy, biopsy, and urine cytology every 3 months; if there is not a complete response of CIS to treatment after 3 months or if CIS recurs, cystectomy must be reconsidered. Severe irritable bladder symptoms. Perforated bladder. Bladder mucosa compromised. Delay administration for at least 2 weeks after transurethral resection and/or fulguration. Maintain adequate hydration. Pregnancy (Cat.C); avoid, both males and females should use effective birth control. Nursing mothers: not recommended.

Adverse reactions: Bladder symptoms (eg, urinary frequency, dysuria, urinary urgency, spasm, hematuria, pain, incontinence, cystitis, nocturia, local burning, urethral pain, pelvic pain, UTI).

How supplied: Single-use vials-4, 24

VEMURAFENIB

R

ZELBORAF Genentech

Kinase inhibitor. Vemurafenib 240mg; tabs.

Indications: Treatment of unresectable or metastatic melanoma with BRAF^{V600E} mutation as detected by an FDA-approved test.

Adults: Swallow whole with water. Take in the AM and PM (approx. 12 hours apart). $\geq 18\text{yrs}$: 960mg twice daily; until disease progression or unacceptable toxicity occurs. Dose modifications for adverse reactions or QTc prolongation: see literature. Dose reductions $<480\text{mg}$ twice daily: not recommended.

Children: $<18\text{yrs}$: not recommended.

Warnings/Precautions: Not for use in wild-type BRAF melanoma. Confirm BRAF^{V600E} mutation-positive melanoma with FDA-approved test before treating. Risk of cutaneous squamous cell carcinoma (cSCC): ≥ 65 years, prior skin cancer, chronic sun exposure; if occurs, do excision and continue without dose adjustment. Do dermatologic evaluation before therapy, every 2 months during, and consider monitoring 6 months after. Long QT syndrome or QTc $>500\text{ms}$, uncorrectable electrolyte abnormalities, or concomitant drugs that prolong the QT interval: not

recommended. Monitor electrolytes before therapy and after dose adjustments. Monitor ECG at Day 15 of treatment, monthly during the 1st 3 months, then every 3 months thereafter, or more as needed. If QTc >500ms, interrupt therapy, correct electrolytes, and control cardiac risk factors. Severe hepatic or renal impairment. Monitor liver enzymes, bilirubin before therapy and monthly, or as needed. Monitor for ophthalmologic reactions routinely. Avoid sun exposure. Pregnancy (Cat.D); avoid. Use adequate contraception during therapy and for at least 2 months after. Nursing mothers: not recommended.

Interactions: Concomitant CYP3A4, CYP1A2 or CYP2D6 substrates with narrow therapeutic indices: not recommended; if CYP1A2 or CYP2D6 substrates unavoidable, consider dose reduction of substrates. Caution with concomitant strong CYP3A4 inhibitors (eg, azole antifungals, clarithromycin) or inducers (eg, phenytoin, rifampin). May potentiate warfarin; monitor INR.

Adverse reactions: Arthralgia, rash, alopecia, fatigue, photosensitivity, nausea, pruritus, skin papilloma; cuSCC, severe hypersensitivity or dermatologic reactions (discontinue if occurs), prolonged QTc, uveitis.

How supplied: Tabs-120

VINBLASTINE

VINBLASTINE FOR INJECTION Bedford
Antimicrotubule agent. Vinblastine (as sulfate) 10mg/vial; lyophilized pld for IV inj or infusion after reconstitution.

Also: Vinblastine

VINBLASTINE INJECTION Abraxis

Vinblastine (as sulfate) 1mg/mL; soln for IV inj or infusion; contains benzyl alcohol.

Indications: Frequently responsive: palliative treatment of generalized Hodgkin's disease, lymphocytic lymphoma, histiocytic lymphoma, mycosis fungoides, advanced carcinoma of the testis, Kaposi's sarcoma, Letterer-Siwe disease. Less frequently responsive: choriocarcinoma resistant to other chemotherapy; breast cancer, unresponsive to endocrine surgery and hormonal therapy.

Adults: See literature. Give by IV once weekly.

1st dose: 3.7mg/m² as a single dose, continue to increase dose by increments (2nd dose: 5.5mg/m², 3rd dose: 7.4mg/m², 4th dose: 9.25mg/m², 5th dose: 11.1mg/m², max dose: 18.5mg/m²) until WBC 3,000cells/mm³ reached, stop at this dose, then administer a dose one increment smaller at weekly intervals for maintenance. Usual weekly dosage: 5.5-7.4mg/m². Do not give the next dose, even if 7 days have elapsed, unless WBC ≥4,000cells/mm³. If oncolytic effect occurs before leukopenia, do not increase the size of subsequent doses. Hepatic impairment: reduce dose by 50% if serum bilirubin >3mg/100mL.

Children: See literature. IV use only. Letterer-Siwe disease: initially 6.5mg/m². Hodgkin's disease:

initially 6mg/m². Testicular germ cell carcinomas: initially 3mg/m². Adjust dose according to hematologic tolerance.

Contraindications: Significant granulocytopenia (unless result of disease being treated). Bacterial infections (treat first).

Warnings/Precautions: For IV use only; fatal if given intrathecally. Hepatic impairment. Avoid in elderly with cachexia or ulcerated skin; or in patients with malignant-cell infiltration of the bone marrow. Pre-existing pulmonary dysfunction. Progressive dyspnea requiring chronic therapy (do not re-administer). Ischemic cardiac disease. Bone marrow suppression; monitor WBC before and during treatment. Avoid contamination of the eyes or injecting into an extremity with poor circulation (thrombosis possible). Avoid extravasation. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: May be potentiated by CYP3A inhibitors (eg, erythromycin). Antagonizes phenytoin.

Adverse reactions: Leukopenia, alopecia, GI upset, paresthesias, malaise, pain; dyspnea, severe bronchospasm.

How supplied: Pwd-10 Soln-1

VINCISTINE

VINCASAR PFS Teva US Generics

Antimicrotubule agent. Vincristine sulfate 1mg/mL; soln for IV inj; contains mannitol; preservative-free.

Indications: Acute leukemia. In combination with other chemotherapeutic agents for Hodgkin's disease, non-Hodgkin's malignant lymphomas (lymphocytic, mixed-cell, histiocytic, undifferentiated, nodular, diffuse types), rhabdomyosarcoma, neuroblastoma, Wilms' tumor.

Adults: Usual dose: 1.4mg/m² IV once weekly. Serum bilirubin >3mg/100mL: reduce dose by 50%.

Children: ≤10kg: initially 0.05mg/kg IV once weekly. >10kg: usual dose: 2mg/m² IV once weekly.

Contraindications: Demyelinating form of Charcot-Marie-Tooth syndrome.

Warnings/Precautions: For IV use only; fatal if given intrathecally. Hepatic dysfunction. Pre-existing neuromuscular disease. Obtain CBCs, platelets before each dose, then periodically. Monitor serum uric acid levels during first 3-4 weeks of treatment. Avoid extravasation. Pregnancy (Cat.D); avoid use. Nursing mothers: not recommended.

Interactions: Concomitant radiotherapy through ports that include the liver: not recommended. Potentiated by CYP3A4 enzyme inhibitors (eg, itraconazole). Antagonizes phenytoin. Caution with other neurotoxic or platinum-containing agents. Separate L-asparaginase dose by 12-24hrs (administer after vincristine). Consider discontinuing drugs that cause urinary retention for the first few days following therapy.

Adverse reactions: GI upset, paralytic ileus (esp. in children; discontinue temporarily if occurs), polyuria,

dysuria, urinary retention, hypertension, hypotension, neuromuscular effects, dyspnea, bronchospasm, alopecia, rash, fever, headache, hypersensitivity reactions, acute uric acid nephropathy.

How supplied: Single-use vials (1mL, 2mL)–1

VINORELBINE

R

NAVELBINE Pierre Fabre

Antimitotubule agent. Vinorelbine (as tartrate) 10mg/mL; soln for IV inj after dilution; preservative-free.

Indications: First-line treatment of ambulatory patients with unresectable, advanced non-small cell lung cancer (NSCLC), as a single agent or in combination with cisplatin. In Stage III NSCLC, use in combination with cisplatin.

Adults: See literature. Give by IV inj over 6–10 minutes. Monotherapy: 30mg/m² once weekly. Combination therapy: 25mg/m² once weekly with cisplatin given every 4 weeks; or 30mg/m² once weekly with cisplatin given on Days 1 and 29, then every 6 weeks. Dose adjustment for toxicities, hepatic impairment: see literature.

Children: Not recommended.

Contraindications: Pretreatment granulocyte counts <1000 cells/mm³.

Warnings/Precautions: IV use only; fatal if given intrathecally. Discontinue if neurotoxicity ≥grade 2. Pre-existing pulmonary dysfunction or neuropathy. Prior irradiation or chemotherapy. Cardiovascular disease. Monitor for myelosuppression, infection, and/or fever; obtain CBCs with differentials prior to each dose. Avoid contamination of the eyes or injecting into an extremity with poor circulation (thrombosis possible). Hepatic injury or impairment. Avoid extravasation. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: May be potentiated by CYP3A inhibitors. Acute pulmonary reactions possible with mitomycin. Increased risk of granulocytopenia with cisplatin. May increase risk of neurotoxicity with paclitaxel. Prior or concomitant radiation therapy; may result in radiosensitizing effects.

Adverse reactions: Myelosuppression (esp. granulocytopenia), inj site reactions, elevated liver enzymes, chest pain, fatigue, GI upset, alopecia, jaw pain, myalgia, arthralgia, rash, severe constipation, paralytic ileus, intestinal obstruction, necrosis, and/or perforation; dyspnea, severe bronchospasm.

How supplied: Single-use vial (1mL, 5mL)–1

VORINOSTAT

R

ZOLINZA Merck

Histone deacetylase inhibitor. Vorinostat 100mg; caps.

Indications: Refractory cutaneous T-cell lymphoma.

Adults: Take with food. Swallow whole. 400mg once daily. If not tolerated, may reduce to 300mg once daily, then to 300mg once daily 5 days/week if needed. Continue until disease progression or not tolerated.

Children: <18yrs: not recommended.

Warnings/Precautions: Renal or hepatic impairment. Monitor for DVT, pulmonary embolism. Correct electrolyte disturbances before starting therapy. Maintain adequate hydration. Diabetes. Monitor CBC, platelets, blood glucose, serum creatinine, electrolytes (esp. potassium, calcium, magnesium) every 2 weeks for 1st 2 months, then monthly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Increased risk of thrombocytopenia and GI bleed with other HDAC inhibitors (eg, valproic acid). Concomitant warfarin: monitor PT, INR.

Adverse reactions: GI upset, fatigue, chills; thrombocytopenia, anemia (may need to modify dose or discontinue); anorexia, dysgeusia, pulmonary embolism, DVT, hyperglycemia.

How supplied: Caps–120

ZOLEDRONIC ACID

R

ZOMETA Novartis

Bisphosphonate. Zoledronic acid 4mg/5mL concentrated soln for IV infusion after dilution; 4mg/100mL ready-to-use soln for IV infusion.

Indications: Hypercalcemia of malignancy. Adjunct in multiple myeloma and bone metastases of solid tumors.

Adults: Give by IV infusion over at least 15 minutes. Hypercalcemia of malignancy (albumin-corrected serum calcium ≥12 mg/dL): max 4mg; allow at least 7 days before retreating. Multiple myeloma or bone metastases: CrCl >60mL/min: 4 mg; CrCl 50–60mL/min: 3.5mg; CrCl 40–49mL/min: 3.3mg; CrCl 30–39mL/min: 3mg; CrCl <30mL/min: see full labeling; all: every 3–4 weeks (give oral multivitamin supplement with calcium 500mg + Vit. D 400 IU daily).

Children: Not recommended.

Warnings/Precautions: Not recommended for use in patients with bone metastases and severe renal impairment. Renal or hepatic insufficiency. Check serum creatinine before each dose: withhold until serum creatinine is within 10% of baseline if serum creatinine increases by 0.5 mg/dL from a normal pre-treatment level, or by 1 mg/dL from an abnormal pre-treatment level, within 2 weeks of next dose. Assure adequate hydration when treating hypercalcemia of malignancy. Closely monitor electrolytes (esp. calcium, magnesium, phosphate), CBC/differential, hematocrit, hemoglobin. Evaluate if thigh or groin pain develops and consider discontinuing if atypical femur fracture is suspected. Aspirin-sensitive asthma. Avoid dental surgery (do preventative dental work before therapy). Elderly. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: Avoid concomitant other bisphosphonates. Additive hypocalcemic effect with aminoglycosides, loop diuretics. Caution with other nephrotoxic drugs (eg, thalidomide).

Adverse reactions: Fever, flu-like syndrome, GI upset, constipation, anemia, dyspnea, electrolyte

disturbances, musculoskeletal pain (may be severe), hypotension, CNS effects, rigors, headache, paresthesia, renal toxicity; jaw osteonecrosis, atypical subtrochanteric and diaphyseal femoral fractures.

How supplied: Single-use vial, ready-to-use bottle-1

SECTION 15: OPHTHALMIC DISORDERS 15A Glaucoma

BIMATOPROST

LUMIGAN Allergan

Prostamide analogue. Bimatoprost 0.01%, 0.03%; oph soln; contains benzalkonium chloride.

Indications: Reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension.

Adults: ≥ 16 yrs: 1 drop once daily in the PM.

Children: < 16 yrs: not recommended.

Warnings/Precautions: Do not exceed recommended dose. Renal or hepatic impairment. Ocular inflammation. Aphakia. Pseudophakia with torn posterior lens capsule. Risk of macular edema. Contact lenses (remove; may reinsert lenses 15 minutes after administration). Pregnancy (Cat.C). Nursing mothers.

Interactions: Allow at least 5 minutes between application of other topical ophthalmic agents.

Adverse reactions: Conjunctival hyperemia, eyelash growth, ocular itching or dryness, visual disturbances, foreign body sensation, other local effects, increased ocular pigmentation (iris, eyelid, eyelashes; may be permanent), other eyelash changes, blepharitis, cataract, keratitis, photophobia, infection, headache, abnormal liver function tests, asthenia, hirsutism.

How supplied: Soln-2.5mL, 5mL, 7.5mL

BRIMONIDINE

ALPHAGAN P Allergan

α -2 agonist. Brimonidine tartrate 0.1%, 0.15%; oph. soln; contains purite.

Indications: Open-angle glaucoma. Ocular hypertension.

Adults and Children: < 2 yrs: not recommended. ≥ 2 yrs: 1 drop every 8 hours.

Contraindications: Concomitant MAOIs.

Warnings/Precautions: Severe cardiovascular disease. Hepatic or renal impairment. Depression. Cerebral or coronary insufficiency. Raynaud's phenomenon. Orthostatic hypotension. Thromboangiitis obliterans. Remove soft contact lenses before use; may reinsert 15 minutes later. Monitor for loss of effect. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: MAOIs: see Contraindications.

Caution with CNS depressants, antihypertensives,

cardiac glycosides, tricyclic antidepressants. Separate administration of other oph drugs by ≥ 5 minutes.

Adverse reactions: Oral dryness, ocular hyperemia, burning, stinging, headache, blurred or abnormal vision, foreign body sensation, fatigue, drowsiness, conjunctival follicles, ocular allergic reactions or pruritus, corneal staining/erosion, photophobia, ocular discomfort or dryness, tearing, upper respiratory symptoms, conjunctival blanching, muscular pain, others.

How supplied: Soln-5mL, 10mL, 15mL

BRINZOLAMIDE

AZOPT Alcon

Carbonic anhydrase inhibitor (sulfonamide).

Brinzolamide 1%; oph. susp; contains benzalkonium chloride.

Indications: Open-angle glaucoma. Ocular hypertension.

Adults: 1 drop 3 times daily.

Children: Not recommended.

Warnings/Precautions: Hepatic impairment. Severe renal impairment (CrCl < 30 mL/min): not recommended. Discontinue if serious systemic, ocular (eg, conjunctivitis, lid edema), or hypersensitivity reactions occur. Soft contact lenses (remove; may reinsert 15 minutes after administration). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant oral carbonic anhydrase inhibitors: not recommended. Separate administration of other oph drugs by ≥ 10 minutes.

Adverse reactions: Blurred vision, bitter/sour taste, blepharitis, dermatitis, dry eye, foreign body sensation, headache, hyperemia; ocular discharge, discomfort, or itch; keratitis, rhinitis.

How supplied: Susp-2.5mL, 5mL, 10mL, 15mL

DORZOLAMIDE

TRUSOPT Merck

Carbonic anhydrase inhibitor (sulfonamide).

Dorzolamide HCl 2%; oph soln; contains benzalkonium chloride.

Indications: Open-angle glaucoma. Ocular hypertension.

Adults and Children: 1 drop 3 times daily.

Warnings/Precautions: Hepatic impairment. Severe renal impairment (CrCl < 30 mL/min): not recommended. Discontinue if ocular effects (eg,

conjunctivitis, lid reactions) occur. Soft contact lenses. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant oral carbonic anhydrase inhibitors: not recommended. May inhibit renal excretion of basic drugs and promote excretion of acidic drugs. May increase salicylate toxicity (acidosis).

Adverse reactions: Burning, stinging, bitter taste, punctate keratitis, ocular allergic reaction, blurred vision, tearing, dryness, photophobia; possible sulfamide systemic effects.

How supplied: Soln-10mL

LATANOPROST**XALATAN** Pfizer Ophthalmics

Prostanoid. Latanoprost 0.005%; oph soln; contains benzalkonium chloride.

Indications: Open-angle glaucoma. Ocular hypertension.**Adults:** 1 drop once daily in the PM.**Children:** Not recommended.**Warnings/Precautions:** Do not exceed recommended dose (may reduce efficacy). Ocular inflammation. Aphakia. Pseudophakia with torn posterior lens capsule. Risk of macular edema. Contact lenses (remove; may reinsert lenses 15 minutes after administration). Pregnancy (Cat.C). Nursing mothers.**Interactions:** Allow at least 5 minutes between application of other topical oph agents.**Adverse reactions:** Blurred vision, burning, stinging, conjunctival hyperemia, foreign body sensation, itching, increased ocular pigmentation (eg, iris, eyelid, eyelashes; may be permanent), punctate epithelial keratopathy, other eyelash/lid changes, photophobia, upper respiratory tract infection, pain, angina, rash; intraocular inflammation, macular edema (including cystoid macular edema).**How supplied:** Soln–2.5mL

Rx

Discontinue at 1st sign of cardiac failure and before surgery. Pregnancy (Cat.C). Nursing mothers: not recommended.**Interactions:** May potentiate systemic β -blockers, reserpine, hypoglycemics and mydriatic effect of topical epinephrine. Additive cardiac and pulmonary effects with anticholinesterase miotics. May antagonize bronchodilation from β -adrenergic agonists. May cause conduction defects with calcium channel blockers, digoxin.**Adverse reactions:** Ocular irritation, sensitization, rash, dizziness, blurred vision, corneal anesthesia, headache, GI upset, paresthesias. Systemic β -blocker effects (bradycardia, arrhythmias, hypotension, bronchospasm, heart failure). Aphakic maculopathy (rare).**How supplied:** Soln–5mL, 10mL, 15mL; Ocudose–60; XE–2.5mL, 5mL**TRAVOPROST****TRAVATAN Z** Alcon

Prostaglandin analogue. Travoprost 0.004%; oph soln; contains sofZia (boric acid, propylene glycol, sorbitol, zinc chloride).

Indications: Reduction of elevated intraocular pressure in open-angle glaucoma or ocular hypertension.**Adults:** ≥ 16 yrs: 1 drop once daily in the PM.**Children:** < 16 yrs: not recommended.**Warnings/Precautions:** Do not exceed recommended dose. Active intraocular inflammation. Aphakia. Pseudophakia with torn posterior lens capsule. Risk of macular edema. Benzalkonium chloride may be absorbed by contact lenses (remove; may reinsert lenses 15 minutes after administration). Pregnancy (Cat.C). Nursing mothers.**Interactions:** Allow at least 5 minutes between application of other topical ophthalmic agents.**Adverse reactions:** Ocular hyperemia, decreased visual acuity; eye discomfort, pain or itching; foreign body sensation, other local reactions, increased ocular pigmentation (iris, eyelid, eyelashes; may be permanent), other eyelash changes, abnormal vision, blepharitis, cataract, conjunctivitis, keratitis, photophobia, allergy, angina, bradycardia, headache.**How supplied:** Soln–2.5mL, 5mL

Rx

TIMOLOL**TIMOPTIC** Aton

Noncardioselective beta-blocker. Timolol (as maleate) 0.25%, 0.5%; oph soln; contains benzalkonium chloride.

Also: Timolol**TIMOPTIC OCUDOSE**

Timolol (as maleate) 0.25%, 0.5%; (0.2mL/dose); oph soln; preservative-free.

Indications: Open-angle glaucoma.**Adults:** Initially 1 drop of 0.25% twice daily; max 1 drop of 0.5% twice daily. Transfer from other drugs, see literature.**Children:** Not recommended.**Also: Timolol****TIMOPTIC-XE**

Timolol maleate 0.25%, 0.5%; oph gel forming soln.

Adults: Invert closed bottle and shake once before each use. 1 drop once daily. Give other oph. drugs at least 10 minutes before.**Children:** Not recommended.**Contraindications:** Greater than 1st-degree AV block. Uncompensated cardiac failure. Cardiogenic shock. Sinus bradycardia. History of bronchospasm. Bronchial asthma. Severe COPD. As sole agent in narrow-angle glaucoma. All contact lenses (Timoptic-XE); soft contact lenses (Timoptic and Timoptic-XE).**Warnings/Precautions:** Poor cardiac reserve should be controlled with digitalis and diuretics. Diabetes. Presbyopia. May mask hypoglycemia or thyrotoxicosis. Myasthenia gravis. Cerebrovascular insufficiency. Measure intraocular pressure after 4 weeks of treatment. Avoid abrupt cessation.

Rx

Rx

Rx

**15B Ocular allergy/
inflammation****CYCLOSPORINE****RESTASIS** Allergan

Immunomodulator (partial)/antiinflammatory.

Cyclosporine 0.05%; oph emulsion; preservative-free

Indications: To increase tear production caused by ocular inflammation in chronic dry eye disease.**Adults:** ≥ 16 yrs: 1 drop every 12 hours.**Children:** < 16 yrs: not recommended.

Rx

Warnings/Precautions: Herpes keratitis. Contact lenses (remove; may reinsert 15 minutes after instillation). Pregnancy (Cat.C). Nursing mothers.

Interactions: Allow at least 15 minutes between dosing of artificial tears.

Adverse reactions: Ocular burning/pain/stinging, conjunctival hyperemia, discharge, foreign body sensation, pruritus, blurring.

How supplied: Single-use vials (0.4mL)–30, 60

KETOROLAC

ACULAR Allergan

NSAID. Ketorolac tromethamine 0.5%; oph soln; contains benzalkonium chloride.

Indications: Ocular itch due to seasonal allergic conjunctivitis. Post-op inflammation after cataract extraction.

Adults and Children: <3yrs: not recommended. ≥3yrs: 1 drop 4 times daily. Post-op: begin 24 hrs post-op and continue for 2 weeks.

Also: Ketorolac

ACULAR PF

Ketorolac tromethamine 0.5%; oph soln; preservative-free.

Indications: Ocular pain or photophobia after incisional refractive surgery.

Adults and Children: <3yrs: not recommended. ≥3yrs: 1 drop 4 times daily as needed for up to 3 days post-op.

Also: Ketorolac

ACULAR LS

Ketorolac tromethamine 0.4%; oph soln; contains benzalkonium chloride.

Indications: Ocular pain and burning/stinging after corneal refractive surgery.

Adults and Children: <3yrs: not recommended. ≥3yrs: 1 drop 4 times daily as needed for up to 4 days post-op.

Contraindications: Aspirin sensitivity.

Warnings/Precautions: Do not administer while wearing contacts. Bleeding tendencies. Complicated or repeat ocular surgeries. Corneal defects/denervation. Ocular surface diseases. Diabetes. Rheumatoid arthritis. May delay wound healing. Monitor cornea; discontinue if corneal epithelial breakdown occurs. Pregnancy (Cat.C): avoid in late pregnancy. Nursing mothers.

Interactions: May potentiate oral anticoagulants.

Adverse reactions: Transient stinging, burning, irritation, superficial keratitis or infections, allergic reactions, corneal edema, increased ocular bleeding (including hyphemas).

How supplied: Soln–3mL, 5mL, 10mL; PF soln (single-use)–12 × 0.4mL; LS soln–5mL

LOTEPREDNOL

LOTEMAX Valeant

Steroid. Loteprednol etabonate 0.5%; oph susp; contains benzalkonium chloride.

Indications: Steroid-responsive ocular diseases. Post-op inflammation after ocular surgery.

Adults: Steroid-responsive diseases: 1–2 drops into affected eye(s) 4 times daily. May give up to 1 drop every 1 hr within the 1st week of therapy. Post-op: 1–2 drops into operated eye(s) 4 times daily beginning 24 hrs after surgery, continue for 2 wks post-op.

Children: Not established.

Also: Loteprednol

LOTEMAX OPH OINT

Loteprednol etabonate 0.5%.

Indications: Post-op inflammation after ocular surgery.

Adults: Apply a small amount (approx. ½ inch ribbon) into the affected eye(s) 4 times daily beginning 24 hrs after surgery, continue for 2 wks post-op.

Children: Not established.

Also: Loteprednol

LOTEMAX OPH GEL

Loteprednol etabonate 0.5%; contains benzalkonium chloride.

Adults: 1–2 drops into operated eye(s) 4 times daily beginning day after surgery, continue for 2 wks post-op.

Children: Not established.

Contraindications: Ocular fungal, viral, or mycobacterial infections.

Warnings/Precautions: Reevaluate if no improvement after 2 days. Prescribe initially and renew after 14 days only after appropriate exam. Corneal or scleral thinning. Glaucoma. History of herpes simplex. Monitor IOP and for secondary infections in prolonged therapy (>10 days). Avoid abrupt cessation. Soft contact lenses (remove during therapy). Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Local reactions (eg, blurred vision, burning, itching, dry eye), photophobia, headache, rhinitis, pharyngitis. May mask or exacerbate ocular infections. Prolonged use may increase: IOP, optic nerve damage, visual acuity and field defects, cataract formation, corneal perforation. May delay healing and increase bleb formation after cataract surgery; also, Oint/Gel: anterior chamber inflammation, conjunctival hyperemia, corneal edema, eye pain.

How supplied: Susp–5mL, 10mL, 15mL, Oint–3.5g; Gel–5g

OLOPATADINE

PATANOL Alcon

Antihistamine/mast cell stabilizer. Olopatadine HCl 0.1%; oph. soln; contains benzalkonium chloride.

Indications: Treatment of signs and symptoms of allergic conjunctivitis.

Adults and Children: <3yrs: not recommended. ≥3yrs: 1 drop in affected eye(s) twice daily (6–8 hours apart).

Warnings/Precautions: Contact lenses (remove; may reinsert 10 minutes after administration, if eye is not red). Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Headache, ocular effects (eg, blurred vision, burning/stinging, dry eye, foreign body sensation, hyperemia, keratitis, lid edema, pruritus), asthenia, cold syndrome, pharyngitis, rhinitis, sinusitis, taste perversion.

How supplied: Soln—5mL

TOBRAMYCIN + DEXAMETHASONE

TOBRADEX Alcon

Aminoglycoside + steroid. Tobramycin 0.3%, dexamethasone 0.1%; oph. susp; contains benzalkonium chloride.

Indications: Ocular inflammation associated with infection or risk thereof.

Adults and Children: <2yrs: not recommended. ≥2yrs: 1–2 drops every 2hrs for 1st 24–48 hrs, then every 4–6 hrs. Reduce dose as condition improves; max 20mL for initial Rx.

Also: Dexamethasone + Tobramycin

TOBRADEX OPH OINT

Tobramycin 0.3%, dexamethasone 0.1%; contains chlorobutanol.

Adults and Children: <2yrs: not recommended. ≥2yrs: apply small amount (½ inch) in conjunctival sac up to 3–4 times daily; max 8g for initial Rx.

Contraindications: Viral, fungal, or mycobacterial infections of the eye.

Warnings/Precautions: Corneal or scleral thinning. Glaucoma. Monitor for secondary infections, intraocular pressure and cataracts in prolonged use. Monitor blood levels in combined aminoglycoside therapy. Avoid abrupt cessation. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Local effects (eg, eye pain, eyelids pruritus, eyelid edema, conjunctival hyperemia or erythema), increased intraocular pressure, glaucoma, cataracts, corneal perforations, optic nerve damage, delayed wound healing, secondary infection.

How supplied: Susp—2.5mL, 5mL, 10mL; Oint—3.5g

15C Ocular infections

CIPROFLOXACIN

CILOXAN Alcon

Quinolone. Ciprofloxacin (as HCl) 0.3%; oph. soln; contains benzalkonium chloride.

Indications: Susceptible infections of conjunctiva and cornea.

Adults and Children: <1yr: not recommended. ≥1yr: Conjunctivitis: 1–2 drops in conjunctival sac(s) every 2 hours while awake for 2 days, then 1–2 drops every 4 hours while awake for next 5 days. Corneal ulcers: 2 drops every 15 minutes for 1st 6 hours,

then 2 drops every 30 minutes for rest of 1st day; 2nd day: 2 drops every 1 hour; 3rd–14th days: 2 drops every 4 hours. May treat for 14 days or until corneal reepithelialization occurs.

Also: Ciprofloxacin

CILOXAN OPH OINT

Ciprofloxacin (as HCl) 0.3%.

Indications: Bacterial conjunctivitis.

Adults and Children: <2yrs: not recommended.

≥2yrs: ½ inch into conjunctival sac 3 times daily for 2 days, then twice daily for 5 days.

Warnings/Precautions: CNS or convulsive disorders. Discontinue if rash occurs. Pregnancy (Cat.C). Nursing mothers.

Interactions: May increase theophylline levels. May potentiate oral anticoagulants. May increase renal toxicity with cyclosporine.

Adverse reactions: Soln: Burning, crystalline precipitates, lid margin crusting, scales, foreign body sensation, pruritus, conjunctival hyperemia, bad taste. Oint: ocular discomfort, blurred vision; may delay corneal healing. Both: superinfection.

How supplied: Soln—2.5mL, 5mL, 10mL; Oint—3.5g

GATIFLOXACIN

ZYMAR Allergan

Quinolone. Gatifloxacin 0.3%; oph soln; contains benzalkonium chloride.

Indications: Susceptible infections of the conjunctiva.

Adults and Children: <1yr: not recommended.

≥1yr: 1 drop every 2 hours while awake for 2 days (up to 8 times daily), then 1 drop 4 times daily while awake for 5 more days.

Warnings/Precautions: Discontinue if superinfection or hypersensitivity occurs. Pregnancy (Cat.C). Nursing mothers.

Interactions: May potentiate theophylline, caffeine, oral anticoagulants, cyclosporine if systemic absorption occurs.

Adverse reactions: Irritation, lacrimation, keratitis, papillary conjunctivitis, chemosis, conjunctival hemorrhage, dry or red eye, headache, blurred vision, taste disturbances, superinfection, anaphylaxis.

How supplied: Soln—5mL

MOXIFLOXACIN

VIGAMOX Alcon

Quinolone. Moxifloxacin (as HCl) 0.5%; oph soln.

Indications: Susceptible infections of the conjunctiva.

Adults and Children: <1yr: not recommended.

≥1yr: 1 drop 3 times daily for 7 days.

Warnings/Precautions: Discontinue if superinfection or hypersensitivity occurs. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Blurred vision, dry eye, keratitis, ocular irritation, hyperemia, pain, pruritus,

subconjunctival hemorrhage, lacrimation, rash, superinfection.

How supplied: Soln-3mL

OFLOXACIN

R

OCUFLOX Allergan

Quinolone. Ofloxacin 0.3%; oph. soln; contains benzalkonium chloride.

Indications: Susceptible infections of the conjunctiva and corneal ulcer.

Adults and Children: <1yr: not recommended.

≥1yr: Conjunctivitis: 1-2 drops every 2-4 hrs for 2 days, then 4 times daily for 5 more days. Corneal ulcer: 1-2 drops every 30 minutes while awake and at 4 hrs & 6 hrs after retiring for sleep for 2 days, then 1-2 drops every 1 hr while awake for days 3 through 7-9, then 1-2 drops 4 times daily through treatment completion.

Warnings/Precautions: Discontinue if superinfection or hypersensitivity occurs. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Possible potentiation of theophylline, caffeine, oral anticoagulants, cyclosporine if systemic absorption occurs.

Adverse reactions: Superinfection, photophobia, lacrimation, transient local reactions including burning, stinging, redness, itching, dry eye; anaphylaxis, Stevens-Johnson syndrome (rare).

How supplied: Soln-5mL

TOBRAMYCIN

R

TOBREX Alcon

Aminoglycoside. Tobramycin 0.3%; oph. soln; contains benzalkonium chloride.

Also: Tobramycin

TOBREX OPH OINT

Tobramycin 0.3%; contains chlorobutanol.

Indications: Susceptible infections of conjunctiva and cornea.

Adults and Children: Severe infections: initially 2 drops every hr or ½ inch of ointment every 3-4 hrs; then may prolong dosing interval. Mild to moderate infections: 1-2 drops every 4 hrs or ½ inch of ointment 2-3 times daily.

Warnings/Precautions: Remove contact lenses before using. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Concomitant systemic aminoglycosides: monitor levels.

Adverse reactions: Superinfection, itching, swelling, erythema, sensitivity (discontinue if occurs); oint: may retard corneal healing.

How supplied: Soln-5mL; Oint-3.5g

HYPERSENSITIVITY to a drug or its class is assumed to be a contraindication in all product monographs, although not explicitly stated.

SECTION 16:

OTIC DISORDERS

16A Ear infections (topicals)

CIPROFLOXACIN + DEXAMETHASONE

R

CIPRODEX OTIC Alcon

Antibiotic (quinolone) + steroid. Ciprofloxacin (as HCl) 0.3%, dexamethasone 0.1%; otic susp.

Indications: Acute otitis media in pediatric patients with tympanostomy tubes. Acute otitis externa.

Adults and Children: <6 months: not recommended. ≥6 months: 4 drops in affected ear(s) twice daily for 7 days.

Contraindications: Viral otic infections (eg, herpes simplex).

Warnings/Precautions: Discontinue if superinfection or hypersensitivity occurs. Reevaluate if no improvement after 1 week. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Ear discomfort/pain, pruritus, debris, dysgeusia, erythema.

How supplied: Susp-7.5mL

CIPROFLOXACIN + HYDROCORTISONE

R

CIPRO HC OTIC Alcon

Antibiotic (quinolone) + steroid. Ciprofloxacin (as HCl) 0.2%, hydrocortisone 1%; otic susp.

Indications: Acute otitis externa.

Adults and Children: To minimize dizziness, warm susp by holding bottle in hand for 1-2 minutes before use. <1yr: not recommended. ≥1yr: 3 drops in affected ear(s) twice daily for 7 days.

Contraindications: Perforated tympanic membrane. Viral otic infections (eg, varicella, herpes simplex).

Warnings/Precautions: Discontinue if hypersensitivity reaction occurs. Reevaluate if no improvement after 1 week. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Headache, pruritus.

How supplied: Susp-10mL (w. dropper)

OFLOXACIN

R

FLOXIN OTIC Daiichi Sankyo

Antibiotic (quinolone). Ofloxacin 0.3%; otic soln.

Indications: Otitis externa in adults and children. Chronic suppurative otitis media in adults with perforated tympanic membrane. Acute otitis media in children with tympanostomy tubes.

Adults and Children: <6months: not recommended. Otitis externa: 6months-13yrs: 5 drops in affected ear(s) once daily. ≥13yrs: 10 drops in affected ear(s) once daily. Both: treat for 7 days.

Acute otitis media: 1–12yrs: 5 drops in affected ear(s) twice daily for 10 days. Chronic suppurative otitis media: ≥ 12 yrs: 10 drops in affected ear(s) twice daily for 14 days.

Warnings/Precautions: Discontinue if hypersensitivity reaction occurs. Reevaluate if no improvement after 1 week. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Pruritus, taste perversion, local reactions, dizziness, earache, headache, vertigo, superinfection, paresthesia, rash.

How supplied: Soln–5mL, 10mL (dropper bottles); Singles 0.25mL (5 drops/container)–20

SECTION 17: PAIN MANAGEMENT 17A Anesthetics

PANCURONIUM

PANCURONIUM BROMIDE INJECTION (various) $\mathcal{R}$

Neuromuscular blocker (nondepolarizing).
Pancuronium bromide 1mg/mL, 2mg/mL; soln for IV inj; contains benzyl alcohol.

Indications: Adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Adults and Children: Individualize. Adjunct to anesthesia: Initially 0.04 to 0.1mg/kg, then may use incremental doses starting at 0.01mg/kg. Relaxation for intubation: inject bolus dose of 0.06 to 0.1mg/kg. Neonates: give test dose 1st of 0.02mg/kg. Monitor with a peripheral nerve stimulator to avoid overdose.

Warnings/Precautions: To be administered under the supervision of experienced clinicians. Have intubation, artificial respiration, oxygen therapy and reversal agents available. Myasthenia gravis or myasthenic (Eaton-Lambert) syndrome (do test dose and monitor). Pre-existing pulmonary disease. Renal disease or failure. Hepatic and/or biliary tract disease. Cardiovascular disease and edematous state. Long-term use in I.C.U. Immobilized for long periods. Severe obesity or neuromuscular disease; monitor airway and ventilation. Electrolyte imbalance. Adrenal cortical insufficiency. Neonates. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Prior administration of succinylcholine may potentiate effects (delay dose or give pancuronium 1st). Potentiated by volatile inhalational anesthetics (eg, enflurane, isoflurane, halothane), aminoglycosides, tetracyclines, bacitracin, polymyxin B, colistin, sodium colistimethate, magnesium salts. Significant additive effects with pancuronium bromide-metocurine and pancuronium bromide-d-tubocurarine combinations than with the individual drugs given alone. Potential severe ventricular arrhythmias in concomitant with tricyclics and halothane. Caution with quinidine injection.

Adverse reactions: Skeletal muscle weakness or prolonged paralysis, circulatory effects, salivation, transient rash; rare: hypersensitivity reactions.

How supplied: Contact supplier.

PHENYLEPHRINE

PHENYLEPHRINE HCl INJECTION (various) $\mathcal{R}$

Sympathomimetic. Phenylephrine HCl 10mg/mL; soln for IV, IM, or SC inj; contains sulfites.

Indications: Prolongation of spinal anesthesia. Vasoconstrictor in regional analgesia.

Adults: Prolongation of spinal anesthesia: add 2–5mg into anesthetic solution. Vasoconstrictor for regional analgesia: add 1mg to every 20mL (1:20,000) of local anesthetic solution.

Children: Not recommended.

Contraindications: Severe hypertension. Ventricular tachycardia.

Warnings/Precautions: Cardiovascular disease. Hypertension. Thyroid disease. Asthma. Sulfite sensitivity. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers.

Interactions: Potentiated by oxytocic drugs, tricyclic antidepressants, or MAOIs. Caution with halothane anesthesia.

Adverse reactions: Headache, reflex bradycardia, excitability, restlessness; rare: arrhythmias.

How supplied: Vial 10mg/mL (1mL, 5mL)–25

PROPOFOL

DIPRIVAN APP $\mathcal{R}$

Sedative-hypnotic. Propofol 10mg/mL; emulsion for IV inj or infusion; contains egg lecithin, soy.

Indications: Induction and maintenance of monitored anesthesia care (MAC) sedation; combined sedation and regional anesthesia; and ICU sedation of intubated, mechanically ventilated adult patients. Induction of general anesthesia in patients ≥ 3 years of age. Maintenance of general anesthesia in patients ≥ 2 months of age.

Adults: See literature. Individualize. Allow 3–5 minutes between dose adjustments. General anesthesia induction (<55yrs): 40mg every 10 seconds until induction onset. Elderly, debilitated, ASA-PS III or IV, cardiac anesthesia, neurosurgery: 20mg every 10 seconds until induction onset. General anesthesia maintenance as infusion (<55yrs and neurosurgery): initially 100–200microgram/kg/min for 10–15 minutes, reduce to 50–100microgram/kg/min. Elderly, debilitated, ASA-PS III or IV: 50–100microgram/kg/min. Cardiac anesthesia: As the primary agent: 100–150microgram/kg/min; with primary opioid: 50–100microgram/kg/min. General anesthesia maintenance as intermittent bolus (<55yrs): increments of 20–50mg as needed. Initiation of MAC sedation: give by slow infusion of 100–150microgram/kg/min for 3–5 minutes or slow injection of 0.5mg/kg over 3–5 minutes followed immediately by maintenance infusion.

Maintenance of MAC sedation (<55yrs): infuse 25–75microgram/kg/min (preferred) or give incremental boluses of 10mg or 20mg; elderly, debilitated, ASA-PS III or IV, neurosurgical patients: reduce dose by 20%. ICU sedation: initially infuse 5 microgram/kg/min for at least 5 minutes; increase in increments of 5–10microgram/kg/min over 5–10minutes until clinical effect is achieved. Maintenance: 5–50microgram/kg/min or higher; continue until 10–15 minutes prior to extubation. May give 10mg or 20mg bolus to rapidly increase depth of sedation in patients not at risk of hypotension.

Children: Individualize. General anesthesia induction (3–16yrs): 2.5–3.5mg/kg given over 20–30 seconds. General anesthesia maintenance (2mos–16yrs): 125–300microgram/kg/min, decrease infusion rate if signs of light anesthesia are not present following the first ½ hour.

Contraindications: Egg or soy product allergy.

Warnings/Precautions: Should be administered only by persons trained in the administration of general anesthesia. Keep resuscitative equipment, artificial ventilation and oxygen readily available; maintain patency of the airway at all times. Initiate drug holiday and supplement lost zinc if infused for >5 days (esp. patients with burns, diarrhea, major sepsis). Hyperlipoproteinemia. Diabetic hyperlipemia. Pancreatitis. Seizure disorder. Increased intracranial pressure. Impaired cerebral circulation. Cardiac depression. Hemodynamically unstable. Correct fluid deficits before administration. Monitor cardiorespiratory status, renal function, triglycerides, serum zinc. Avoid abrupt cessation. American Society of Anesthesiologists Physical Status (ASA-PS) III or IV, elderly debilitated: avoid rapid bolus administration. Labor & delivery, nursing mothers: not recommended. Pregnancy (Cat.B).

Interactions: Potentiation with volatile inhalational anesthetics (eg, enflurane, isoflurane, halothane), parental narcotics (eg, morphine, meperidine, fentanyl) or combinations of opioids and sedatives (eg, benzodiazepines, barbiturates, chloral hydrate, droperidol), other CNS depressants; reduce dose. Children: concomitant fentanyl may cause serious bradycardia.

Adverse reactions: Hypotension, bradycardia, inj site pain, apnea, propofol infusion syndrome with high-dose infusions (>5mg/kg/h for >48hrs); rare: anaphylaxis, phlebitis, thrombosis, perioperative myoclonia. Children: also movement, hypertension, rash, pruritis, tachycardia nodal, arrhythmia.

How supplied: Ready-to use vial (20mL, 50mL, 100mL)–1

ROCURONIUM BROMIDE

ZEMURON Merck

Neuromuscular blocker (nondepolarizing). Rocuronium bromide 10mg/mL; soln for IV inj.

Indications: Adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal

muscle relaxation during surgery or mechanical ventilation.

Adults: See literature. Individualize. Tracheal intubation: initially 0.45–0.6mg/kg; or may give bolus dose of 0.9–1.2mg/kg. All given under opioid/nitrous oxide/oxygen anesthesia. Rapid sequence intubation (premedicate and anesthetize adequately): 0.6–1.2mg/kg. Maintenance dose: 0.1mg, 0.15mg, or 0.2mg/kg given at 25% recovery of T_1 (3 twitches in train-of-four). Continuous infusion: initiate at rate of 10–12micrograms/kg/min only after spontaneous recovery from intubating dose; may need additional bolus doses to maintain adequate block. Monitor with a peripheral nerve stimulator for drug response, dose adjustments, evaluate recovery and to avoid overdosage.

Children: See literature. Individualize. Initial intubation or sevoflurane induction: 0.45–0.6mg/kg. Halothane induction: 0.6mg/kg. General anesthesia: sevoflurane induction and isoflurane/nitrous oxide (maintenance): bolus dose of 0.15mg/kg; halothane (maintenance): (3months to adolescence): 0.075–0.125mg/kg upon return of T_1 to 0.25% to provide relaxation for 7 to 10 minutes; Or, continuous infusion: initiate at rate of 12micrograms/kg/min upon return of T_1 to 10% (1 twitch in train-of-four). Monitor with a peripheral nerve stimulator for twitch response.

Warnings/Precautions: To be administered under the supervision of experienced clinicians. Have intubation, artificial respiration, oxygen therapy and reversal agents available. Must be accompanied by adequate anesthesia or sedation. To prevent residual paralysis, should extubate only after neuromuscular block recovery. Long-term use in I.C.U. Immobilized for long periods. Malignant hyperthermia; confirm and treat prior to starting anesthesia. Cardiovascular disease or advanced age (possible delay in onset time). Neuromuscular disease, carcinomatosis, cachectic, or debilitated patients; reduce initial dose. Cerebral palsy (resistance may occur). Severe acid-base and/or electrolyte abnormalities. Pulmonary hypertension or valvular heart disease. Myasthenia gravis or myasthenic (Eaton-Lambert) syndrome (do test dose and monitor). Renal or significant hepatic impairment. Discontinue if extravasation occurs; restart in another vein. Elderly. Children (rapid sequence intubation: not recommended). Labor & delivery (rapid sequence intubation in Cesarean section: not recommended). Pregnancy (Cat.C).

Interactions: Potentiated by inhalation anesthetics (eg, enflurane, isoflurane, halothane), antibiotics (eg, aminoglycosides, vancomycin, tetracyclines, bacitracin, polymyxins, colistin, sodium colistimethate), lithium, magnesium salts, local anesthetics, procainamide, quinidine (caution). Antagonized by anticonvulsants (eg, carbamazepine, phenytoin). Prolonged QTc interval with general anesthetics in children. Caution with other nondepolarizing muscle relaxants or succinylcholine

(give rocuronium only after succinylcholine recovery). Myopathy with concomitant corticosteroids.

Adverse reactions: Transient hypotension, hypertension, arrhythmia, abnormal ECG, tachycardia, nausea, vomiting, asthma, hiccup, rash, inj site edema, pruritus, anaphylaxis, residual paralysis, myopathy, increased pulmonary vascular resistance.

How supplied: Multi-dose vials (5mL, 10mL)–10

SUCCINYLCHOLINE

R

QUELICIN Hospira

Skeletal muscle relaxant (depolarizing).

Succinylcholine chloride 20mg/mL, 100mg/mL; soln for IM or IV inj.

Indications: Adjunct to general anesthesia to facilitate tracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Adults: Individualize. Patients homozygous for atypical plasma cholinesterase gene: give test dose of 5–10mg (1mg/mL solution) by slow IV infusion. Short surgical (tracheal intubation): usual dose: 0.6mg/kg IV; range: 0.3–1.1mg/kg IV. Long surgical: (1–2mg/mL solution) by continuous infusion given at a rate of 2.5–4.3mg/min; alternatively by intermittent IV inj: initially 0.3–1.1mg/kg, followed by 0.04–0.07mg/kg. If suitable vein is inaccessible, may give by IM inj: up to 3–4mg/kg, max 150mg total dose.

Children: See literature. Emergency tracheal intubation: infants and small children: 2mg/kg IV; older pediatric patients and adolescents: 1mg/kg IV. If suitable vein is inaccessible, may give by IM inj: up to 3–4mg/kg, max 150mg total dose.

Contraindications: History of malignant hyperthermia or skeletal muscle myopathies. Acute phase of injury following major burns, multiple trauma, extensive denervation of skeletal muscle, or upper motor neuron injury.

Warnings/Precautions: To be administered only by those skilled in management of artificial respiration. Have intubation, adequate ventilation, oxygen therapy available. Should not be administered prior to induction of unconsciousness (unless emergency). Pretreatment with anticholinergic agents (eg, atropine) may reduce occurrence of bradyarrhythmias. Caution in patients with reduced plasma cholinesterase activity in presence of gene abnormalities (eg, heterozygous or homozygous for atypical plasma cholinesterase gene), pregnancy, severe hepatic or renal disease, malignant tumors, infections, burns, anemia, heart disease, peptic ulcer, myxedema, or drugs affecting cholinesterase activity (see Interactions). Electrolyte abnormalities, digitalis toxicity, acute phase of injury (see Contraindications), chronic abdominal infection, subarachnoid hemorrhage, or conditions causing degeneration of central and peripheral nervous systems: increased risk of hyperkalemia. Hypokalemia or hypocalcemia (neuromuscular blockade may be prolonged). Monitor for possible transition into Phase II block (see literature). Glaucoma or eye injury. Bone

fractures or muscle spasm. Children with skeletal muscle myopathy. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers.

Interactions: Potentiated by promazine, oxytocin, aprotinin, certain non-penicillin antibiotics, quinidine, β -adrenergic blockers, procainamide, lidocaine, trimethaphan, lithium carbonate, magnesium salts, quinine, chloroquine, diethyl ether, isoflurane, desflurane, metoclopramide, terbutaline, chronically administered oral contraceptives, glucocorticoids, certain MAOIs, organophosphates, ecothiophate, and certain antineoplastic. Antagonized by anticholinergics.

Adverse reactions: Respiratory depression or apnea (may be prolonged), cardiac arrest, malignant hyperthermia, arrhythmias, bradycardia, tachycardia, hyper- or hypotension, hyperkalemia, increased intraocular pressure, increased intragastric pressure, muscle fasciculation, jaw rigidity, post-op muscle pain, rhabdomyolysis with possible myoglobinuric acute renal failure, excessive salivation, rash, hypersensitivity reactions; children: acute rhabdomyolysis with hyperkalemia, ventricular dysrhythmias and cardiac arrest (rare).

How supplied: Single-dose vial 20mg/mL (5mL)–1 (preservative-free)

Single-dose syringe 100mg/mL (10mL)–1 (preservative-free)

Multi-dose vial 20mg/mL (10mL)–1

VECURONIUM

R

VECURONIUM BROMIDE FOR INJECTION (various)

Neuromuscular blocker (nondepolarizing).

Vecuronium bromide 10mg/10mL; pwd for IV inj after reconstitution; contains benzyl alcohol, mannitol.

Indications: Adjunct to general anesthesia to facilitate endotracheal intubation, and to provide skeletal muscle relaxation during surgery or mechanical ventilation.

Adults and Children: <7wks: not recommended.

Individualize. >7wks–10yrs: see literature.

≥10yrs: Relaxation for intubation: inject bolus dose of 0.08–0.1mg/kg; may reduce dose to 0.06–0.085mg/kg if given >5 minutes after start of inhalation agent or when steady state has been achieved. Give 1microgram/kg/min (range: 0.8–1.2microgram/kg/min) by continuous IV infusion 20–40 minutes after initial dose. Inhalation anesthetics (eg, enflurane, isoflurane): reduce infusion rate 25–60%, 45–60 minutes after initial dose. Intubation with succinylcholine: reduce initial vecuronium dose to 0.04–0.06mg/kg with inhalation anesthesia; and to 0.05–0.06mg/kg with balanced anesthesia. Prolonged surgery: maintenance dose of 0.01–0.015mg/kg, within 25–40 minutes of initial dose. During surgery under halothane anesthesia: initial dosing range from 0.15mg/kg up to 0.28mg/kg have been given. Monitor with a peripheral nerve stimulator to avoid overdosage.

Warnings/Precautions: To be administered under the supervision of experienced clinicians.

Have intubation, artificial respiration, oxygen therapy and reversal agents available. Myasthenia gravis or myasthenic (Eaton-Lambert) syndrome (do test dose and monitor). Renal failure. Hepatic impairment. Cardiovascular disease and edematous state. Long-term use in I.C.U. Immobilized for long periods. Severe obesity or neuromuscular disease; monitor airway and ventilation. Electrolyte imbalance. Adrenal cortical insufficiency. Malignant hyperthermia. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Prior administration of succinylcholine may potentiate effects (delay vecuronium dose). Potentiated by volatile inhalational anesthetics (eg, enflurane, isoflurane, halothane), aminoglycosides, tetracyclines, bacitracin, polymyxin B, colistin, sodium colistimethate, magnesium salts. Additive effects with pancuronium, d-tubocurarine, metocurine, and gallamine. Caution with quinidine injection.

Adverse reactions: Skeletal muscle weakness or prolonged paralysis, muscle atrophy, respiration insufficiency, apnea; rare: hypersensitivity reactions.

How supplied: Contact supplier.

17B Fibromyalgia

DULOXETINE

R

CYMBALTA Lilly

Serotonin and norepinephrine reuptake inhibitor.

Duloxetine (as HCl) 20mg, 30mg, 60mg; e-c pellets in caps.

Indications: Fibromyalgia.

Adults: Swallow whole. Initially 30mg once daily for 1 week, then increase to 60mg once daily.

Children: Not recommended.

Contraindications: Allow at least 14 days after MAOI discontinuance before starting duloxetine; allow at least 5 days after duloxetine discontinuance before starting an MAOI. Concomitant linezolid or IV methylene blue. Uncontrolled narrow-angle glaucoma.

Warnings/Precautions: Suicidal tendencies (monitor). Severe renal impairment (CrCl<30mL/min), end stage renal disease, hepatic insufficiency, evidence of chronic liver disease, or substantial alcohol use: not recommended. History of seizure or mania/hypomania. Controlled narrow-angle glaucoma. Decreased GI motility. Cardiac disease. Monitor BP prior to and during therapy. Diabetes. Avoid abrupt cessation. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; consider tapering, see literature for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant thioridazine (may cause arrhythmias): not recommended. Potentiated by CYP1A2 inhibitors; avoid (eg, cimetidine, fluvoxamine, quinolones). May potentiate or be potentiated by CYP2D6 inhibitors (eg, paroxetine, fluoxetine, quinidine) or substrates (eg, tricyclics, phenothiazines, type 1C antiarrhythmics) or

other highly protein-bound drugs; caution with CYP2D6 substrates with narrow therapeutic indexes. Caution with potent CYP1A2 inhibitors, antihypertensives, other drugs that induce orthostatic hypotension. Caution with triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort; may cause serotonin syndrome. Monitor concomitant CNS-acting drugs, and with those that affect gastric pH (eg, proton pump inhibitors). Increased bleeding risk with aspirin, anticoagulants, NSAIDs.

Adverse reactions: Nausea, dry mouth, constipation, somnolence, hyperhidrosis, decreased appetite, weight changes, GI disturbances, fatigue, dizziness, increased sweating, mania/hypomania, tremor, blurred vision, insomnia, hot flushes, urinary hesitation/retention, abnormal ejaculation, genital disorders, decreased libido, increased BP, orthostatic hypotension, syncope, hepatotoxicity (eg, elevated liver transaminases, cholestatic jaundice); discontinue if occurs, hyponatremia, asthenia, others; rare: seizure.

How supplied: Caps 20mg-60; 30mg-30, 90, 1000; 60mg-30, 1000

MILNACIPRAN

R

SAVELLA Forest and Cypress

Serotonin and norepinephrine reuptake inhibitor

(SNRI). Milnacipran HCl 12.5mg, 25mg, 50mg, 100mg; tabs.

Indications: Fibromyalgia.

Adults: May take with food. Titrate dose. Day 1: 12.5mg once. Days 2-3: 12.5mg twice daily. Days 4-7: 25mg twice daily. After Day 7: 50mg twice daily (recommended dose); max 100mg twice daily. Severe renal impairment (CrCl 5-29mL/min): maintenance 25mg twice daily; max 50mg twice daily. Withdraw gradually.

Children: <17yrs: not recommended.

Contraindications: Allow at least 14 days after MAOI discontinuance before starting milnacipran; allow at least 5 days after discontinuing milnacipran before starting an MAOI. Uncontrolled narrow-angle glaucoma.

Warnings/Precautions: Suicidal ideation (monitor). Substantial alcohol abuse, chronic liver disease, end stage renal disease: not recommended. Hypertension. Heart disease. Arrhythmias. Monitor BP and heart rate; reduce dose or discontinue if elevated BP persists. Controlled narrow-angle glaucoma. Seizure disorder. Mania. Severe hepatic dysfunction. Discontinue if liver dysfunction develops. Volume depleted. GU obstruction. Risk of bleeding. Reevaluate periodically. Write Rx for smallest practical amount. Pregnancy (Cat.C; see full labeling for effects on fetus). Nursing mothers.

Interactions: See Contraindications. Concomitant serotonin precursors (eg, tryptophan), serotonergics (eg, triptans, tramadol): not recommended. Avoid IV digoxin (postural hypotension, tachycardia). May potentiate anticoagulants (eg, aspirin, NSAIDs, coumadin). May antagonize certain antihypertensives (eg, clonidine). Serotonin syndrome with SSRIs, SNRIs, lithium,

tramadol, triptans (monitor). Caution with other CNS-active drugs or those that can increase BP. Arrhythmias, hypertension with epinephrine, norepinephrine.

Adverse reactions: Nausea, headache, constipation, dizziness, insomnia, hot flush, hyperhidrosis, palpitations, increased heart rate, dry mouth, hypertension; rare: GI effects in men; hyponatremia (esp. in elderly); serotonin syndrome; seizure.

How supplied: Tabs-60; Titration Pack (4 week supply)-1

PREGABALIN

LYRICA Pfizer

alpha2-delta ligand. Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg; caps.

Also: Pregabalin

LYRICA ORAL SOLUTION

Pregabalin 20mg/mL

Indications: Fibromyalgia.

Adults: ≥18yrs: initially 75mg twice daily, may increase to 150mg twice daily within 1 week as tolerated; max 450mg/day. Renal impairment (CrCl <60mL/min): reduce dose (see literature); hemodialysis: give supplemental dose after session.

Children: <18yrs: not recommended.

Warnings/Precautions: Avoid abrupt cessation (taper over ≥1 week). Discontinue if angioedema, hypersensitivity reactions, myopathy or markedly elevated creatine kinase levels occur. CHF. Ocular conditions. Diabetes (monitor skin integrity). Suicidal tendencies (monitor). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Additive edema, weight gain with thiazolidinediones.

Adverse reactions: Dizziness, somnolence, other CNS effects, dry mouth, edema, ocular/visual effects (eg, blurring), weight gain, thinking abnormal (primarily difficulty with concentration/attention), infection, asthenia, paresthesias, elevated creatine kinase, decreased platelets, arrhythmias (PR prolongation); male-mediated teratogenicity; may be tumorigenic.

How supplied: Caps-90; Soln-16oz

CV

CV

Indications: Tension (or muscle contraction) headache.

Adults: 1-2 tabs or caps every 4 hours as needed; max 6/day.

Children: Not recommended.

Contraindications: Porphyria. Also with Codeine: post-op pain management in children who have undergone tonsillectomy and/or adenoidectomy.

Warnings/Precautions: Hepatotoxicity (acetaminophen >4g/day). Drug abusers. Impaired hepatic or renal function (monitor). Acute abdomen. Depression. Suicidal tendencies. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended. Also with Codeine: risk of respiratory depression and death related to ultra-rapid metabolizers of codeine (esp. in children in post-op tonsillectomy and/or adenoidectomy). Obstructive sleep apnea. Head injury. Increased intracranial pressure. Impaired thyroid or adrenocortical function. GI or GU obstruction. Addison's disease. Labor and delivery.

Interactions: Potentiation with alcohol, general anesthetics, MAOIs, tranquilizers, or other CNS depressants. Induction of drug-metabolizing hepatic enzymes. Acetaminophen may cause false (+) urine test for 5-hydroxyindoleacetic acid.

Adverse reactions: Drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, abdominal pain, intoxicated feeling, depression, confusion, paradoxical excitement, abuse potential, skin reactions; overdose: respiratory depression, hepatotoxicity.

How supplied: Tabs-100, 500; Caps-100

BUTALBITAL + ASPIRIN + CAFFEINE

CIII

FIORINAL Actavis

Barbiturate + salicylate. Butalbital 50mg, aspirin 325mg, caffeine 40mg; tabs; caps.

Also: Codeine + Butalbital + Aspirin + Caffeine

FIORINAL w. CODEINE

Opioid + barbiturate + salicylate.

Codeine phosphate 30mg, butalbital 50mg, aspirin 325mg, caffeine 40mg; caps.

Indications: Tension (or muscle contraction) headache.

Adults: 1-2 tabs or caps every 4 hours, as needed; max 6/day.

Children: Not recommended.

Contraindications: Aspirin or NSAID allergy. Porphyria. Hemorrhagic diathesis. Peptic ulcer or other serious GI lesions. Also with Codeine: post-op pain management in children who have undergone tonsillectomy and/or adenoidectomy.

Warnings/Precautions: Drug abusers. Impaired hepatic or renal function (monitor). Depression. Suicidal tendencies. Asthma. Bleeding disorders. Underlying hemostatic defects. Varicella or influenza in children or teenagers. Elderly. Debilitated. Labor

R

CIII

17C Migraine and headache

BUTALBITAL + ACETAMINOPHEN + CAFFEINE

FIORICET Actavis

Barbiturate + analgesic. Butalbital 50mg, acetaminophen 300mg, caffeine 40mg; tabs.

Also: Butalbital + Acetaminophen + Caffeine + Codeine

FIORICET w. CODEINE

Opioid + barbiturate + analgesic.

Codeine phosphate 30mg, butalbital 50mg, acetaminophen 300mg, caffeine 40mg; caps.

& delivery. Pregnancy (Cat.C). Nursing mothers: not recommended. Also with Codeine: risk of respiratory depression and death related to ultra-rapid metabolizers of codeine (esp. in children in post-op tonsillectomy and/or adenoidectomy). Obstructive sleep apnea. Head injury. Increased intracranial pressure. Acute abdomen. Impaired thyroid or adrenocortical function. Addison's disease. GI or GU obstruction.

Interactions: Potentiation with alcohol, general anesthetics, tranquilizers, other CNS depressants, anticoagulants, hypoglycemics, insulin, plasma protein bound drugs, MAOIs, tricyclic antidepressants, anticholinergics. Concomitant NSAIDs increase risk of GI bleeding. May antagonize uricosurics, oral anticoagulants, antibiotics, corticosteroids. Induction of drug-metabolizing hepatic enzymes. Increased levels of 6-mercaptopurine, methotrexate.

Adverse reactions: Drowsiness, dizziness, sedation, intoxicated feeling, nausea, vomiting, difficulty swallowing, heartburn, abdominal pain, depression, prolonged bleeding time, paradoxical excitement, constipation, abuse potential, skin reactions, anaphylaxis; overdosage: respiratory depression, salicylism.

How supplied: Caps-100, 500; W. Codeine-100

DIHYDROERGOTAMINE

R

D.H.E. 45 Valeant

Ergot alkaloid. Dihydroergotamine mesylate 1mg/mL; for IM, IV, or SC inj.

Indications: Acute treatment of migraine headache or cluster headache episodes.

Adults: 1mL IV at 1 hour intervals; max 2 doses/day. Or, 1mL IM or SC at 1-hour intervals; max 3 doses/day. For all: max 6 doses/week. Do not use chronically.

Children: Not recommended.

Contraindications: Ischemic heart disease. Coronary artery vasospasm (eg, Prinzmetal's angina) or myocardial ischemia. Peripheral artery disease. Sepsis. Post-vascular surgery. Uncontrolled hypertension. Other significant cardiovascular disease. Severely impaired hepatic or renal function. Basilar or hemiplegic migraine. Concomitant potent CYP3A4 inhibitors (eg, ritonavir, nelfinavir, indinavir, erythromycin, clarithromycin, troleandomycin, ketoconazole, itraconazole) or other vasoconstrictors. Within 24 hours of sumatriptan, zolmitriptan, other 5-HT₁ agonists, or ergot-type drugs. Pregnancy (Cat.X). Nursing mothers.

Warnings/Precautions: Confirm diagnosis. Exclude underlying cardiovascular disease, supervise 1st dose, and consider monitoring ECG in patients with likelihood of unrecognized coronary disease (eg, postmenopausal women, men over age 40, hypercholesterolemia, hypertension, obesity, diabetes, smokers, strong family history). Monitor cardiovascular function in long-term intermittent use. Compromised circulation. Elderly.

Interactions: See Contraindications. Potentiated by CYP3A4 inhibitors (eg, protease inhibitors, macrolides, azole antifungals, saquinavir, nefazodone, fluoxetine, fluvoxamine, grapefruit juice, zileuton), propranolol, nicotine.

Adverse reactions: Numbness, pain, weakness of extremities, epigastric distress, tachycardia or bradycardia, nausea, vomiting, localized edema and itching, cardiac or cerebrovascular events; myocardial and peripheral vascular ischemia or vasoconstriction (ergotism; discontinue if occurs); rare: fibrotic complication.

How supplied: Amps (1 mL)-10

DIVALPROEX

R

DEPAKOTE AbbVie

Divalproex sodium 125mg, 250mg, 500mg; delayed-release tabs.

Indications: Prophylaxis of migraine headaches.

Adults: ≥16yrs: initially 250mg twice daily; usual max 1g/day.

Children: <16yrs: not recommended.

Also: Divalproex

R

DEPAKOTE ER

Divalproex sodium 250mg, 500mg; ext-rel tabs.

Adults: Swallow whole. 500mg once daily for 1 week, then 1g once daily.

Children: Use other forms.

Contraindications: Hepatic disease. Significant hepatic dysfunction. Urea cycle disorders.

Warnings/Precautions: Discontinue if hepatic dysfunction, pancreatitis, thrombocytopenia, or hyperammonemic encephalopathy occurs. History of liver disease. Increased hepatotoxicity risk with congenital metabolic disorders, multiple AEDs, severe seizure disorders with mental retardation, organic brain disorders, in children <2 years of age. Monitor liver function and symptoms (esp. 1st 6 months). Follow-up if symptoms of hyperammonemia occur. Suicidal tendencies (monitor). Depakote ER is not bioequivalent to delayed-release tabs on mg/mg basis. Avoid abrupt cessation. Monitor platelets, bleeding time (at baseline, before surgery, and in pregnancy); reevaluate periodically. May affect HIV or CMV viral load (*in vitro*). Elderly (monitor fluid and nutritional intake, and for somnolence). Pregnancy (Cat.D): apprise females of childbearing potential of risks to fetus (eg, neural tube defects). Nursing mothers: not recommended.

Interactions: Monitor levels of valproate, ethosuximide, other anticonvulsants, and whenever an enzyme inducer is added or withdrawn. Potentiates carbamazepine, diazepam, ethosuximide, lamotrigine, phenobarbital, phenytoin, tolbutamide, warfarin, zidovudine, amitriptyline, nortriptyline. Potentiated by aspirin, felbamate. Levels reduced by rifampin, phenytoin, carbamazepine, phenobarbital, carbapenem antibiotics. CNS depression with alcohol, other CNS depressants. Clonazepam may induce absence status in patients with history of absence

seizures. May interfere with urine ketone and thyroid tests. Others: see literature.

Adverse reactions: GI upset, asthenia, somnolence, dizziness, abdominal pain, tremor, weight gain, back pain, alopecia, hepatotoxicity, acute pancreatitis, thrombocytopenia, clotting abnormalities, hyperammonemia, others.

How supplied: Tabs 125mg–100; Tabs 250mg, 500mg–100, 500; ER 250mg–60; ER 250mg, 500mg–100, 500

PROPRANOLOL

INDERAL Akrimax
beta-blocker. Propranolol HCl 10mg, 20mg, 40mg, 60mg, 80mg; scored tabs.

Indications: Migraine prophylaxis.

Adults: Initially 80mg daily in divided doses. Usual range: 160–240mg daily. Discontinue if poor result after 4–6 weeks.

Children: Not recommended.

Also: Propranolol

INDERAL LA
Propranolol HCl 60mg, 80mg, 120mg, 160mg; sust-rel caps.

Adults: Initially 80mg daily. Usual range: 160–240mg daily. Discontinue if poor result after 4–6 weeks.

Children: Not recommended.

Contraindications: Asthma. Sinus bradycardia. 2nd or 3rd-degree AV block. Overt heart failure. Cardiogenic shock.

Warnings/Precautions: CHF. Wolff-Parkinson-White syndrome. Renal or hepatic dysfunction. Bronchospastic disease, COPD. Diabetes. Hyperthyroidism. Surgery. SLE. Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiated by alcohol, CNS depressants, other antihypertensives, antithyroid drugs, haloperidol, chlorpromazine, cimetidine. Bradycardia with catecholamine-depleting drugs. Antagonized by NSAIDs, barbiturates, rifampin, phenytoin. May increase cardiac effects of calcium channel blockers, digitalis, lidocaine. Potentiates theophylline, antipyrine, lidocaine. May block epinephrine. May interfere with glaucoma screening tests.

Adverse reactions: Heart failure, hypotension, bronchospasm, bradycardia, heart block, fatigue, dizziness, depression, GI upset, skin reactions (eg, rash, Stevens-Johnson syndrome, urticaria), pharyngitis, agranulocytosis.

How supplied: Tabs 60mg–100; 10mg, 20mg, 40mg, 80mg–100, 5000; LA–100

RIZATRIPTAN

MAXALT Merck
Selective 5-HT_{1B/1D} receptor agonist. Rizatriptan (as benzoate) 5mg, 10mg; tabs.

Also: Rizatriptan

MAXALT-MLT
Rizatriptan (as benzoate) 5mg, 10mg; orally-disintegrating tabs; peppermint flavor; contains phenylalanine.

Indications: Acute treatment of migraine.

Adults: ≥18yrs: Initially 5 or 10mg; may repeat after 2 hrs; max 30mg/day. Concomitant propranolol: use 5mg dose; max 3 doses/day. The safety of treating, on average, more than 4 headaches in a 30-day period has not been established.

Children: <18yrs: not recommended.

Contraindications: Ischemic heart disease (eg, angina pectoris, history of MI, documented silent ischemia). Coronary artery vasospasm (eg, Prinzmetal's angina). Uncontrolled hypertension.

Other significant cardiovascular disease. Basilar or hemiplegic migraine. Within 24 hours of other 5-HT₁ agonists or ergot-type drugs. During or within 2 weeks after discontinuing MAOIs.

Warnings/Precautions: Confirm diagnosis. Reevaluate if angina or ischemia symptoms (eg, ischemic bowel syndrome) occur, or if no response after 1st dose. Exclude underlying cardiovascular disease, supervise 1st dose, and consider monitoring ECG in patients with likelihood of unrecognized coronary disease (eg, post-menopausal women, men over age 40, hypertension, hypercholesterolemia, obesity, diabetes, smokers, strong family history).

Monitor cardiovascular function in long-term intermittent use. Peripheral vascular or colonic ischemia following other 5-HT₁ agonists. Hepatic dysfunction. Dialysis. Pregnancy (Cat.C). Nursing mothers.

Interactions: MAOIs, methysergide, other ergotamines, or other 5-HT₁ agonists: see Contraindications. Caution with SSRIs. Exposure increased by propranolol.

Adverse reactions: Asthenia, somnolence, dizziness, paresthesia, chest/jaw/throat pressure or other pain, dry mouth, nausea, headache; serious cardiac events (rare).

How supplied: Both–18

SUMATRIPTAN

IMITREX INJECTION GlaxoSmithKline
Selective 5-HT_{1B/1D} receptor agonist. Sumatriptan (as succinate) 4mg/0.5mL, 6mg/0.5mL; for SC inj.

Indications: Acute treatment of migraine or cluster headaches.

Adults: ≥18yrs: 6mg SC (may start at lower dose if 6mg not tolerated). Reevaluate if no response. May repeat after 1 hour; max two 6mg doses in 24 hours.

Children: <18yrs: not recommended.

Also: Sumatriptan

IMITREX TABLETS
Sumatriptan (as succinate) 25mg, 50mg, 100mg.

Indications: Acute treatment of migraine.

Adults: ≥18yrs: 25–100mg once, swallow whole with fluids as soon as possible after migraine onset; may repeat dose at intervals of at least 2hrs, max 200mg/day; or single-dose tablets up to 100mg/day if injection has been used. Hepatic dysfunction: max 50mg/dose. The safety of treating an average of more than 4 headaches in a 30-day period has not been established.

Children: <18yrs: not recommended.

Also: Sumatriptan**IMITREX NASAL SPRAY**

Sumatriptan 5mg, 20mg; per spray.

Adults: ≥ 18 yrs: 5mg, 10mg, or 20mg once. Reevaluate if no response. May repeat once after 2hrs; max 40mg/day. The safety of treating an average of more than 4 headaches in a 30-day period has not been established.

Children: < 18 yrs: not recommended.

Contraindications: Do not give intravenously. History, symptoms, or signs of ischemic cardiac (eg, MI, angina pectoris, silent myocardial ischemia), cerebrovascular (eg, stroke, TIA), or peripheral vascular (eg, ischemic bowel disease) syndromes. Vasospastic coronary artery disease. Uncontrolled hypertension. Basilar or hemiplegic migraine. Severe hepatic impairment. Within 24 hours of ergot-type drugs (eg, methysergide, dihydroergotamine), or other 5-HT₁ agonists. During or within 2 weeks after discontinuing MAO-A inhibitors (MAOI type A).

Warnings/Precautions: Confirm diagnosis. Avoid excessive use. Exclude underlying cardiovascular disease, supervise 1st dose, and consider monitoring ECG in patients with likelihood of unrecognized coronary artery disease (eg, postmenopausal women, hypercholesterolemia, men over age 40, hypertension, obesity, diabetes, smokers, strong family history). Monitor cardiovascular function in long-term intermittent use. Instruct patient on use of autoinjector. Peripheral vascular or colonic ischemia following other 5-HT₁ agonists. Hepatic or renal dysfunction. Seizure risk. Elderly: not recommended. Pregnancy (Cat.C). Nursing mothers (avoid nursing for 12 hours after treatment).

Interactions: Ergotamines, other 5-HT₁ agonists, MAOIs: see Contraindications. Serotonin syndrome with SSRIs (eg, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline) or SNRIs (eg, duloxetine, venlafaxine).

Adverse reactions: Tingling, hot sensation, flushing; chest/neck/sinus/jaw discomfort; dizziness, muscle pain/weakness, fatigue, drowsiness, anxiety, sweating, local reactions, seizures, colonic ischemia, drug overuse headache (discontinue if occurs); rare: serious cardiac and cerebrovascular events (including fatalities), vision loss. Nasal spray: also dysgeusia.

Note: Register pregnant patients exposed to sumatriptan by calling (800) 336-2176.

How supplied: Inj kit (2 prefilled cartridges + 1 Pen)-1; Refills (2 prefilled cartridges)-1; Single-dose vials (6mg/0.5mL)-5; Tabs-9; Nasal spray (single dose)-6

TOPIRAMATE

TOPAMAX TABLETS Janssen

Sulfamate. Topiramate 25mg, 50mg, 100mg, 200mg.

Also: Topiramate**TOPAMAX SPRINKLE CAPS**

Topiramate 15mg, 25mg; coated beads in caps.

Indications: Migraine prophylaxis.

Adults: May swallow caps whole or sprinkle contents onto soft food (swallow immediately). Titrate in 1-week intervals. Initially 25mg once daily in the PM, then 25mg twice daily, then 25mg in the AM and 50mg in the PM, then 50mg twice daily. Renal impairment (CrCl < 70 mL/min): reduce dose by $\frac{1}{2}$. Hemodialysis: may need extra dose.

Children: Not recommended.

Warnings/Precautions: Discontinue if acute myopia and secondary angle-closure glaucoma occur. Hepatic or renal impairment. Kidney stones. Maintain adequate hydration and caloric intake; avoid ketogenic diets. Monitor serum bicarbonate during therapy; consider reducing dose or discontinuing if acidosis occurs. Inborn errors of metabolism, reduced mitochondrial activity: increased risk of hyperammonemia; measure ammonia levels if encephalopathic symptoms occur. Monitor closely for oligohydrosis and hyperthermia (esp. children). Suicidal tendencies (monitor). Avoid abrupt cessation. Fetal toxicity. Labor & delivery. Pregnancy (Cat.D). Nursing mothers.

Interactions: Contraindicated with metformin during metabolic acidosis condition. Avoid concomitant other carbonic anhydrase inhibitors (eg, zonisamide, acetazolamide, dichlorphenamide). Phenytoin, carbamazepine, valproic acid, lamotrigine reduce topiramate levels. Topiramate reduces valproic acid levels. May increase phenytoin levels. May antagonize digoxin, oral contraceptives, risperidone. CNS depression potentiated with alcohol, other CNS depressants. Hyperammonemia (w/and w/o encephalopathy) and/or hypothermia possible with valproic acid. Caution with other drugs that interfere with temperature regulation (eg, anticholinergics, carbonic anhydrase inhibitors). Monitor lithium levels with high-dose topiramate.

Adverse reactions: Paresthesia, anorexia, weight decrease, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, difficulty with memory, difficulty with concentration/attention, cognitive problems, confusion, mood problems, fever, infection, flushing; kidney stones, hyperchloremic acidosis, hyperammonemia.

How supplied: Tabs, caps-60

17D Narcotic analgesics**BUPRENORPHINE**

CIII

BUTRANS Purdue Pharma L.P.

Opioid analgesic. Buprenorphine 5mcg/hr, 10mcg/hr, 20mcg/hr; transdermal patch.

Indications: Moderate to severe chronic pain when continuous opioid analgesia is needed for extended time period. Not for use: as an as-needed (prn) analgesic; for mild or acute pain; or post-op pain unless previously on chronic opioid therapy, or if pain expected to be persistent.

Adults: ≥ 18 yrs: Apply one patch to clean, dry, hairless, intact skin on upper outer arm, upper chest, upper back, or side of chest every 7 days. Cleanse application site with water only. Do not cut patch. Rotate sites (allow ≥ 21 days before reapplication to same site). Individualize. Opioid-naïve, or oral morphine < 30 mg/day or equivalent: one 5 mcg/hr patch. Converting from oral morphine equivalents 30–80 mg/day: Taper current opioids for up to 7 days to ≤ 30 mg/day oral morphine equivalents before starting, then initiate with Butrans 10 mcg/hr patch; may use short-acting analgesics until Butrans efficacy is attained. Conversion from higher opioid doses: not recommended; see literature. Increase dose only after patient is exposed to previous dose for at least 72 hrs. Max one 20 mcg/hr patch per week. Severe hepatic impairment: use alternative therapy. Monitor use. Reevaluate periodically. Withdraw gradually.

Children: < 18 yrs: not recommended.

Contraindications: Significant respiratory depression. Acute or severe bronchial asthma. Paralytic ileus.

Warnings/Precautions: Pulmonary disease (eg, COPD, cor pulmonale); monitor for respiratory depression (esp. within the first 24–72 hrs of initiating therapy and after dose increases). CNS depression. Long QT syndrome or history thereof: avoid; doses > 20 microgram/hr increase risk of QT prolongation. Unstable cardiac disease. Unstable atrial fibrillation. Unstable CHF. Active MI. Bradycardia. Hypokalemia. Hypovolemia. Head injury. Increased intracranial pressure. Impaired consciousness or coma; avoid. Fever. Seizure disorders. Biliary tract disease. GI obstruction. Acute pancreatitis. Abuse potential (monitor). Monitor liver function in susceptible patients (eg, alcohol or substance abuse, liver disease). Avoid external heat (eg, thermal wraps, sunlamps); risk of overdose. Dispose properly. Elderly. Cachectic. Debilitated. Accidental exposure (esp. children). Labor and delivery, pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Avoid concomitant Class 1A (eg, quinidine, procainamide, disopyramide) or Class III antiarrhythmics (eg, sotalol, amiodarone, dofetilide). Potentiation with alcohol. CNS and respiratory depressants (eg, benzodiazepines, muscle relaxants, sedatives, hypnotics, general anesthetics, antiemetics, other tranquilizers, phenothiazines). Caution with CYP3A4 inhibitors. Monitor with CYP3A4 inducers (eg, phenobarbital, carbamazepine, phenytoin, rifampin). Increased risk of urinary retention and/or severe constipation with anticholinergics; monitor.

Adverse reactions: CNS and respiratory depression, hypotension, GI upset, headache, application site reactions (eg, pruritus, erythema, rash), dizziness, constipation, somnolence, peripheral edema, dry mouth.

How supplied: Patch-4 (w. disposal units)

CODEINE + ACETAMINOPHEN CIII

TYLENOL w. CODEINE #3 Janssen
Opioid + analgesic. Codeine phosphate 30mg, acetaminophen 300mg; tabs; contains sulfites.

Also: Codeine + Acetaminophen CIII
TYLENOL w. CODEINE #4

Codeine phosphate 60mg, acetaminophen 300mg; tabs; contains sulfites.

Indications: Mild to moderately severe pain.

Adults: #3: 1–2 tabs every 4 hours. #4: 1 tab every 4 hours.

Children: Not recommended.

Contraindications: Post-op pain management in children who have undergone tonsillectomy and/or adenoidectomy.

Warnings/Precautions: Risk of respiratory depression and death related to ultra-rapid metabolizers of codeine (esp. in children in post-op tonsillectomy and/or adenoidectomy). Hepatotoxicity (w. acetaminophen > 4 g/day). Obstructive sleep apnea. Head injury. Increased intracranial pressure. Acute abdomen. Impaired renal, hepatic, thyroid, or adrenocortical function. GI or GU obstruction. Addison's disease. Asthma. Drug abusers. Sulfite sensitivity. Elderly. Debilitated. Labor and delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiation with alcohol, general anesthetics, tranquilizers (eg, chlorthalidopexide, sedative-hypnotics), other CNS depressants, MAOIs, tricyclic antidepressants, anticholinergics.

Adverse reactions: Drowsiness, lightheadedness, dizziness, sedation, shortness of breath, nausea, vomiting, constipation, urinary retention, rash; overdose: respiratory depression, hepatotoxicity.

How supplied: #3–100, 1000; #4–100, 500

FENTANYL CII

ABSTRAL ProStrakan

Opioid. Fentanyl 100mcg, 200mcg, 300mcg, 400mcg, 600mcg, 800mcg; sublingual tablets.

Indications: Breakthrough pain, in opioid-tolerant patients already receiving and who are tolerant to continuous opioid therapy for underlying persistent cancer pain. Opioid-tolerant patients are those taking: Oral morphine ≥ 60 mg/day, oxycodone ≥ 30 mg/day, hydromorphone ≥ 8 mg/day, oxymorphone ≥ 25 mg/day, or equianalgesic dose of another opioid for ≥ 1 week; or transdermal fentanyl ≥ 25 mcg/hr.

Adults: ≥ 18 yrs: Do not chew, suck, swallow tablets. Allow tablets to dissolve in sublingual cavity. Do not eat or drink until tablet completely dissolves. Individualize. Initially one 100mcg dose; if adequate analgesia is obtained within 30min, continue to treat subsequent episodes with this dose. If inadequate, give 2nd dose (after 30min). For future episodes, if analgesia is not obtained with 100mcg dose, titrate in increments of 100mcg up to 400mcg as needed; if 400mcg dose is inadequate, titrate to 600mcg dose, then 800mcg dose if needed. May use 100mcg or

200mcg tablets for any single dose; max 4 tabs at one time. Max 2 doses/episode, up to 4 episodes/day. Wait at least 2hrs before treating another episode. Maintenance: use only one tablet of appropriate strength. Do not convert from other fentanyl products on a mcg per mcg basis or interchange with other fentanyl products. Rescue medication may be used.

Children: <18yrs: not recommended.

Contraindications: Not for opioid non-tolerant patients. Acute or post-op pain (including headache/migraine, dental pain, or ER).

Warnings/Precautions: Respiratory disorders or depression. Head injury. Increased intracranial pressure. Bradycardia. Impaired pulmonary, cardio, renal, or hepatic function. Elderly. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Not recommended within 14 days of MAOIs. Potentiates CNS depression with alcohol, other CNS depressants (eg, phenothiazines, skeletal muscle relaxants, antihistamines, hypnotics).

Potentiated by CYP3A4 inhibitors (eg, macrolides, azole antifungals, aprepitant, protease inhibitors, nefazodone, verapamil, diltiazem). Antagonized by CYP3A4 inducers (eg, barbiturates, efavirenz, modafinil, nevirapine, anticonvulsants, pioglitazone, troglitazone, rifabutin, rifampin, St John's wort).

Adverse reactions: Nausea, somnolence, headache, constipation; respiratory/circulatory depression.

Note: Available by restricted distribution program. Call (888) 227-8725 to enroll. Properly handle and dispose; may be fatal to children.

How supplied: Sublingual tabs-32

FENTANYL

CII

ACTIQ Teva CNS

Opioid. Fentanyl (as citrate) 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, 1600mcg; units for oral transmucosal administration; raspberry-flavored.

Indications: Breakthrough cancer pain in patients who are receiving and are tolerant to opioids (opioid tolerance is defined as taking at least 60mg of morphine/day, transdermal fentanyl 25micrograms/hour, or equianalgesic dose of another opioid for at least one week).

Adults: ≥16yrs: Place unit between cheek and lower gum, occasionally switching sides. Suck (do not chew) over 15 minutes; if excessive opioid effects occur, remove unit and reduce next dose. Initially one 200mcg unit. Titrate, evaluating dose over several episodes of pain, until a single unit provides adequate analgesia. If re-dosing for one pain episode is needed, start second unit 15 minutes after first unit is finished; max 2 units/episode. Wait 4 hours before treating another episode. Prescribe 6 units during titration. After a successful dose is determined: max 4 units/day. Discontinue gradually.

Children: <16yrs: not recommended. May be fatal to children.

Contraindications: Acute or post-op pain. Non-opioid tolerant patients.

Warnings/Precautions: Be fully familiar with opioid analgesia. Not interchangeable with any other fentanyl product on a microgram per microgram basis. COPD. Predisposition to hypoventilation. Head injury. Increased intracranial pressure. Bradycardia. Biliary colic. Impaired consciousness. Cardiac, renal, or hepatic disease. Elderly. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: During or within 14 days of MAOIs: not recommended. Avoid grapefruit or grapefruit juice. Additive CNS depression with alcohol, other CNS depressants, inhibitors of CYP3A4 (eg, azole antifungals, macrolides, certain protease inhibitors). May be antagonized by drugs that induce CYP3A4. Caution with respiratory depressants.

Adverse reactions: Nausea, somnolence, dizziness, asthenia, respiratory and/or circulatory depression, hypotension, shock.

How supplied: Units-30

FENTANYL

CII

DURAGESIC Janssen

Opioid. Fentanyl 12mcg/hour, 25mcg/hour, 50mcg/hour, 75mcg/hour, 100mcg/hour; transdermal system.

Indications: Moderate-to-severe chronic pain that requires continuous, around-the-clock opioid analgesia for an extended period of time and cannot be managed by lesser means (eg, NSAIDs, opioid combination products, or immediate-release opioids). For use in opioid-tolerant patients only.

Adults: Apply to clean, dry, intact, non-irradiated skin; hold in place for 30 seconds. May be worn for 72 hours. Conversion from other opiates: see literature.

Children: Apply to clean, dry, intact, non-irradiated area on upper back; hold in place for 30 seconds; monitor adhesion; may be worn for 72 hours. <2yrs: not recommended. ≥2yrs: base initial dose on previous daily oral morphine dose: see full labeling.

Contraindications: Opioid non-tolerant patients. Acute or post-op pain, or mild or intermittent pain that can be managed by lesser means. Significant respiratory depression. Acute or severe bronchial asthma. Paralytic ileus.

Warnings/Precautions: Abuse potential. Respiratory depression; monitor closely when initiating therapy (esp. first 24-72 hours) and after dose increases. Accidental exposure or ingestion may cause fatal overdose (esp. in children). Chronic pulmonary disease. Head injuries. Increased intracranial pressure. Brain tumors. Fever. Avoid external heat sources. Bradycardia. Hepatic or renal impairment. Biliary tract disease. Acute pancreatitis. Drug abusers. Clinicians should be fully experienced in use of continuous opioid analgesia. If adverse reactions occur, monitor for at least 24 hours after patch is removed. Avoid abrupt cessation. Monitor use in children. Elderly. Cachectic. Debilitated.

Pregnancy (Cat.C). Labor and delivery, nursing mothers: not recommended.

Interactions: During or within 14 days of MAOIs: not recommended. Potentiated by alcohol, other CNS depressants (eg, sedatives, hypnotics, tranquilizers, phenothiazines): significantly reduce dose for one or both drugs. Potentiated by CYP3A4 inhibitors (eg, erythromycin, ketoconazole, ritonavir, itraconazole, troleandomycin, clarithromycin, nelfinavir, nefazodone, amiodarone, amprenavir, aprepitant, diltiazem, fluconazole, fosamprenavir, verapamil, grapefruit juice); monitor, may need to adjust dose. Antagonized by CYP3A4 inducers (eg, rifampin).

Adverse reactions: Hypoventilation, hypo- or hypertension, GI upset, somnolence, asthenia, sweating, apnea, dyspnea, dry mouth, headache, chest pain, arrhythmias, CNS depression or disturbances, urinary retention, pruritus, local reactions. Children: also fever, insomnia.

How supplied: Patch-5

FENTANYL

CII

FENTORA Teva CNS

Opioid analgesic. Fentanyl (as citrate) 100mcg, 200mcg, 400mcg, 600mcg, 800mcg; buccal tabs.

Indications: Management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. Opioid-tolerant patients are those taking oral morphine ≥ 60 mg/day, transdermal fentanyl ≥ 25 mcg/hr, oxycodone ≥ 30 mg/day, oral hydromorphone ≥ 8 mg/day, or equivalent, for ≥ 1 week.

Adults: Place tablet in buccal cavity (above a rear molar, between upper cheek and gum). Do not swallow whole, split, suck, or chew. Individualize; not interchangeable on a mcg/mcg basis with other oral fentanyl products. Initially 100mcg/dose; if pain unrelieved, may repeat in 30minutes, then must wait at least 4hrs before treating another episode. Previously on oral fentanyl: see literature. Reevaluate maintenance pain therapy if > 4 doses/24hrs is needed.

Children: <18yrs: not recommended.

Contraindications: Not for opioid intolerant patients. Not for treating acute or post-operative pain. During or within 14 days of MAOIs.

Warnings/Precautions: Respiratory depression. $>$ Grade 1 mucositis. Head injury. CNS depression. Increased intracranial pressure. Impaired cardiovascular (eg, bradyarrhythmias), pulmonary, hepatic, renal, thyroid function. Avoid abrupt cessation. Reevaluate periodically. Elderly. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: See Contraindications. Potentiates CNS depression with benzodiazepines, barbiturates, alcohol, other CNS depressants, other psychoactive substances. Potentiated by CYP3A4 inhibitors (eg, erythromycin, clarithromycin, fluconazole, ketoconazole, itraconazole, troleandomycin, ritonavir,

nelfinavir, amprenavir, fosamprenavir, aprepitant, nefazodone, verapamil, diltiazem, grapefruit juice); monitor for extended period of time. Antagonized by CYP3A4 inducers.

Adverse reactions: GI upset, constipation, local reactions, fatigue, anemia, dizziness, peripheral edema, dehydration, headache.

Note: For use only by clinicians trained to use CII opioids for cancer pain. Caution patients and caregivers in proper handling and disposal; may be fatal to children.

How supplied: Tabs-28 (4 tabs $\times$ 7 cards)

FENTANYL

CII

ONSOLIS Meda

Opioid. Fentanyl (as citrate) 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg; buccal soluble film.

Indications: Breakthrough pain, only in opioid-tolerant patients who are already receiving and are tolerant to continuous (not "as needed") opioid therapy for underlying persistent cancer pain. Opioid-tolerant patients are those taking oral morphine ≥ 60 mg/day, transdermal fentanyl ≥ 25 mcg/hr, oral oxycodone ≥ 30 mg/day, oral hydromorphone ≥ 8 mg/day, oral oxycodone ≥ 30 mg/day, or equianalgesic dose of another opioid for ≥ 1 week.

Adults: ≥ 18 yrs: Do not cut film. Place on moistened area inside cheek; wait at least 5min before drinking liquids, do not manipulate film or eat until film has dissolved. Titrate with 200mcg film(s) then switch to one film at the titrated dose. Initially 200mcg; titrate in 200mcg increments, up to max 4×200 mcg films or one 1200mcg film. Max one dose/episode; no more than 4 doses/day at least 2hrs apart. If titrating above 4×200 mcg films, switch to one 1200mcg film; max 1200mcg/dose. Do not convert from other fentanyl products on a mcg-mcg basis. Do not interchange with other fentanyl products. Do not put one film on top of another. May use another rescue drug 30min after film placement if needed.

Children: <18yrs: not recommended.

Contraindications: Not for opioid non-tolerant patients. Acute or post-op pain (including headache/migraine, dental pain, or ER).

Warnings/Precautions: Respiratory disorders or depression. Head injury. Increased intracranial pressure. Bradycardia. Impaired pulmonary, cardiovascular, renal, or hepatic function. Store and dispose of properly. Elderly. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Not recommended within 14 days of MAOIs. Potentiates CNS depression with alcohol, other CNS depressants (eg, phenothiazines, skeletal muscle relaxants, antihistamines, hypnotics). Potentiated by CYP3A4 inhibitors (eg, macrolides, azole antifungals, aprepitant, protease inhibitors, nefazodone, verapamil, diltiazem). Antagonized by CYP3A4 inducers (eg, barbiturates, efavirenz,

modafinil, nevirapine, anticonvulsants, pioglitazone, troglitazone, rifabutin, rifampin, St John's wort).

Adverse reactions: GI upset, dizziness, dehydration, dyspnea, somnolence; respiratory or circulatory depression, hypotension, shock, drowsiness, anticholinergic effects, others.

Note: Available by restricted distribution program. Call (877) 4ONSOLIS or visit www.OnsolisFocus.com to enroll. Caution patients and caregivers in proper handling and disposal; may be fatal to children.

How supplied: Films–30

HYDROCODONE + ACETAMINOPHEN

CIII

VICODIN AbbVie

Opioid + analgesic. Hydrocodone bitartrate 5mg, acetaminophen 300mg; scored tabs.

Indications: Moderate to moderately severe pain.

Adults: 1–2 tabs every 4–6 hrs as needed; max 8 tabs/24 hrs.

Children: Not established.

Also: Hydrocodone + Acetaminophen

CIII

VICODIN ES

Hydrocodone bitartrate 7.5mg, acetaminophen 300mg; scored tabs.

Also: Hydrocodone + Acetaminophen

CIII

VICODIN HP

Hydrocodone bitartrate 10mg, acetaminophen 300mg; scored tabs.

Adults: 1 tab every 4–6 hrs as needed; max 6 tabs/24 hrs.

Children: Not established.

Warnings/Precautions: Risk of hepatotoxicity may result with acetaminophen doses >4g per day or involving more than one acetaminophen-containing product. Head injury. Increased intracranial pressure. Acute abdomen. Impaired renal, hepatic, thyroid, pulmonary, or adrenocortical function. GI or GU obstruction. Asthma. Post-op. Drug abusers. Elderly. Debilitated. Labor and delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiation with alcohol, CNS depressants, MAOIs, tricyclic antidepressants, anticholinergics.

Adverse reactions: CNS/respiratory depression, lightheadedness, GI upset, constipation, urinary retention, rash; hypersensitivity/anaphylaxis, hepatotoxicity (overdosage).

How supplied: Tabs–100, 500

HYDROCODONE + IBUPROFEN

CIII

VICOPROFEN AbbVie

Opioid + NSAID. Hydrocodone bitartrate 7.5mg, ibuprofen 200mg; tabs.

Indications: Short-term (generally <10 days) management of acute pain.

Adults: ≥16yrs: 1 tab every 4–6 hours as needed; max 5 tabs/day.

Children: <16yrs: not recommended.

Contraindications: Aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. Head injury. Increased intracranial pressure. Acute abdomen. Active peptic ulcer. History of upper GI disease. Impaired renal, hepatic, thyroid, pulmonary, or adrenocortical function. GI or GU obstruction. Asthma. Edema. Hypertension. Heart failure. Bleeding disorders. Diabetes. Monitor blood, hepatic, renal, and visual function. Dehydration. Post-op (may suppress cough reflex). Drug abusers. Discontinue if visual or liver dysfunction occurs. Elderly. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Avoid aspirin. Alcohol, other CNS depressants potentiated. May potentiate, or be potentiated by, MAOIs or tricyclic antidepressants. Increases serum lithium levels. May increase bleeding with anticoagulants. Paralytic ileus may occur with anticholinergics. May increase toxicity of methotrexate. May reduce efficacy of, and increase risk of renal failure with, ACE inhibitors, diuretics.

Adverse reactions: Headache, somnolence, constipation, dizziness, GI upset/bleed, rash (discontinue if occurs), respiratory depression, anemia, mood changes, confusion, anaphylaxis; aseptic meningitis (rare); others. See literature re: risk of cardiovascular events.

How supplied: Tabs–100, 500

HYDROMORPHONE

CII

DILAUDID Purdue Pharma LP.

Opioid. Hydromorphone HCl 2mg, 4mg, 8mg; tabs; contains sulfites.

Indications: Management of pain where an opioid analgesic is appropriate.

Adults: Individualize. Initially 2–4mg every 4–6 hours as needed; use 8mg tab only when clinically appropriate. Elderly, renal or hepatic impairment: use lower starting dose.

Children: Not recommended.

Also: Hydromorphone

CII

DILAUDID ORAL LIQUID

Hydromorphone HCl 5mg/5mL; contains sulfites.

Adults: Individualize. 2.5–10mg every 3–6 hours as needed.

Children: Not recommended.

Contraindications: Respiratory depression in the absence of resuscitative equipment. Asthma. Obstetrical analgesia.

Warnings/Precautions: COPD. Cor pulmonale. Head injury. Increased intracranial pressure. Acute abdomen. GI surgery. Impaired renal, hepatic, thyroid, pulmonary, or adrenocortical function. GI or GU obstruction. Gallbladder disease. Biliary tract disease or surgery. Acute pancreatitis. Convulsive disorders. Toxic psychosis. Delirium tremens. Kyphoscoliosis. Circulatory shock. Drug abusers. Elderly. Debilitated. Neonate withdrawal syndrome in physically dependent

mothers. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiation with alcohol, CNS depressants, tricyclics, phenothiazines. May be antagonized by mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol, buprenorphine). May potentiate neuromuscular blocking agents.

Adverse reactions: Sedation, GI upset, constipation, urinary retention, respiratory depression, orthostatic hypotension.

How supplied: Tabs: 2mg, 8mg–100; 4mg–100, 500; Oral liq–pt

HYDROMORPHONE

CII

DILAUDID INJECTION Purdue Pharma L.P.

Opioid. Hydromorphone HCl 1mg/mL, 2mg/mL, 4mg/mL; soln for IV, IM or SC inj.

Indications: Management of pain where an opioid analgesic is appropriate.

Adults: Individualize. Initially 1–2mg SC or IM, or 0.2–1mg by slow IV every 2–3 hours as needed. Elderly, debilitated: initially 0.2mg IV. Renal or hepatic impairment: initially ¼ to ½ the usual dose. Conversion from prior opioid: see literature.

Children: Not recommended.

Also: Hydromorphone

DILAUDID-HP INJECTION

CII

Hydromorphone HCl 10mg/10mL soln; or 250mg/vial pld for reconstitution.

Indications: Management of moderate-to-severe pain in opioid-tolerant patients who require higher doses of opioids.

Adults: For use in opioid-tolerant patients only. Base starting dose on prior Dilaudid inj or prior dose of alternate opioid: see literature.

Children: Not recommended.

Contraindications: Respiratory depression in the absence of resuscitative equipment. Asthma. GI obstruction. Paralytic ileus. Dilaudid-HP: not opioid tolerant.

Warnings/Precautions: COPD. Cor pulmonale. Head injury. Increased intracranial pressure. Acute abdomen. GI surgery. Impaired renal, hepatic, thyroid, pulmonary, or adrenocortical function. GI or GU obstruction. Gallbladder disease. Biliary tract disease or surgery. Acute pancreatitis. Convulsive disorders. Toxic psychosis. Delirium tremens. Kyphoscoliosis. Circulatory shock. Drug abusers. Elderly. Debilitated. Neonate withdrawal syndrome in physically dependent mothers. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiation with alcohol, CNS depressants, tricyclics, phenothiazines. May be antagonized by mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, butorphanol, buprenorphine). May potentiate neuromuscular blocking agents. During or within 14 days of MAOIs. Anticholinergic effects with anticholinergics.

Adverse reactions: Lightheadedness, dizziness, sedation, GI upset, sweating, flushing, dysphoria, euphoria, dry mouth, pruritus; orthostatic hypotension, syncope, circulatory depression.

How supplied: Inj: 1mL amp (1mg/mL, 2mg/mL, 4mg/mL)–10; 2mg/mL–25; HP: 10mg/mL (1mL amp, 5mL amp)–10; single-dose vial (50mL)–1; 250mg–1

HYDROMORPHONE

CII

EXALGO Mallinckrodt

Opioid. Hydromorphone HCl 8mg, 12mg, 16mg, 32mg; ext-rel tabs; contains sulfites.

Indications: Moderate to severe pain in opioid-tolerant patients when continuous opioid analgesia is needed for an extended time period. Not for as-needed use or to treat acute or post-op pain.

Adults: Not for initial use. Swallow whole. Take once daily. >17yrs: Individualize based on prior analgesic treatment experience. Monitor closely within first 24–72 hours of starting therapy. See literature for converting from other opioids. Discontinuation of therapy: taper gradually by 25–50% every 2 or 3 days down to a dose of 8mg before discontinuing. Moderate hepatic impairment: start with 25% of normal dose; severe hepatic impairment: consider alternate therapy. Moderate renal impairment: start with 50% of normal dose; severe renal impairment: start with 25% of normal dose or consider alternate therapy.

Children: ≤17yrs: not established.

Contraindications: Opioid non-tolerant. Significant respiratory depression. Asthma (acute or severe). Sulfite allergy. Known or suspected paralytic ileus. GI or GU obstruction or stricture.

Warnings/Precautions: Increased risk of fatal respiratory depression (esp. when initiating therapy and during dose increases); monitor. Abuse potential (monitor routinely). Accidental exposure may result in fatal overdose (esp. children). Significant COPD or cor pulmonale. Increased intracranial pressure. Head injury. Impaired consciousness or coma: avoid. Renal or hepatic impairment. GI surgery. Biliary tract disease. Acute pancreatitis. Convulsive disorders. Avoid abrupt cessation. Elderly. Cachectic. Debilitated. Neonates. Obstetrical analgesia, labor and delivery, nursing mothers: not recommended. Pregnancy (Cat.C).

Interactions: Not recommended within 14 days of MAOIs. Potentiation with alcohol, CNS depressants (eg, hypnotics, sedatives, anesthetics, antipsychotics); avoid. Mixed agonist/antagonist opioids (eg, buprenorphine, nalbuphine, pentazocine) may reduce effects and precipitate withdrawal symptoms. Additive anticholinergic effects (eg, urinary retention, constipation) with other anticholinergics.

Adverse reactions: Constipation, GI upset, somnolence, headache, asthenia, dizziness, rash, orthostatic hypotension, urinary retention, respiratory or circulatory depression, syncope.

How supplied: Tabs–100

MEPERIDINE**DEMEROL** Sanofi Aventis*Opioid.* Meperidine HCl 50mg, 100mg; tabs.**Also: Meperidine****DEMEROL SYRUP***Meperidine HCl* 50mg/5mL; alcohol-free; banana flavor.**Indications:** Moderate to severe pain.**Adults:** 50–150mg every 3–4 hours as needed.**Children:** 0.5–0.8mg/lb up to adult dose every 3–4 hours as needed. Dilute syrup in ½ glass water.**Contraindications:** During or within 14 days of MAOIs.**Warnings/Precautions:** Head injury. Intracranial lesions. Increased intracranial pressure. Acute abdomen. Convulsive disorders. Impaired respiratory, renal, hepatic, thyroid, or adrenocortical function. Volume depletion. Supraventricular tachycardias. GI or GU obstruction. Drug abusers. Elderly. Debilitated. Pregnancy. Nursing mothers.**Interactions:** MAOIs (toxicity, may be fatal).

Potentiation with alcohol, CNS depressants, phenothiazines, tricyclics.

Adverse reactions: Dizziness, sedation, sweating, dry mouth, nausea, vomiting, constipation, urinary retention, hypotension, rash; convulsions with large doses; respiratory/circulatory depression, high abuse potential.**How supplied:** Tabs–100, 500; Syrup–pt

CII

CII

Interactions: Potentiation with CNS depressants such as alcohol, sedatives, antihistamines, psychotropics (eg, MAOIs, phenothiazines, butyrophenones, and tricyclic antidepressants). Increased risk of respiratory depression with neuroleptics.**Adverse reactions:** Respiratory and CNS depression, GI upset, constipation, headache, lightheadedness, dizziness, orthostatic hypotension, syncope, dysphoria, euphoria, pruritus.**How supplied:** Ampuls (0.5mg/mL, 1mg/mL)–10**MORPHINE**

CII

INFUMORPH Baxter*Opioid.* Morphine sulfate 10mg/mL, 25mg/mL; soln for continuous microinfusion devices for intrathecal or epidural infusion; preservative-free.**Indications:** For the treatment of intractable chronic pain.**Adults:** ≥18yrs: Individualize. Epidural: opioid-naïve: 3.5–7.5mg/day; opioid-tolerant: 4.5–10mg/day, may increase to 20–30mg/day. Intrathecal: opioid-naïve: 0.2–1mg/day; opioid-tolerant: 1–10mg/day.**Children:** <18yrs: not recommended.**Contraindications:** Infection at injection site. Concomitant anticoagulant therapy. Bleeding diathesis.**Warnings/Precautions:** Be fully familiar with management of respiratory depression with this drugs use. Have intubation, artificial respiration, and reversal agent (naloxone HCl) available. Monitor closely for at least 24 hrs after dosing. Indwelling intrathecal catheter: monitor for inflammatory masses that may result in neurologic impairment. Respiratory depression. COPD. Chronic asthma. Upper airway obstruction. Head injury. Pupillary changes (miosis). Increased intracranial/intraocular pressure. Shock. Renal or hepatic impairment. Biliary tract disease. GI or GU obstruction. Volume-depleted. Impaired myocardial function. Kyphoscoliosis. Convulsive disorders. Drug abusers. Neonates. Elderly. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.**Interactions:** Potentiation with CNS depressants such as alcohol, sedatives, antihistamines, psychotropics (eg, MAOIs, phenothiazines, butyrophenones, and tricyclic antidepressants). Increased risk of respiratory depression with neuroleptics.**Adverse reactions:** Respiratory and CNS depression, GI upset, constipation, headache, lightheadedness, dizziness, orthostatic hypotension, syncope, dysphoria, euphoria, pruritus.**How supplied:** Dosette ampuls (10mg/mL, 25mg/mL)–1**MORPHINE**

CII

MS CONTIN Purdue Pharma L.P.*Opioid.* Morphine sulfate 15mg, 30mg, 60mg, 100mg, 200mg; controlled-rel tabs.**Indications:** Management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.**MORPHINE**

CII

DURAMORPH Baxter*Opioid.* Morphine sulfate 0.5mg/mL, 1mg/mL; soln for IV, epidural, or intrathecal inj; preservative-free.**Indications:** For the management of pain not responsive to non-narcotic analgesics.**Adults:** ≥18yrs: Individualize. IV: 2mg–10mg/70kg of body weight. Epidural: initially 5mg, reevaluate after 1 hour, may administer additional incremental doses of 1–2mg at intervals sufficient to assess effectiveness. Max: 10mg/24 hours. Intrathecal: 0.2–1mg/24hrs.**Children:** <18yrs: not recommended.**Contraindications:** Acute bronchial asthma. Upper airway obstruction.**Warnings/Precautions:** Be fully familiar with management of respiratory depression with this drugs use. Have intubation, artificial respiration, and reversal agent (naloxone HCl) available. Monitor closely for at least 24 hrs after dosing. For epidural or intrathecal inj: infection at injection site, concomitant anticoagulant therapy, bleeding diathesis; evaluate risk/benefit potential. Respiratory depression. COPD. Head injury. Pupillary changes (miosis). Increased intracranial/intraocular pressure. Shock. Renal or hepatic impairment. Biliary tract disease. GI or GU obstruction. Volume-depleted. Impaired myocardial function. Kyphoscoliosis. Convulsive disorders. Drug abusers. Neonates. Elderly. Debilitated. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Not for use: as an as-needed (prn) analgesic, for pain that is mild or not expected to persist for an extended period of time, for acute pain, in the immediate post-op period for patients not previously taking the drug, or for post-op pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the post-op pain is expected to be moderate to severe and persist for an extended period of time.

Adults: Do not break, crush, or chew. Usually not for initial therapy; begin with an immediate-release product and convert to a controlled-release product. Individualize. Give twice daily (every 12hrs) or 3 times daily (every 8hrs). Dosage adjustments may be made every 1–2 days. Converting from other morphine formulations, other opioids: see full labeling.

Children: <18yrs: not established.

Contraindications: Significant respiratory depression. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment. Known or suspected paralytic ileus.

Warnings/Precautions: Abuse potential. Life-threatening respiratory depression; monitor for first 24–72 hours after initiating therapy and during dose increases. Accidental ingestion may cause fatal overdose (esp. in children). 100mg, 200mg tabs: for use in opioid-tolerant patients only. Head injury. Increased intracranial pressure. CNS depression. Coma. Shock. Impaired renal, hepatic, or pulmonary function. COPD. Cor pulmonale. GI or GU obstruction. Drug abusers. Elderly. Cachectic. Debilitated. Biliary tract disease. Acute pancreatitis. Convulsive disorders. Acute alcoholism. Avoid abrupt cessation. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Potentiation with alcohol, CNS depressants (reduce initial dose of either). Do not use within 14 days of MAOIs. Severe hypotension with phenothiazines, general anesthetics. Avoid muscle relaxants. Antagonizes diuretics. Possible withdrawal symptoms with mixed agonist/antagonist opioids; avoid. Paralytic ileus with anticholinergics. May be potentiated by PGP inhibitors (eg, quinidine). Potentiated by cimetidine; monitor.

Adverse reactions: Sedation, GI upset, constipation, urinary retention, respiratory depression, orthostatic hypotension, syncope, dysphoria, euphoria.

How supplied: 15mg, 200mg–100; 30mg, 60mg, 100mg–100, 500

MORPHINE + NALTREXONE

Cl

EMBEDA King

Opioid + opioid antagonist. Morphine sulfate, naltrexone HCl; 20mg/0.8mg, 30mg/1.2mg, 50mg/2mg, 60mg/2.4mg, 80mg/3.2mg, 100mg/4mg; ext-rel caps.

Indications: Moderate to severe pain management when continuous, around-the-clock opioid is needed for an extended time period. Not for use: as an as-needed (prn) analgesic, for pain that is mild or not

expected to persist for an extended period of time, for acute pain, or for postoperative pain unless the patient is already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate to severe and persist for an extended period of time.

Adults: Swallow whole, or sprinkle pellets on applesauce; do not chew pellets. Do not give via NG or gastric tubes. ≥ 18 yrs: individualize; give on 24 hour or 12 hour schedule. Opioid-naïve: start at lowest dose. Adjust at intervals of 1–2 days.

Withdraw gradually. Converting from other morphine formulations, other opioids: see full labeling.

Children: <18yrs: not established.

Contraindications: Concomitant alcohol (increases morphine absorption; may be fatal). Significant respiratory depression, acute or severe bronchial asthma (in unmonitored settings or in absence of resuscitative equipment). Paralytic ileus.

Warnings/Precautions: Abuse potential. Life-threatening respiratory depression possible; monitor first 24–72hrs after initiating therapy and during dose increases. Accidental ingestion may cause fatal overdose (esp. in children). Ingestion of tampered product may precipitate withdrawal symptoms in opioid-tolerant; overdose in opioid-naïve. 100mg/4mg strength for opioid-tolerant only. Head injury. Increased intracranial pressure. COPD. Cor pulmonale. Seizure disorders. Shock. CNS depression. Impaired pulmonary, renal, or hepatic function. GI or GU obstruction. Biliary tract disease. Acute pancreatitis. Volume-depleted. Acute alcoholism. Elderly. Cachectic. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Do not use during or within 14 days of MAOIs. Co-ingestion of alcohol may cause potential fatal overdose. CNS depression with other CNS depressants (eg, antiemetics, phenothiazines, sedatives, hypnotics, general anesthetics, tranquilizers; reduce initial dose of either). Avoid muscle relaxants. Paralytic ileus with anticholinergics. May be potentiated by PGP inhibitors (eg, quinidine). Antagonizes diuretics. Possible withdrawal symptoms, antagonism of analgesia with mixed agonist/antagonist opioids; avoid. Potentiated by cimetidine; monitor.

Adverse reactions: Constipation, GI upset, somnolence; respiratory depression/arrest, apnea, circulatory depression, cardiac arrest, hypotension, shock.

How supplied: Caps 20mg/0.8mg, 30mg/1.2mg–75; 50mg/2mg–150; 60mg/2.4mg, 80mg/3.2mg–200; 100mg/4mg–300

NALBUPHINE

R

NALBUPHINE HCl INJECTION (various)

Opioid (agonist-antagonist). Nalbuphine HCl 10mg/mL, 20mg/mL; SC, IM or IV inj; vials; amps.

Indications: Moderate to severe pain. Pre-op and post-op pain. Supplement to anesthesia. Prepartum pain.

Adults: 10mg/70kg IM, SC or IV every 3–6 hours as needed.

Children: <18yrs: not recommended.

Warnings/Precautions: Head injury. Increased intracranial pressure. Biliary tract surgery. Impaired respiratory, cardiac, renal, or hepatic function. MI. Hypertension. Drug abusers. Asthma (sulfites). Labor and delivery (esp. premature). Pregnancy.

Interactions: Potentiation with alcohol, CNS depressants. May precipitate withdrawal in narcotic addicts.

Adverse reactions: Sedation, diaphoresis, nausea, dizziness, dry mouth, headache, depression, dependence, possible withdrawal after prolonged use.

How supplied: Contact supplier.

OXYCODONE

CII

OXYCONTIN Purdue Pharma L.P.

Opoid. Oxycodone HCl 10mg, 15mg, 20mg, 30mg, 40mg, 60mg, 80mg; controlled-release tabs.

Indications: Moderate-to-severe pain when continuous, around-the-clock opiod analgesic is needed for extended time period. Not for use: as an as-needed (prn) analgesic, for pain that is mild or not expected to persist for an extended period of time, for acute pain, the immediate post-op period (1st 24 hours after surgery) or for post-op pain unless already receiving chronic opiod therapy prior to surgery or if the post-op pain is expected to be moderate-to-severe and persist for an extended period of time.

Adults: See full labeling. Swallow whole. ≥ 18 yrs: individualize; usually given on a 12-hour schedule. Opoid-naïve: initially 10mg every 12 hours. Adjust dose at 1–2 day intervals. Conversion from other opioids or combinations: see full labeling. Debilitated, non-opioid tolerant, hepatic dysfunction or concomitant CNS depressants: reduce dose by $\frac{1}{3}$ to $\frac{1}{2}$. 60mg and 80mg tabs, a single dose >40 mg, or a total daily dose >80 mg: for use in opiod-tolerant patients only.

Children: <18yrs: not established.

Contraindications: Significant respiratory depression. Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment. Known or suspected paralytic ileus or GI obstruction.

Warnings/Precautions: Abuse potential. Life-threatening respiratory depression; monitor first 24–72hrs during initiation of therapy and following dose increases. Accidental ingestion may cause fatal overdose (esp. in children). Head injury. Increased intracranial pressure. CNS depression. Impaired consciousness or coma. Convulsive disorders. Shock. Impaired pulmonary, renal, or hepatic function. COPD. Cor pulmonale. Difficulty swallowing. Underlying GI disorders (eg, esophageal or colon cancer with a small GI lumen). Biliary tract disease. Acute pancreatitis. Acute alcoholism. Avoid abrupt cessation. Reevaluate periodically. Drug abusers. Elderly. Cachectic. Debilitated. Pregnancy (Cat.B). Labor & delivery, nursing mothers: not recommended.

Interactions: Potentiation with alcohol, other CNS depressants, anticholinergics, MAOIs, tricyclic antidepressants, phenothiazines, general anesthetics, skeletal muscle relaxants. Potentiated by CYP3A4 inhibitors (eg, macrolides, azole antifungals, protease inhibitors). Possibly potentiated by CYP2D6 inhibitors (eg, quinidine, fluoxetine). May be antagonized by CYP3A4 inducers (eg, rifampin, carbamazepine, phenytoin), mixed agonist/antagonist analgesics (eg, pentazocine, nalbuphine, and butorphanol); avoid. May reduce the efficacy of diuretics.

Adverse reactions: Somnolence, constipation, nausea, vomiting, dizziness, pruritus, headache, dry mouth, sweating, asthenia; respiratory or CNS depression, hypotensive effects (monitor), seizures.

How supplied: Tabs–100

OXYCODONE + ACETAMINOPHEN

CII

PERCOCET Endo

Opoid + analgesic. Oxycodone HCl, acetaminophen; 2.5mg/325mg, 5mg/325mg, 7.5mg/325mg, 7.5mg/500mg, 10mg/325mg, 10mg/650mg; tabs.

Indications: Moderate to moderately severe pain.

Adults: 2.5mg/325mg: 1–2 tabs every 6hrs as needed. 5mg/325mg, 7.5mg/325mg, 7.5mg/500mg, 10mg/325mg, 10mg/650mg: 1 tab every 6hrs as needed. Max 4g acetaminophen/day.

Children: Not recommended.

Warnings/Precautions: Head injury. Increased intracranial pressure. Acute abdominal conditions. Severe pulmonary, renal, hepatic, thyroid, or adrenocortical dysfunction. Asthma. GI or GU obstruction. Drug abusers. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiation with alcohol, other CNS depressants, MAOIs, tricyclic antidepressants, anticholinergics.

Adverse reactions: Lightheadedness, dizziness, sedation, nausea, vomiting, euphoria, dysphoria, constipation, urinary retention, rash; overdosage: respiratory depression, hepatotoxicity.

How supplied: Tabs–100, 500

OXYCODONE + ACETAMINOPHEN

CII

TYLOX Janssen

Opoid + analgesic. Oxycodone HCl 5mg, acetaminophen 500mg; caps; contains sulfites.

Indications: Moderate to moderately severe pain.

Adults: 1 cap every 6 hrs as needed.

Children: Not recommended.

Warnings/Precautions: Head injury. Increased intracranial pressure. Acute abdomen. Impaired renal, hepatic, thyroid, or adrenocortical function. GI or GU obstruction. Asthma. Drug abusers. Labor and delivery. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiation with alcohol, CNS depressants, MAOIs, tricyclic antidepressants, anticholinergics.

Adverse reactions: Dizziness, sedation, GI upset, constipation, urinary retention, rash, respiratory depression; overdose: hepatotoxicity.

How supplied: Caps-100

OXYMORPHONE

CII

OPANA ER Endo

Opioid. Oxymorphone HCl 5mg, 7.5mg, 10mg, 15mg, 20mg, 30mg, 40mg; ext-rel tabs.

Indications: Moderate-to-severe pain when the use of a continuous, around-the-clock opioid is required for an extended period of time. Not for use: as an as-needed (prn) analgesic, for pain that is mild or not expected to persist for an extended period of time, for acute pain, or for postoperative pain unless already receiving chronic opioid therapy prior to surgery or if the postoperative pain is expected to be moderate-to-severe and persist for an extended period of time.

Also: *Oxymorphone*

CII

OPANA

Oxymorphone HCl 5mg, 10mg; immediate-rel tabs.

Indications: Moderate to severe acute pain when opioid use is appropriate.

Adults: Individualize. Take on empty stomach.

May give Opana as needed on an every 4–6 hrs schedule; Opana ER is given on a continuous basis every 12hrs. ≥ 18 yrs: Opioid-naïve: Opana: 5–20mg every 4–6 hrs as needed. Opana ER: Swallow whole; 5mg every 12 hrs, titrate by 5–10mg every 12 hours every 3–7 days; if breakthrough pain occurs: adjust dose or use a small-dose rescue medication (eg, immediate-release oxymorphone). Converting from Opana to Opana ER: Give half the total daily Opana dose as Opana ER every 12 hrs. Converting from parenteral oxymorphone, or other opioids to Opana or Opana ER: see full labeling. Mild hepatic impairment, renal impairment (CrCl < 50 mL/min), or elderly (≥ 65 yrs): opioid-naïve: initiate with 5mg dose; opioid-experience: initiate at 50% lower than normal starting dose and titrate slowly. Concomitant other CNS depressants: reduce initial dose.

Children: < 18 yrs: not established.

Contraindications: Significant respiratory depression. Acute or severe bronchial asthma. Hypercarbia. Known or suspected paralytic ileus. Moderate-to-severe hepatic impairment.

Warnings/Precautions: Abuse potential. Life-threatening respiratory depression; monitor first 24–72hrs after initiating therapy and during dose increases. Accidental ingestion may cause fatal overdose (esp. in children). Head injury. Increased intracranial pressure. CNS depression. Impaired consciousness or coma. Convulsive disorders. Shock. Impaired pulmonary, hepatic, or renal function. GI obstruction. COPD. Cor pulmonale. Biliary tract disease. Acute pancreatitis. Acute alcoholism. Avoid abrupt cessation. Re-evaluate periodically. Drug

abusers. Elderly. Cachectic. Debilitated. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Co-ingestion of alcohol may cause fatal overdose; avoid. Potentiates CNS depression with benzodiazepines, barbiturates, other CNS depressants and other psychoactive substances (avoid). Possible withdrawal symptoms with mixed agonist/antagonist opioids (eg, pentazocine, nalbuphine, butorphanol); avoid. Paralytic ileus with anticholinergics. Potentiated by cimetidine; monitor.

Adverse reactions: Constipation, GI upset, dizziness, somnolence, pruritus, headache, sweating increased, dry mouth, sedation, insomnia, fatigue, appetite decreased, abdominal pain; hypotensive effects, CNS and respiratory depression, seizures.

How supplied: Opana ER-60; Opana-100

TAPENTADOL

CII

NUCYNTA Janssen

Opioid. Tapentadol 50mg, 75mg, 100mg tabs.

Indications: Moderate to severe acute pain.

Adults: ≥ 18 yrs: 50–100mg every 4–6 hours depending upon pain intensity. First day of dosing: may give second dose one hour after first dose if adequate pain relief not attained with first dose; subsequent doses should be given every 4–6 hours. Max 700mg/day on the first day, 600mg/day on subsequent days. Moderate hepatic impairment: initially 50mg every 8 hours; max 3 doses/24 hours.

Children: < 18 yrs: not recommended (accidental ingestion may result in fatal overdose).

Contraindications: Significant respiratory depression, acute or severe asthma or hypercarbia (in unmonitored settings or in the absence of resuscitative equipment). Paralytic ileus. During or within 14 days of MAOIs.

Warnings/Precautions: Severe renal or hepatic impairment: not recommended. Asthma. COPD or cor pulmonale: monitor for respiratory depression; consider alternative non-opioid analgesics. CNS depression. Coma. Severe obesity. Sleep apnea syndrome. Myxedema. Hyphoscoliosis. Hypovolemia. Circulatory shock; avoid. Head injury. Increased intracranial pressure. Seizure disorders. GI or GU obstruction. Biliary tract disease. Acute pancreatitis. Drug abusers; monitor. Avoid abrupt cessation. Elderly. Debilitated. Cachectic. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: See Contraindications. Additive CNS depression, hypotension with other CNS depressants (eg, alcohol, other opioids, sedatives, hypnotics, general anesthetics, phenothiazines, tranquilizers); consider reducing dose. Serotonin syndrome possible with concomitant SSRIs, SNRIs, tricyclics, MAOIs, triptans, other drugs that impair metabolism of serotonin. Concomitant mixed agonists/antagonists, (butorphanol, nalbuphine, pentazocine), partial

agonists (eg, buprenorphine), and anticholinergics: not recommended.

Adverse reactions: Nausea, vomiting, dizziness, somnolence; respiratory or CNS depression, hypotension (monitor).

How supplied: Tabs—100

TAPENTADOL

CII

NUCYNTA ER Janssen

Opioid. Tapentadol 50mg, 100mg, 150mg, 200mg, 250mg; ext-rel tabs.

Indications: For use when a continuous, around-the-clock opioid analgesic is needed for an extended period of time to treat: 1) moderate to severe chronic pain; 2) neuropathic pain associated with diabetic peripheral neuropathy (DPN). Not for as-needed use.

Adults: Individualize. Swallow whole; do not break, chew, dissolve or crush tabs. Monitor for respiratory depression within the first 72hrs. ≥ 18 yrs: Usual dose: 100–250mg twice daily (approx. every 12 hours). Opioid-naïve: initially 50mg twice daily (approx. every 12 hours); then titrate to optimal dose within therapeutic range of 100–250mg twice daily. Converting from Nucynta to Nucynta ER: divide total daily dose of Nucynta into two equal doses of Nucynta ER separated by 12 hour intervals. Nucynta ER doses > 500 mg: not recommended. Converting from oxycodone CR and other opioids to Nucynta ER: see literature. Moderate hepatic impairment: initially 50mg once every 24 hours; max 100mg once daily.

Children: < 18 yrs: not recommended (accidental ingestion may result in fatal overdose).

Contraindications: Significant respiratory depression, severe asthma or hypercarbia (in unmonitored settings or in the absence of resuscitative equipment). Paralytic ileus. During or within 14 days of MAOIs.

Warnings/Precautions: Not for management of acute or post-op pain. Severe renal or hepatic impairment: not recommended. Moderate hepatic impairment. COPD, cor pulmonale: consider alternative non-opioid analgesics. CNS depression. Coma. Head injury. Increased intracranial pressure. Hypovolemia. Circulatory shock; avoid. Seizure disorders. GI or GU obstruction. Paralytic ileus. Biliary tract disease. Acute pancreatitis. Drug abusers; monitor. Avoid abrupt cessation. Elderly. Debilitated. Cachectic. Pregnancy (Cat.C). Monitor neonates, whose mothers have been taking Nucynta ER, for respiratory depression. Labor & delivery, nursing mothers: not recommended.

Interactions: See Contraindications. Avoid concomitant alcohol or alcohol-containing medications; may cause fatal overdose. Additive CNS depression, hypotension with other CNS depressants (eg, general anesthetics, phenothiazines, other tranquilizers, sedatives, hypnotics, alcohol); consider reducing dose. Serotonin syndrome possible with concomitant SSRIs, SNRIs, tricyclics, MAOIs, triptans, other drugs that impair metabolism of

serotonin. Concomitant mixed agonists/antagonists, (butorphanol, nalbuphine, pentazocine), partial agonists (eg, buprenorphine), and anticholinergics: not recommended.

Adverse reactions: Nausea, constipation, headache, dizziness, somnolence; respiratory or CNS depression, hypotension (monitor).

How supplied: ER tabs—60

17E Nonnarcotic analgesics

ACETAMINOPHEN

R

OFIRMEV Cadence

Analgesic/antipyretic. Acetaminophen 10mg/mL; soln for IV infusion; preservative-free.

Indications: Management of mild to moderate pain or moderate to severe pain with adjunctive opioid analgesics. Fever.

Adults: Give by IV infusion over 15 minutes.

< 50 kg: 15mg/kg every 6 hours (or 12.5mg/kg every 4 hours); max single dose: 15mg/kg (up to 750mg), max daily dose: 75mg/kg/24 hours (up to 3750mg). ≥ 50 kg: 15mg/kg every 6 hours (or 650mg every 4 hours); max single dose: 1000mg, max daily dose: 4000mg/24 hours. Minimum dosing interval: 4 hours.

Children: Give by IV infusion over 15 minutes; small volume doses (up to 60mL), place in syringe and administer using syringe pump. < 2 yrs: not studied. ≥ 2 yrs: 15mg/kg every 6 hours (or 12.5mg/kg every 4 hours); max single dose: 15mg/kg, max daily dose: 75mg/kg/24 hours. Minimum dosing interval: 4 hours.

Contraindications: Severe hepatic impairment. Severe active liver disease.

Warnings/Precautions: Hepatic impairment. Active hepatic disease. Alcoholism. Chronic malnutrition. Severe hypovolemia. Severe renal impairment (CrCl ≤ 30 mL/min). Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with CYP2E1 inhibitors or inducers. Doses of 4000mg/day may increase INR, monitor warfarin.

Adverse reactions: GI upset, headache, insomnia; also children: constipation, pruritus, agitation, atelectasis; hepatotoxicity (with high doses), anaphylaxis.

How supplied: Single-use vials (1000mg/vial)—24

ACETAMINOPHEN

OTC

TYLENOL McNeil Cons & Specialty

Analgesic/antipyretic. Acetaminophen 325mg; scored tabs.

Indications: Minor aches and pain. Fever.

Adults: 650mg every 4–6 hours; max 4g/day.

Children: Under 6 yrs: use pediatric forms.

6–11 yrs: 325mg every 4–6 hours; max 1.625g/day.

Also: Acetaminophen

OTC

EXTRA STRENGTH TYLENOL

Acetaminophen 500mg; tabs; caplets; gels; gelpcaps.

Also: Acetaminophen
EXTRA STRENGTH TYLENOL GOTABS
 Acetaminophen 500mg; chew tabs; contains potassium 5mg, sodium 3mg; per tab.

Also: Acetaminophen
OTC
TYLENOL ADULT EXTRA STRENGTH LIQUID
 Acetaminophen 500mg/15mL; mint flavor; alcohol 7%.
Adults: 1g every 4–6 hours; max 4g/day.
Children: Use pediatric forms.

Warnings/Precautions: Hepatic dysfunction. Pregnancy. Nursing mothers.

Interactions: Hepatotoxicity risk increased by chronic, heavy alcohol use.

Adverse reactions: Hepatotoxicity (overdose).

How supplied: Tabs 325mg–100; Ext str tabs–30, 60, 100, 200; Ext str caplets–10, 24, 50, 100, 175, 250; Ext str gels–24, 50, 100; Ext str gels–24, 50, 100, 225; Ext str rapid-release gels–72, 100; Ext str GoTabs–6; Adult liq–8oz

CARBAMAZEPINE

CARBATROL Shire
Dibenzazepine. Carbamazepine 100mg, 200mg, 300mg; ext-rel caps.

Indications: Trigeminal or glossopharyngeal neuralgia.

Adults: 200mg once on day 1; increase by 200mg/day every 12hrs as needed; max 1.2g/day. Usual maintenance: 400–800mg/day. Attempt to taper or discontinue every three months.

Children: See full labeling.

Contraindications: History of bone marrow depression. Sensitivity to tricyclic antidepressants. During or within 14 days of MAOIs. Concomitant nefazodone, delavirdine.

Warnings/Precautions: Evaluate for presence of HLA-B*1502 allele (esp. in Asians), if present carbamazepine should not be used; increased risk of severe dermatological reactions. History of cardiac, hepatic, renal, or hematopoietic dysfunction. Not for trivial aches/pains. Do baseline CBCs then periodically; discontinue if significant bone marrow depression occurs. Monitor lipid profile, and ophthalmic, hepatic, and renal function. Consider discontinuing if hyponatremia occurs. Increased intraocular pressure. Activation of latent psychosis. Suicidal tendencies (monitor). Reevaluate periodically. Avoid abrupt cessation. Elderly. Labor & delivery. Pregnancy (Cat.D). Nursing mothers: not recommended.

Interactions: See Contraindications. Possible hyperpyretic crisis, seizures and death with MAOIs. Carbamazepine levels increased by CYP3A4 inhibitors (eg, cimetidine, macrolides, danazol, delavirdine, diltiazem, fluoxetine, isoniazid, ketoconazole, loratadine, propoxyphene, itraconazole, nicotinamide, niacinamide, valproate, verapamil). Carbamazepine levels decreased by CYP3A4 inducers (eg, cisplatin, doxorubicin, felbamate, phenobarbital, phenytoin, primidone, rifampin, theophylline). May increase levels of clomipramine, phenytoin, primidone.

OTC
 May decrease levels of phenytoin, warfarin, oral contraceptives, doxycycline, theophylline, haloperidol, acetaminophen, alprazolam, clonazepam, clobazepam, delavirdine, ethosuximide, valproate, others metabolized by CYP3A4. May increase lithium toxicity. May reduce effectiveness of hormonal contraceptives and delavirdine. May alter thyroid function with other anticonvulsants. May interfere with some pregnancy tests or thyroid function tests.

Adverse reactions: Dizziness, drowsiness, nausea, vomiting, CHF, edema, hyper- or hypotension, arrhythmias, liver or urinary disorders, dyspnea, lens opacities, arthralgia, fever; rarely: rash (may be serious, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), aplastic anemia, agranulocytosis, bone marrow depression, hypersensitivity reactions; others (see full labeling).

How supplied: Caps–120

CARBAMAZEPINE

EPITOL Teva US Generics

TEGRETOL Novartis
Dibenzazepine. Carbamazepine 100mg +, 200mg; scored tabs; + chewable.

Also: Carbamazepine

TEGRETOL-XR

Carbamazepine 100mg, 200mg, 400mg; ext-rel tabs.

Indications: Trigeminal or glossopharyngeal neuralgia.

Adults: Initially 100mg twice daily with food, gradually increasing in increments of 100mg twice daily as needed. Maintenance: usually 400–800mg daily; range 200mg–1.2g daily. Taper dosage or discontinue if possible at 3 month intervals.

Children: Not applicable.

Also: Carbamazepine

TEGRETOL SUSPENSION

Carbamazepine 100mg/5mL; citrus-vanilla flavor; contains sorbitol.

Adults: Initially 50mg 4 times daily with food, gradually increasing in increments of 50mg 4 times daily as needed. Maintenance: usually 400–800mg daily; range 200mg–1.2g daily. Taper dosage or discontinue if possible at 3 month intervals.

Children: Not applicable.

Contraindications: History of bone marrow depression. Sensitivity to tricyclic antidepressants. During or within 14 days of MAOIs. Concomitant nefazodone.

Warnings/Precautions: Evaluate for presence of HLA-B*1502 allele (esp. in Asians), if present carbamazepine should not be used; increased risk of severe dermatological reactions. History of cardiac, hepatic, renal, or hematopoietic dysfunction, or adverse hematologic reaction to other drugs. Do baseline CBCs then periodically; discontinue if significant bone marrow depression occurs. Monitor lipid profile, ophthalmic, hepatic, and renal function. Glaucoma. Activation of latent psychosis. Suicidal tendencies (monitor). Use

minimum effective dose and change dose gradually. Avoid abrupt cessation. Convert tabs to susp with same quantity of mg/day in smaller, more frequent doses; convert tabs to XR on mg/mg basis. Elderly. Labor & delivery. Pregnancy (Cat.D). Nursing mothers.

Interactions: See Contraindications. Possible hyperpyretic crisis, seizures and death with MAOIs. Increased plasma levels with CYP3A4 inhibitors (eg, aprepitant, cimetidine, ciprofloxacin, danazol, diltiazem, macrolides, erythromycin, troleandomycin, clarithromycin, fluoxetine, fluvoxamine, nefazodone, trazodone, loxapine, olanzapine, quetiapine, lorazepam, terfenadine, omeprazole, oxybutynin, dantrolene, isoniazid, niacinamide, nicotinamide, ibuprofen, propoxyphene, ketoconazole, itraconazole, fluconazole, voriconazole, acetazolamide, verapamil, ticlopidine, grapefruit juice, protease inhibitors, valproate). Decreased plasma levels with CYP3A4 inducers (eg, cisplatin, doxorubicin, felbamate, fosphenytoin, rifampin, phenobarbital, phenytoin, primidone, methsuximide, theophylline, aminophylline). May increase levels of clomipramine, phenytoin, primidone, cyclophosphamide. May decrease levels of phenytoin, warfarin, doxycycline, theophylline, haloperidol, acetaminophen, alprazolam, clozapine, oral contraceptives, anticonvulsants, aripiprazole, others metabolized by CYP3A4. May increase lithium toxicity. Monitor tacrolimus, temsirolimus, lapatinib (adjust dose). May alter thyroid function with other anticonvulsants. Do not give susp formulation simultaneously with other liquid drugs or diluents. May interfere with some pregnancy tests, thyroid function tests. Others (see full labeling).

Adverse reactions: Drowsiness, dizziness, GI upset, heart failure, edema, hyper- or hypotension, arrhythmias, liver and urinary disorders, dyspnea, lens opacities, arthralgia, fever, hyponatremia; rarely: rash (may be serious, eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), aplastic anemia, agranulocytosis, bone marrow depression; drug reaction with eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity.

How supplied: Tabs-100; XR tabs-100; Susp-450mL

CELECOXIB

CELEBREX Pfizer
NSAID (COX-2 inhibitor). Celecoxib 50mg, 100mg, 200mg, 400mg; caps.

Indications: Acute pain.

Adults: ≥18yrs: 400mg once then 200mg more on 1st day if needed, then 200mg twice daily. <50kg: start at lowest recommended dose.

Children: Not recommended.

Contraindications: Sulfonamide or aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease or severe hepatic impairment: not recommended. Renal or liver dysfunction; reduce dose by 50% in

moderate hepatic insufficiency (Child-Pugh class B). Discontinue if liver disease or systemic effects (eg, eosinophilia, rash) develops. History or risk of GI bleed/ulcer (monitor). Fluid retention. Heart failure. Hypertension. Asthma. Alcoholism. Dehydrated. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Caution with drugs that inhibit CYP2C9 (eg, fluconazole) or are metabolized by CYP2D6. May antagonize, or increase risk of renal failure with ACEIs, diuretics. Increased risk of GI bleed with aspirin (except low-dose), corticosteroids, smoking, anticoagulants. May potentiate lithium. Monitor warfarin.

Adverse reactions: GI upset/pain, edema, pharyngitis, increase AST/ALT, GI ulcer/bleed; rare: intracranial bleed, liver failure. See literature re: risk of cardiovascular events.

How supplied: Caps 100mg, 200mg-100, 500; 50mg, 400mg-60

DICLOFENAC POTASSIUM

CATAFLAM Novartis
NSAID (benzeneacetic acid deriv.). Diclofenac potassium 50mg; tabs.

Indications: Pain.

Adults: 50mg 3 times daily; may give 100mg initially.

Children: Not recommended.

Contraindications: Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. Peptic ulcer. GI bleeding. Monitor AST/ALT within 4 weeks and then periodically; also blood, hepatic, and renal function in chronic use. Edema. Cardiac failure. Hypertension. Hepatic porphyria. Elderly. Debilitated. Pregnancy (Cat.C).

Nursing mothers: not recommended.

Interactions: Digoxin, methotrexate, cyclosporine, lithium toxicity. Antagonizes diuretics. May increase serum potassium level with K⁺-sparing diuretics. Avoid aspirin. Monitor oral anticoagulants, insulin and sulfonylureas. Increased risk of GI bleed with alcohol.

Adverse reactions: Peptic ulcer, GI bleeding, elevated AST/ALT, abdominal discomfort, constipation, diarrhea, indigestion, nausea, abdominal distention, headache, dizziness, fluid retention, rash (discontinue if occurs), pruritus, tinnitus. See literature re: risk of cardiovascular events.

How supplied: Tabs-100

DIFLUNISAL

DIFLUNISAL (various)
Salicylate. Diflunisal 250mg, 500mg; tabs.

Indications: Mild to moderate pain.

Adults: 0.5-1g once then 250-500mg every 8-12 hrs.

Children: Not recommended.

Contraindications: Aspirin allergy. Varicella or influenza in teenagers. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. Active peptic ulcer or GI bleeding. History of GI disease. Cardiac failure. Hypertension. Impaired renal or hepatic function. Volume depletion. Bleeding disorders. Sepsis. Diabetes. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C in 1st and 2nd trimesters). Nursing mothers: not recommended.

Interactions: Avoid methotrexate, indomethacin. Oral anticoagulants potentiated. Increased acetaminophen and hydrochlorothiazide serum levels. Reduced absorption with antacids.

Adverse reactions: Peptic ulcer, GI bleeding, nausea, dyspepsia, GI pain, diarrhea, rash (discontinue if occurs), headache, dizziness, edema, nephritis. See literature re: risk of cardiovascular disease.

How supplied: Contact supplier.

DULOXETINE

CYMBALTA Lilly

Serotonin and norepinephrine reuptake inhibitor. Duloxetine (as HCl) 20mg, 30mg, 60mg; e-c pellets in caps.

Indications: Diabetic peripheral neuropathic pain.

Adults: Swallow whole. 60mg once daily (may start at lower dose if 60mg not tolerated); renal impairment: consider lower starting dose and slow titration.

Children: Not recommended.

Contraindications: Allow at least 14 days after MAOI discontinuance before starting duloxetine; allow at least 5 days after duloxetine discontinuance before starting an MAOI. Concomitant linezolid or IV methylene blue. Uncontrolled narrow-angle glaucoma.

Warnings/Precautions: Suicidal tendencies (monitor). Severe renal impairment (CrCl < 30mL/min), end stage renal disease, hepatic insufficiency, evidence of chronic liver disease, or substantial alcohol use: not recommended. History of seizure or mania/hypomania. Controlled narrow-angle glaucoma. Decreased GI motility. Cardiac disease. Monitor BP prior to and during therapy. Diabetes. Avoid abrupt cessation. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; consider tapering, see literature for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant thioridazine (may cause arrhythmias): not recommended. Potentiated by CYP1A2 inhibitors; avoid (eg, cimetidine, fluvoxamine, quinolones). May potentiate or be potentiated by CYP2D6 inhibitors (eg, paroxetine, fluoxetine, quinidine) or substrates (eg, tricyclics, phenothiazines, type 1C antiarrhythmics) or other highly protein-bound drugs; caution with CYP2D6 substrates with narrow therapeutic indexes. Caution with potent CYP1A2 inhibitors, antihypertensives, other drugs that induce orthostatic hypotension. Caution with triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort; may cause serotonin syndrome. Monitor concomitant CNS-

acting drugs, and with those that affect gastric pH (eg, proton pump inhibitors). Increased bleeding risk with aspirin, anticoagulants, NSAIDs.

Adverse reactions: Nausea, dry mouth, constipation, somnolence, hyperhidrosis, decreased appetite, weight changes, GI disturbances, fatigue, dizziness, increased sweating, mania/hypomania, tremor, blurred vision, insomnia, hot flushes, urinary hesitation/retention, abnormal ejaculation, genital disorders, decreased libido, increased BP, orthostatic hypotension, syncope, hepatotoxicity (eg, elevated liver transaminases, cholestatic jaundice); discontinue if occurs, hyponatremia, asthenia, others; rare: seizure.

How supplied: Caps 20mg-60; 30mg-30, 90, 1000; 60mg-30, 1000

ETODOLAC

ETODOLAC CAPSULES (various)
NSAID (pyranocarboxylic acid deriv.). Etodolac 200mg, 300mg; caps.

Also: Etodolac

ETODOLAC TABLETS
Etodolac 400mg, 500mg.

Indications: Pain.

Adults: Initially 200mg-400mg every 6-8 hrs as needed; usual max 1g/day in divided doses; may increase to 1.2g/day when needed.

Children: Not recommended.

Contraindications: Aspirin allergy. Late pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Discontinue if signs/symptoms of liver disease develop. History of upper GI disease. Asthma. Renal or hepatic impairment. Advanced kidney disease: not recommended. Heart failure. Hypertension. Edema. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Dehydrated. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Antacids reduce serum levels. Avoid salicylates, phenylbutazone. Monitor anticoagulants, cyclosporine, lithium, digoxin, methotrexate. Renal toxicity may be potentiated with diuretics. May antagonize ACE inhibitors.

Adverse reactions: Dyspepsia, GI upset, edema, asthenia/malaise, dizziness, dysuria, urinary frequency, depression, nervousness, renal or hepatic toxicity, rash (discontinue if occurs), pruritus, chills/fever, GI bleed, peptic ulcer. See literature re: risk of cardiovascular events.

How supplied: Contact supplier.

GABAPENTIN

NEURONTIN CAPSULES Pfizer
Gabapentin 100mg, 300mg, 400mg.

Also: Gabapentin

NEURONTIN TABLETS
Gabapentin 600mg, 800mg; scored.

Also: Gabapentin**NEURONTIN ORAL SOLUTION**

Gabapentin 250mg/5mL; strawberry-anise flavor.

Indications: Postherpetic neuralgia.

Adults: 300mg once on day 1, twice daily on day 2, and 3 times daily on day 3; may titrate up to usual max 1.8g/day in 3 divided doses (doses up to 3.6g/day have been used without added benefit). Renal dysfunction: CrCl 30–59mL/min: 400–1400mg/day twice daily; CrCl 15–29mL/min: 200–700mg once daily; CrCl ≤15mL/min: 100–300mg once daily (see literature); hemodialysis: 125–350mg after session.

Children: Not recommended.

Warnings/Precautions: Renal dysfunction.

Suicidal tendencies (monitor). Avoid abrupt cessation. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates CNS depression with alcohol, morphine, other CNS depressants. Give 2 hrs after antacids. May antagonize hydrocodone. May interfere with some urine protein tests (eg, Multistix-SG).

Adverse reactions: Dizziness, somnolence, peripheral edema, GI upset, ataxia, visual disturbances, thought disorder, abnormal gait, incoordination.

How supplied: Caps, tabs–100; Soln–470mL

R

hepatotoxicity develops), blurred vision, rash/serious skin infections (discontinue if occurs), peripheral edema, anemia/blood dyscrasias, hypertension, renal papillary necrosis, aseptic meningitis. See literature re: risk of cardiovascular events.

How supplied: Single-dose vials (400mg/4mL, 800mg/8mL)–25

IBUPROFEN

R

IBUPROFEN TABLETS (various)

NSAID (propionic acid deriv.). Ibuprofen 400mg, 600mg, 800mg.

Also: Ibuprofen

OTC

IBUPROFEN CHEWABLE TABLETS

Ibuprofen 50mg, 100mg; citrus flavor; contains phenylalanine.

Indications: Mild to moderate pain. Fever.

Adults: Pain: 400mg every 4–6 hrs as needed.

Children: Use caplets, chewables, suspension, or drops. <6 months: not recommended. ≥6 months: Fever <102.5°F: 5mg/kg every 6–8 hours. Fever >102.5°F or pain: 10mg/kg every 6–8 hours; max 40mg/kg/day.

Contraindications: Aspirin allergy. 3rd trimester pregnancy. Coronary artery bypass graft surgery.

Warnings/Precautions: Advanced renal disease: not recommended. History of upper GI disease.

Active peptic ulcer. Impaired renal or hepatic function. Edema. Hypertension. Cardiac failure. Bleeding disorders. Diabetes. Monitor blood, hepatic, renal, and ocular function in chronic use. Discontinue if visual or liver dysfunction occurs. Dehydration. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid aspirin. May increase bleeding with anticoagulants, toxicity of methotrexate.

Increases serum lithium levels. May decrease effect of furosemide, thiazide diuretics.

Adverse reactions: Peptic ulcer or perforation, GI bleeding, vision disorders, nausea, epigastric pain, heartburn, dizziness, rash (discontinue if occurs), edema, renal papillary necrosis, jaundice, hepatitis. See literature re: risk of cardiovascular events.

How supplied: Contact supplier.

R

IBUPROFEN

CALDOLOR Cumberland

NSAID (propionic acid deriv.). Ibuprofen 100mg/mL; for IV infusion after dilution.

Indications: Mild-to-moderate pain. Moderate-to-severe pain adjunct to opioids. Fever.

Adults: ≥17yrs: Give by IV infusion over 30 minutes. Use lowest effective dose. Maintain adequate hydration. Pain: 400mg–800mg every 6 hours as needed. Fever: initially 400mg, followed by 400mg every 4–6 hours or 100–200mg every 4 hours as needed. Max: 3200mg/day.

Children: <17yrs: not recommended.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery. 3rd trimester pregnancy.

Warnings/Precautions: Advanced renal disease: not recommended. History of ulcer disease or GI bleeding. Active peptic ulcer. Impaired renal or hepatic function. Asthma. Edema. Hypertension; monitor BP. Heart failure. Bleeding disorders. Monitor blood, hepatic and renal function in chronic use. Discontinue if visual, rash or liver dysfunction occurs. Dehydration. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C: <30 weeks gestation, Cat.D: ≥30 weeks gestation). Nursing mothers: not recommended.

Interactions: Avoid aspirin. May antagonize ACE inhibitors, diuretics. Increased risk of GI bleed with oral corticosteroids, anticoagulants (monitor), alcohol, smoking. Increases lithium levels. May increase toxicity of methotrexate.

Adverse reactions: Nausea, flatulence, vomiting, dyspepsia, headache, hemorrhage, dizziness; GI ulcer/bleed, elevated liver enzymes (discontinue if

KETOROLAC

R

KETOROLAC IV/IM (various)

NSAID (pyrrolo-pyrrole deriv.). Ketorolac tromethamine 15mg/mL, 30mg/mL; for IM or IV inj; contains alcohol.

Indications: Short-term management of moderately severe, acute pain requiring opioid-level analgesia.

Adults: Do not exceed 5 days' combined (inj + tabs) therapy or recommended dose (may use as-needed opioids for breakthrough pain if appropriate). 17–64yrs (normal renal function): 60mg IM or 30mg IV once; or, 30mg IM or IV every 6 hours. ≥65yrs, or <110lbs, or renal impairment: 30mg IM or 15mg IV once; or, 15mg every 6 hours.

Children: <17yrs: not established.

Contraindications: Aspirin allergy. Peptic ulcer. GI bleed or perforation. As prophylactic analgesic before any major surgery. Treatment of peri-op pain in CABG setting. Advanced renal impairment. Hypovolemia. Cerebrovascular bleeding. Hemorrhagic diathesis. Incomplete hemostasis. Bleeding disorders or high risk of bleeding. Concomitant probenecid, salicylates, pentoxifylline, other NSAIDs. Epidural or intrathecal inj. Labor & delivery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Risk of serious GI events. Inflammatory bowel disease. Coagulation disorders. Avoid in peri-op use. Caution with post-op use when hemostasis is critical. Renal or hepatic dysfunction. Discontinue if abnormal liver function tests occur. Correct hypovolemia first. Hypertension (monitor). Cardiac decompensation. May prolong bleeding time. Asthma. Elderly. Debilitated. Pregnancy (Cat.C; avoid in late pregnancy). Nursing mothers.

Interactions: See Contraindications. Monitor anticoagulants closely. Antagonizes furosemide, possibly antiepileptics. May increase serum lithium, methotrexate levels. ACEIs, diuretics increase renal toxicity risk. Hallucinations with fluoxetine, thiothixene, alprazolam. Apnea with non-depolarizing muscle relaxants. Caution with concomitant SSRIs; may increase GI bleeding risk.

Adverse reactions: Inj site pain, headache, abdominal pain, dyspepsia, nausea, vomiting, dizziness, drowsiness, edema, hypertension, pruritus, rash, stomatitis, purpura, sweating, peptic ulcer, GI bleed/perforation, bleeding, renal or liver failure, anaphylaxis, skin reactions.

How supplied: Contact supplier.

KETOROLAC

KETOROLAC TABLETS (various)
Ketorolac tromethamine 10mg; tabs.

Indications: Short-term management of moderately severe, acute pain requiring opioid-level analgesia.

Adults: Use tabs only as continuation therapy to inj. Do not exceed 5 days' combined (inj + tabs) therapy or recommended dose (may use as-needed opioids for breakthrough pain if appropriate). After inj therapy: 17–64yrs (normal renal function): 20mg once then 10mg every 4–6 hours; max 40mg/day. ≥65yrs, or <110lbs, or renal impairment: 10mg once then 10mg every 4–6 hours; max 40mg/day.

Children: <17yrs: not established.

Contraindications: Aspirin allergy. Peptic ulcer. GI bleed or perforation. As prophylactic analgesic before any major surgery. Treatment of peri-op pain in CABG setting. Advanced renal impairment. Hypovolemia. Cerebrovascular bleeding. Hemorrhagic diathesis. Incomplete hemostasis. Bleeding disorders or high risk of bleeding. Concomitant probenecid, salicylates, pentoxifylline, other NSAIDs. Labor & delivery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Risk of serious

GI events. Inflammatory bowel disease. Coagulation disorders. Avoid in peri-op use. Caution with post-op use when hemostasis is critical. Renal or hepatic dysfunction. Discontinue if abnormal liver function tests occur. Correct hypovolemia first. Hypertension (monitor). Cardiac decompensation. May prolong bleeding time. Asthma. Elderly. Debilitated. Pregnancy (Cat.C; avoid in late pregnancy). Nursing mothers.

Interactions: See Contraindications. Monitor anticoagulants closely. Antagonizes furosemide, possibly antiepileptics. May increase serum lithium, methotrexate levels. ACEIs, diuretics increase renal toxicity risk. Hallucinations with fluoxetine, thiothixene, alprazolam. Apnea with non-depolarizing muscle relaxants. Caution with concomitant SSRIs; may increase GI bleeding risk.

Adverse reactions: Headache, abdominal pain, dyspepsia, nausea, vomiting, dizziness, drowsiness, edema, hypertension, pruritus, rash, stomatitis, purpura, sweating, peptic ulcer, GI bleed/perforation, bleeding, renal or liver failure, anaphylaxis, skin reactions.

How supplied: Contact supplier.

NAPROXEN

NAPROSYN Roche
NSAID (arylacetic acid deriv.). Naproxen 250mg, 375mg, 500mg; tabs.

Also: Naproxen
NAPROSYN SUSPENSION

Naproxen 125mg/5mL; pineapple-orange flavor.

Indications: Mild to moderate pain.

Adults: Initially 500mg, then 500mg every 12 hrs or 250mg every 6–8 hrs; max 1.25g (first day), then max 1g/day.

Children: <2yrs: not recommended. ≥2yrs: use susp forms of naproxen.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation). Advanced renal disease: not recommended. Active peptic ulcer. History of GI or inflammatory bowel disease. Impaired renal or hepatic function. Hypovolemia. Heart failure. Salt depletion. Edema. Hypertension. Preexisting asthma. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid concomitant aspirin. May potentiate protein-bound drugs (eg, hydantoins, sulfonamides, sulfonylureas). Monitor oral anticoagulants. Increased risk of GI bleeding with oral corticosteroids, SSRIs, smoking, alcohol. May antagonize diuretics, β-blockers, ACEIs, ARBs or other antihypertensives. Increased renal toxicity with ACEIs or ARBs. Methotrexate excretion reduced.

Increases serum lithium levels. Probenecid increases plasma levels and delays elimination. Concomitant H₂ blockers, sucralfate, intensive antacid therapy: use immediate-release forms of naproxen. Cholestyramine may delay absorption.

Adverse reactions: GI bleeding, peptic ulcer, constipation, heartburn, abdominal pain, nausea, headache, dizziness, drowsiness, pruritus, rash (discontinue if occurs), tinnitus, edema, nephritis, nephrotic syndrome, jaundice, hepatitis. See full labeling re: risk of cardiovascular or GI events.

How supplied: Tabs-100; Susp-pt

NAPROXEN SODIUM

ANAPROX Roche

NSAID (arylacetic acid deriv.). Naproxen sodium 275mg; tabs.

Also: Naproxen sodium

ANAPROX DS

Naproxen sodium 550mg; tabs.

Indications: Mild to moderate pain.

Adults: Initially 550mg, then 550mg every 12 hrs or 275mg every 6-8 hrs; max 1.375g (first day), then max 1.1g/day.

Children: <2yrs: not recommended. ≥2yrs: use susp form of naproxen.

Contraindications: Aspirin allergy. Coronary artery bypass graft surgery.

Warnings/Precautions: Increased risk of serious cardiovascular events, MI, and stroke. Increased risk of serious GI adverse events (eg, bleeding, ulceration, perforation). Advanced renal disease: not recommended. Active peptic ulcer. History of GI or inflammatory bowel disease. Impaired renal or hepatic function. Hypovolemia. Heart failure. Salt depletion. Edema. Hypertension. Preexisting asthma. Bleeding disorders. Monitor blood, hepatic, renal, and ocular function in chronic use. Elderly. Debilitated. Pregnancy (Cat.C); avoid in late pregnancy. Nursing mothers: not recommended.

Interactions: Avoid concomitant aspirin. May potentiate protein-bound drugs (eg, hydantoins, sulfonamides, sulfonylureas). Monitor oral anticoagulants. Increased risk of GI bleeding with oral corticosteroids, SSRIs, smoking, alcohol. May antagonize diuretics, β-blockers, ACEIs, ARBs, or other antihypertensives. Increased renal toxicity with ACEIs or ARBs. Methotrexate excretion reduced. Increases serum lithium levels. Probenecid increases plasma levels and delays elimination. Concomitant H₂ blockers, sucralfate, intensive antacid therapy: use immediate-release forms of naproxen. Cholestyramine may delay absorption.

Adverse reactions: GI bleeding, peptic ulcer, constipation, heartburn, abdominal pain, nausea, headache, dizziness, drowsiness, pruritus, rash (discontinue if occurs), tinnitus, edema, nephritis, nephrotic syndrome, jaundice, hepatitis. See full labeling re: risk of cardiovascular or GI events.

How supplied: Tabs 275mg-100; 550mg-100

PREGABALIN

LYRICA Pfizer

alpha2-delta ligand. Pregabalin 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg; caps.

Also: Pregabalin

LYRICA ORAL SOLUTION

Pregabalin 20mg/mL.

Indications: Neuropathic pain associated with diabetic peripheral neuropathy (DPN) or spinal cord injury. Postherpetic neuralgia (PHN).

Adults: ≥18yrs: DPN: initially 50mg 3 times daily, may increase to 100mg 3 times daily within 1 week. Spinal cord injury: initially 75mg twice daily, may increase to 150mg twice daily within 1 week, then max 600mg/day after 2 weeks as tolerated. PHN: initially 75mg twice daily or 50mg 3 times daily; max 300mg/day after 1 week then 600mg/day after 2 weeks as tolerated (see literature). For all: renal impairment (CrCl <60mL/min): reduce dose (see literature); hemodialysis: give supplemental dose after session.

Children: <18yrs: not recommended.

Warnings/Precautions: Avoid abrupt cessation (taper over ≥1 week). Discontinue if angioedema, hypersensitivity reactions, myopathy or markedly elevated creatine kinase levels occur. CHF. Ocular conditions. Diabetes (monitor skin integrity). Suicidal tendencies (monitor). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Additive edema, weight gain with thiazolidinediones.

Adverse reactions: Dizziness, somnolence, other CNS effects, dry mouth, edema, ocular/visual effects (eg, blurring), weight gain, thinking abnormal (primarily difficulty with concentration/attention), infection, asthenia, paresthesias, elevated creatine kinase, decreased platelets, arrhythmias (PR prolongation); male-mediated teratogenicity; may be tumorigenic.

How supplied: Caps-90; Soln-16oz

PROMETHAZINE

PROMETHAZINE HCl INJECTION (various)

Phenothiazine. Promethazine HCl 25mg/mL, 50mg/mL; sol for IM or IV inj; contains sulfites.

Indications: Adjunct to analgesics for control of postoperative pain. Special surgical situations (ie, bronchoscopy, ophthalmic surgery, poor risk patients) to reduce amounts of narcotic analgesic as an adjunct to anesthesia and analgesia.

Adults: 25-50mg IM or IV.

Children: <2yrs: see Contraindications. ≥2yrs: should not exceed half that of suggested adult dose (see literature).

Contraindications: Children <2 years. Coma. Intra-arterial or subcutaneous injection.

Warnings/Precautions: Sulfite sensitivity. CNS depression. Impaired respiratory function (eg, COPD, sleep apnea). Narrow-angle glaucoma. GI or GU obstruction. Cardiovascular or liver disease. Seizure

disorders. Peptic ulcer. Bone marrow depression. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Caution with epinephrine, anticholinergics, MAOIs. May alter hCG pregnancy test results and glucose tolerance tests.

Adverse reactions: Inj site reactions, CNS depression/drowsiness, lowered seizure threshold, cholestatic jaundice, anticholinergic and extrapyramidal effects, neuroleptic malignant syndrome, photosensitivity, hypo- or hypertension, rash, blood dyscrasias, nausea, dry mouth, paradoxical reactions; children: respiratory depression (may be fatal).

How supplied: Contact supplier.

TRAMADOL

ULTRAM ER Janssen

Opioid. Tramadol HCl 100mg, 200mg, 300mg; ext-rel tabs.

Indications: Moderate to moderately severe chronic pain when continuous analgesia is needed for an extended period of time.

Adults: Swallow whole. ≥ 18 yrs: initially 100mg once daily, then may increase by 100mg every 5 days; max 300mg/day. Renal dysfunction (CrCl < 30 mL/min) or severe hepatic impairment: not recommended.

Children: < 18 yrs: not recommended.

Also: Tramadol

ULTRAM

Tramadol HCl 50mg; scored tabs.

Indications: Moderate to moderately severe pain.

Adults: ≥ 17 yrs: 50–100mg every 4–6 hours; max 400mg/day. Or, 25mg in AM on 1st day, increase by 25mg every 3 days (ie, to 25mg four times daily), then increase by 50mg every 3 days (ie, to 50mg four times daily), then increase to 50–100mg every 4–6 hours; max 400mg/day. > 75 years: max 300mg/day. Renal dysfunction (CrCl < 30 mL/min): max 100mg every 12 hours. Cirrhosis: max 50mg every 12 hours.

Children: < 17 yrs: not recommended.

Contraindications: Acute intoxication with alcohol, hypnotics, narcotics, centrally-acting analgesics, other opioids, or psychotropic drugs.

Warnings/Precautions: Do not give to opioid-dependent patients. Respiratory depression. Increased intracranial pressure. Head injury. Seizure disorders. Acute abdomen. Renal or hepatic impairment. Suicidal ideation. Drug abusers. Avoid abrupt cessation. Elderly (esp. > 75 years). Labor & delivery, pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Concomitant MAOIs, carbamazepine, alcohol, or other forms of tramadol: not recommended. Increased risk of seizures and/or serotonin syndrome with SSRIs, SNRIs, tricyclics, cyclobenzaprine, promethazine, opioids, MAOIs, naloxone, triptans, linezolid, lithium, neuroleptics, others that lower seizure threshold. Potentiation with alcohol, other CNS depressants; reduce dose. May

be potentiated by CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine, amitriptyline). May potentiate digoxin, warfarin. May be affected by CYP3A4 inhibitors (eg, ketoconazole, erythromycin) or CYP3A4 inducers (eg, rifampin, St. John's Wort).

Adverse reactions: Dizziness, GI upset, constipation, headache, somnolence, pruritus, CNS stimulation, asthenia, sweating, dry mouth, seizures, anaphylaxis.

How supplied: ER tabs–30; Tabs–100

TRAMADOL + ACETAMINOPHEN

ULTRACET Janssen

Opioid + non-opioid analgesic. Tramadol HCl 37.5mg, acetaminophen 325mg; tabs.

Indications: Short-term (≤ 5 days) management of acute pain.

Adults: 2 tabs every 4–6 hours; max 8 tabs/day. Renal dysfunction (CrCl < 30 mL/min): max 2 tabs every 12 hours.

Children: Not recommended.

Contraindications: Acute intoxication with alcohol, hypnotics, narcotics, centrally-acting analgesics, other opioids, or psychotropics.

Warnings/Precautions: Do not give to opioid-dependent patients. Hepatic impairment: not recommended. Respiratory depression. Increased intracranial pressure. Head injury. Seizure disorders. Acute abdomen. Suicidal ideation. Renal impairment. Avoid abrupt cessation. Elderly. Drug abusers. Labor & delivery, pregnancy (Cat.C), nursing mothers: not recommended.

Interactions: Concomitant MAOIs, carbamazepine, alcohol, other tramadol or acetaminophen-containing products: not recommended. Increased risk of seizures and/or serotonin syndrome with SSRIs, SNRIs, tricyclics, cyclobenzaprine, promethazine, opioids, MAOIs, naloxone, triptans, linezolid, lithium, neuroleptics, others that lower seizure threshold. Potentiation with alcohol, other CNS depressants; reduce dose. May be potentiated by CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine, amitriptyline). May potentiate digoxin, warfarin. May be affected by CYP3A4 inhibitors (eg, ketoconazole, erythromycin) or CYP3A4 inducers (eg, rifampin, St. John's wort).

Adverse reactions: Somnolence, constipation, dizziness, sweating, GI upset, anorexia, dry mouth, pruritus, insomnia, prostate disorders, seizures, anaphylaxis, hepatotoxicity (overdosage).

How supplied: Tabs–100

17F Topical pain relief

LIDOCAINE

LIDOCAINE JELLY (various)

Topical anesthetic. Lidocaine HCl 2%; aqueous.

Indications: Anesthesia in procedures of urethra, painful urethritis. Anesthetic lubricant for endotracheal intubation.

Adults and Children: See literature.

Also: Lidocaine**LIDOCAINE OINTMENT**

Lidocaine 5%; water miscible.

Indications: Anesthesia of oropharyngeal mucosa. Anesthetic lubricant for endotracheal intubation.**Adults:** Apply up to 6 inches (5g); max 17–20g/day.**Children:** <10yrs: apply up to 4.5mg/kg; avoid prolonged use or on large areas.**Warnings/Precautions:** Sepsis. Traumatized mucosa. Severe shock. Heart block. Monitor for familial malignant hyperthermia (eg, tachycardia, tachypnea). Avoid eyes. Do not eat for 1 hour after oral application. Children, elderly, debilitated, acutely ill: reduce dose. Pregnancy (Cat.B). Nursing mothers.**Adverse reactions:** CNS effects (eg, dizziness, visual disturbances, tremor, respiratory depression), bradycardia, hypotension.**How supplied:** Contact supplier.**LIDOCAINE****LIDODERM Endo**

Topical anesthetic. Lidocaine 5%; adhesive patch.

Indications: Postherpetic neuralgia.**Adults:** Apply to intact skin, covering most painful area. To adjust dose, cut patches before removing release liner. Remove if irritation or burning occurs; do not reapply until irritation subsides. May apply up to 3 patches at once for up to 12 hours of a 24-hour period. Hepatic impairment or debilitated: use smaller treatment areas.**Children: Not recommended.****Warnings/Precautions:** Do not apply to broken or inflamed skin. Avoid eyes, mucous membranes, longer duration of application, and application of more than 3 patches. Do not ingest; may be toxic to children and pets. Hepatic disease. Small patients. Pregnancy (Cat.B). Labor & delivery. Nursing mothers. **Interactions:** Toxicity may be potentiated by Class I antiarrhythmics (eg, tocainide, mexiletine). Additive effects with other local anesthetics.**Adverse reactions:** Local effects (eg, erythema, edema), allergic reactions (eg, urticaria, angioedema, bronchospasm).**How supplied:** Patches (10cm × 14cm)–30**SECTION 18:****POISONING & DRUG DEPENDENCE
18A Addiction/dependence****DISULFIRAM****ANTABUSE** Teva US Generics

Alcohol deterrent. Disulfiram 250mg, 500mg; tabs.

Indications: Adjunct in management of chronic alcoholic patients who want to remain sober.**Adults:** Abstain for at least 12 hrs. Initially 500mg once daily for 1–2 weeks then 250mg once daily; max 500mg daily. Continue until patient develops basis for self-control.**Children: Not established.**

R

Contraindications: Severe cardiovascular disease. Psychosis. Allergy to thiuram in pesticides and rubber. Concomitant metronidazole, paraldehyde, alcohol-containing products.**Warnings/Precautions:** Never administer when in a state of alcohol intoxication. Advise family members of alcohol effect. Diabetes. Hypothyroidism. Epilepsy. Cerebral damage. Nephritis. Hepatic cirrhosis or insufficiency. Ethylene dibromide inhalation. Monitor hepatic function, electrolytes, blood, CBCs. Alcohol trial in patients >50yrs: not recommended. Pregnancy. Nursing mothers.**Interactions:** See Contraindications. Alcohol-like reaction to metronidazole, paraldehyde, alcohol-containing drugs and elixirs, some so-called alcohol-free beverages, tonics, foods, aftershave, back rubs. Potentiates phenytoin, oral anticoagulants, isoniazid.**Adverse reactions:** Optic, peripheral and polyneuritis; peripheral neuropathy, drowsiness, rash, psychosis, hepatitis.**How supplied:** Tabs–100**NALTREXONE****REVIA** Teva US Generics

Opioid antagonist. Naltrexone HCl 50mg; scored tabs.

Indications: Adjunct in treatment of alcohol or narcotic dependence.**Adults:** Confirm 7–10 day opioid-free period, if questionable do Narcan challenge test (see literature). ≥18yrs: Alcoholism: 50mg daily. Narcotic dependence: Initially 25mg, if no withdrawal symptoms increase to 50mg daily; alternative dosing schedules: see literature.**Children: <18yrs: not recommended.****Contraindications:** Concomitant opioids, current opioid dependence, or acute opioid withdrawal. Failed Narcan challenge test or (+) urine screen for opioids. Acute hepatitis. Liver failure.**Warnings/Precautions:** Liver disease. Monitor liver function. Warn patients of danger of attempting to overcome opiate blockade. Severe renal dysfunction. Possible acute abstinence syndrome. Depression. Suicidal ideation. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Thioridazine increases sedation. Antagonizes opioids (eg, antitussives, antidiarrheals, analgesics). Disulfiram.**Adverse reactions:** Hepatotoxicity, withdrawal reactions; others, see literature.**How supplied:** Tabs–30, 100**18B Poisoning/overdose****ACETYL CYSTEINE****ACETADOTE** Cumberland

Acetylcysteine 200mg/mL; soln for IV infusion after dilution; preservative-free.

Indications: To minimize hepatic injury after acetaminophen overdose.

R

Adults and Children: Administer within 8 hours for maximal protection against hepatic injury.

Estimate time of acetaminophen ingestion. If <24 hours since overdose, obtain serum acetaminophen level 4 hours post-ingestion or as soon as possible thereafter and plot level on nomogram, draw second level 4–6 hours after first; if either falls above toxicity line, initiate therapy. If >8 hours post-ingestion, start treatment immediately. If time of ingestion unknown: consider empiric initiation of treatment. 300mg/kg given as 3 separate doses and administered over a total of 21 hours. See full labeling for preparation based on patient weight. >100kg: loading dose: 15,000mg over 1 hour; first maintenance dose: 5,000mg over 4 hours; second maintenance dose: 10,000mg over 16 hours.

Warnings/Precautions: Asthma. History of bronchospasm. Monitor for severe anaphylactoid reactions; may treat with antihistamines and epinephrine; interrupt or discontinue treatment if persistent. Monitor liver enzymes, creatinine, BUN, blood glucose, electrolytes. Hepatic or renal impairment: see full labeling. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Allergic reactions (eg, rash, urticaria/facial flushing, pruritus, edema, tachycardia, hypotension, bronchospasm), GI upset.

How supplied: Single-use vial (30mL)–4

DEFEROXAMINE

DEFERAL Novartis

Iron chelating agent. Deferoxamine mesylate 250mg/mL; for inj after reconstitution.

Indications: Acute iron intoxication. Chronic iron overload due to multiple transfusions.

Adults and Children: Routes other than IM: see literature. <3yrs: not recommended. ≥3yrs: acute iron toxicity: 1g IM initially followed by 500mg every 4 hours for 2 doses; repeat every 4–12 hours if needed; max 6g/day. Chronic iron overload: see literature.

Contraindications: Severe renal disease. Anuria.

Warnings/Precautions: Ocular or auditory disturbances. Perform visual acuity tests, slit-lamp exams, funduscopy and audiometry with prolonged therapy. High doses in patients with low ferritin levels may retard growth. Acute respiratory distress syndrome with high IV doses. Flushing, urticaria, hypotension, and shock if given rapid IV. Monitor changes in renal function. Discoloration of urine. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: Possible impairment of cardiac function with concomitant high dose Vit. C; give max adult dose: 200mg in divided doses. May cause temporary impairment of consciousness with prochlorperazine.

Adverse reactions: Localized skin reactions, hypersensitivity, tachycardia, hypotension, shock, dysuria, leg cramps, fever, GI upset; increased serum creatinine, acute renal failure, renal tubular disorder; rare: *Yersinia* infections, mucormycosis.

How supplied: Vials 500mg, 2g–4

DIGOXIN IMMUNE FAB

DIGIFAB BTG International

Digoxin binder. Digoxin Immune Fab (ovine) 40mg/vial; IV inj after reconstitution; preservative-free.

Indications: Digoxin toxicity or overdose.

Adults and Children: See literature. Dose based on amount of digoxin or digitoxin to be neutralized. Contents of 1 vial neutralizes 0.5mg digoxin.

Warnings/Precautions: Previous allergies to antibiotics, sheep antibodies, papain or papaya extracts. Monitor potassium, renal, and cardiac function. Postpone redigitalization until Fab fragments cleared. Interferes with digitalis immunoassays. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Symptoms of digoxin withdrawal. Hypokalemia.

How supplied: Single-use vial–1

FLUMAZENIL

ROMAZICON Roche

Benzodiazepine antagonist. Flumazenil 0.1mg/mL; IV inj.

Indications: Reversal of benzodiazepine sedative effects in overdose, general anesthesia or conscious sedation.

Adults: Overdose: Give dose over 30 seconds by IV infusion. Initially: 0.2mg. After 30 seconds (if needed), 0.3mg. Then 0.5mg at 60 second intervals up to 3mg cumulative dose. Usual range: 1–3mg. If partial response occurs at 3mg cumulative dose, may titrate up to 5mg cumulative dose. Conscious sedation, general anesthesia, resedation: see literature.

Children: <1yr: not recommended. 1–17yrs: for reversal of benzodiazepine-induced conscious sedation only. See literature.

Contraindications: Patients treated with benzodiazepines for life threatening conditions. Mixed overdose patients when seizures likely (esp. cyclic antidepressants).

Warnings/Precautions: Monitor for resedation (at least 2 hrs), respiratory depression, other residual benzodiazepine effects, seizures. Seizure disorders or risk. Drug or alcohol dependence. Head injury. Panic disorder. Hepatic disease. Counsel on post-procedure period (see literature). Labor & delivery: not recommended. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid use until neuromuscular blockade reversed. Avoid alcohol, sedatives for 18–24 hrs after treatment. Potentiates toxicity of cyclic antidepressant or mixed drug overdose.

Adverse reactions: Seizures, local reactions, dizziness, increased sweating, headache, blurred vision, GI upset, agitation, benzodiazepine withdrawal syndrome.

How supplied: Vials (5mL, 10mL)–10

NALOXONE

R

NARCAN Endo*Narcotic antagonist.* Naloxone 0.02mg/mL, 0.4mg/mL, 1mg/mL; IV, IM or SC inj; amps (paraben-free); vials.**Indications:** Reversal of narcotic depression, including respiratory. Diagnosis of acute opioid overdose.**Adults:** See literature. Post-op: 0.1–0.2mg IV, IM or SC, repeat 2–3 minutes until desired response. Overdose: 0.4–2mg IV, IM or SC, repeat 2–3 minutes; if no response after 10mg reevaluate. Both may require repeated doses depending on duration of narcotic activity.**Children:** See literature. Post-op: 0.005–0.01mg/kg IV, IM or SC, repeat 2–3 minutes until desired response. Overdose: 0.01mg/kg initially; inadequate response 0.1mg/kg body weight. Neonates, post-op: 0.01mg/kg, repeat 2–3 minutes until desired response.**Warnings/Precautions:** Possible acute abstinence syndrome. Monitor patients with satisfactory response due to long duration of some narcotics. Post-op use in cardiac disease. Pregnancy (Cat.B). Nursing mothers.**Interactions:** Caution with cardiotoxic drugs. Incomplete reversal of buprenorphine.**Adverse reactions:** Reversal of narcotic depression: nausea, vomiting, sweating, tachycardia, increase blood pressure, tremulousness, seizures, cardiac arrest. Post-op reversal of analgesia and excitement.**How supplied:** Amps 0.02mg, 1mg (2mL)–10 0.4mg (1mL)–10 Vials 0.4mg, 1mg (10mL)–1**PROTAMINE SULFATE**

R

PROTAMINE SULFATE Abraxis*Heparin antagonist.* Protamine sulfate 10mg/mL; soln for inj; preservative-free.**Indications:** Treatment of heparin overdose.**Adults:** Give by slow IV inj over 10 minutes. Determine dose by coagulation studies; dose requirement decreases with time elapsed after heparin administration. 1mg neutralizes ≥ 100 units of heparin; max 50mg/dose.**Children:** Not recommended.**Warnings/Precautions:** Avoid rapid administration. Fish allergy. Previous exposure to protamine (including insulin). Severe left ventricular dysfunction. Abnormal pulmonary hemodynamics. Previous vasectomy. Pregnancy (Cat.C). Nursing mothers.**Interactions:** Incompatible with certain antibiotics (eg, cephalosporins, penicillins).**Adverse reactions:** Hypotension, bradycardia, transient flushing, feeling of warmth, dyspnea, GI upset, lassitude, pulmonary edema, anaphylaxis, cardiovascular collapse, pulmonary vasoconstriction, pulmonary hypertension.**How supplied:** Vial (5mL)–25 25mL–1**SODIUM POLYSTYRENE SULFONATE**

R

KAYEXALATE Covis*Cation exchange resin.* Sodium polystyrene sulfonate; pwd; sodium content 4.1mEq/g.**Indications:** Hyperkalemia.**Adults:** See literature. Oral: 15g 1–4 times daily, as a susp. Rectal enema: 30–50g in 100mL every 6 hrs.**Children:** See literature. Use 1g per 1mEq of potassium as basis of calculation.**Contraindications:** Hypokalemia. Obstructive bowel disease. Neonates.**Warnings/Precautions:** Hypokalemia. Monitor electrolytes, ECG. Hypermagnesemia. CHF.

Hypertension. Edema. Risk of constipation/impaction (eg, history of impaction, chronic constipation, inflammatory bowel disease, ischemic colitis, vascular intestinal atherosclerosis, previous bowel resection, bowel obstruction); discontinue if significant constipation develops. Monitor for intestinal necrosis (esp. in children). Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid non-adsorbable cation donating antacids and laxatives (eg, magnesium hydroxide, aluminum hydroxide). Sorbitol may cause intestinal necrosis (concomitant use not recommended). Digoxin toxicity potentiated by hypokalemia. Reduces absorption of thyroxine, lithium.**Adverse reactions:** GI irritation/ulceration/necrosis, sodium retention, hypokalemia, hypocalcemia, hypomagnesemia, fecal impaction, ischemic colitis.**How supplied:** Jar (453g)–1**18C Smoking****BUPROPION**

R

BUPROBAN Teva US Generics*Aminoketone.* Bupropion HCl 150mg; sust-rel tabs.**Indications:** Aid in smoking cessation.**Adults:** Swallow whole. Set target quit date within 1–2 weeks after start. Treat for 7–12 weeks; reevaluate if no significant progress by week 7; up to 6 months' therapy has been shown to be effective.Avoid bedtime dosing. ≥ 18 yrs: initially 150mg once daily for 3 days, then 150mg twice daily at least 8 hrs apart; max 300mg/day in divided doses. Severe hepatic cirrhosis: max 150mg every other day. Mild-moderate hepatic cirrhosis, renal impairment: may give less often.**Children:** < 18 yrs: not recommended.**Contraindications:** Seizure disorders. Bulimia. Anorexia nervosa. Within 14 days of MAOIs. Abrupt withdrawal of sedatives or alcohol. Other forms of bupropion (eg, Wellbutrin).**Warnings/Precautions:** Psychiatric disorders (monitor). History or risk of seizures; discontinue if

seizure occurs: do not restart. Depression: clinical worsening or suicidal risk (monitor). Bipolar disorder. Psychosis. Hypertension. Unstable heart disease. Recent MI. CHF. Hepatic or renal impairment (monitor closely). Elderly. Labor & delivery. Pregnancy (Cat.C): not recommended, attempt nondrug treatment first. Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid alcohol. May use with transdermal nicotine (monitor for hypertension). MAOIs, levodopa, amantadine may increase toxicity. Caution with drugs that lower seizure threshold (eg, quinolones, theophylline, antiarrhythmics, anorectics, CNS stimulants, systemic steroids, antidepressants, antipsychotics), or factors that lower seizure threshold (eg, opiate or cocaine addiction, excessive use of alcohol or sedatives). Caution with drugs metabolized by CYP2B6 (eg, orphenadrine, cyclophosphamide) or CYP2D6 including tricyclic antidepressants, SSRIs (eg, paroxetine, fluoxetine, sertraline), antipsychotics (eg, haloperidol, risperidone, thioridazine), β -blockers (eg, metoprolol), Class 1C antiarrhythmics (eg, propafenone, flecainide); consider dose reduction. May be affected by metabolic enzyme inducers (eg, carbamazepine, phenobarbital, phenytoin) or inhibitors (eg, cimetidine). Smoking cessation potentiates theophylline, warfarin, insulin, β -blockers, pentazocine, oxazepam, tricyclics (eg, imipramine), caffeine, acetaminophen, adrenergic antagonists (eg, prazosin, labetalol), others. Smoking cessation antagonizes adrenergic agonists (eg, isoproterenol, phenylephrine), others.

Adverse reactions: Dry mouth, insomnia, dizziness, rash (rarely may be serious, eg, erythema multiforme, Stevens-Johnson syndrome), pruritus, constipation, asthenia, fever, headache, palpitations, sweating, visual changes, anorexia, GI effects, urinary frequency; serious neuropsychiatric symptoms (eg, behavioral changes, agitation, depression, suicidal ideation, hallucinations), cardiovascular effects.

How supplied: Tabs-60; Advantage Pack (1 $\times$ 60 tabs)-1

NICOTINE

OTC

COMMIT LOZENGE GlaxoSmithKline
Nicotine polacrilex 2mg, 4mg; contains phenylalanine.

Indications: Adjunct in smoking cessation therapy.

Adults: Use 2mg if patient smoked first cigarette ≥ 30 minutes after waking up; use 4mg if patient smoked first cigarette within 30 minutes of waking up. Dissolve over 20-30 minutes; minimize swallowing. ≥ 18 years: 1 lozenge every 1-2 hours (at least 9/day) for 6 weeks, then every 2-4 hours for 3 weeks, then every 4-8 hours for 3 weeks, then stop; max 5 lozenges/6 hours (20 lozenges/day).

Children: <18yrs: not recommended.

Contraindications: Concurrent smoking or use of other nicotine products.

Warnings/Precautions: Peptic ulcer disease. Diabetes. History of heart disease, recent heart attack, uncontrolled hypertension. Reevaluate if persistent indigestion, severe sore throat, or palpitations occurs. Low doses may be toxic to children and pets. Pregnancy (attempt non-drug treatment first). Nursing mothers.

Interactions: Do not eat or drink for 15 minutes before and during use. Smoking cessation potentiates theophylline, insulin, β -blockers, pentazocine, oxazepam, tricyclic antidepressants (eg, imipramine), caffeine, acetaminophen, adrenergic antagonists (eg, prazosin, labetalol), others. Smoking cessation antagonizes adrenergic agonists (eg, isoproterenol, phenylephrine), others.

Adverse reactions: Mouth or throat irritation, headache, upset stomach, hiccups, dizziness, palpitation, hypertension.

How supplied: Lozenges-72, 168

NICOTINE

OTC

NICODERM CQ GlaxoSmithKline
Nicotine 7mg/24hr, 14mg/24hr, 21mg/24hr; transdermal patch (clear or original color).

Indications: Adjunct in smoking cessation therapy.

Adults: Apply to clean, dry, nonhairy site on trunk or upper outer arm; rotate application site. Remove patch after 16 or 24 hours; if vivid dreams or other sleep disturbances occur, remove at bedtime and reapply in AM. >10 cigarettes/day: initially one 21mg patch daily for 6 weeks; then one 14mg patch daily for 2 weeks, then one 7mg patch daily for 2 weeks, then stop. ≤ 10 cigarettes/day: initially one 14mg patch daily for 6 weeks then one 7mg patch daily for 2 weeks, then stop.

Children: Not recommended.

Contraindications: Concurrent smoking or use of other nicotine products.

Warnings/Precautions: Avoid immediately post-MI, in arrhythmias, or severe or worsening angina pectoris. Hypertension. Vasospastic or coronary heart disease. Hepatic or severe renal impairment. Hyperthyroidism. Pheochromocytoma. Diabetes. Allergy to adhesive tape, other skin problems. Peptic ulcer disease. Low doses may be toxic to children and pets. Pregnancy (Cat.D): not recommended (attempt nondrug treatment first). Nursing mothers.

Interactions: Smoking cessation potentiates theophylline, insulin, β -blockers, pentazocine, oxazepam, tricyclic antidepressants (eg, imipramine), caffeine, acetaminophen, adrenergic antagonists (eg, prazosin, labetalol), others. Smoking cessation antagonizes adrenergic agonists (eg, isoproterenol, phenylephrine), others.

Adverse reactions: Local irritation, GI upset, headache, dizziness, palpitations, hypertension.

How supplied: Nicoderm CQ-7, 14; Clear Nicoderm CQ-14

SECTION 19: PSYCHIATRIC DISORDERS 19A ADHD/narcolepsy

AMPHETAMINE + DEXTROAMPHETAMINE

ADDERALL XR Shire

Amphetamine. Mixed salts of a single-entity amphetamine product (each cap contains equal parts dextroamphetamine saccharate, dextroamphetamine sulfate, amphetamine aspartate monohydrate, amphetamine sulfate); 5mg, 10mg, 15mg, 20mg, 25mg, 30mg; ext-rel caps.

Indications: Attention deficit hyperactivity disorder.

Adults and Children: Swallow whole or may sprinkle contents of caps on applesauce; do not chew beads. <6yrs: not studied. 6–12yrs: initially 10mg once daily in the AM, may increase by 5–10mg/day at weekly intervals; max 30mg/day. 13–17yrs: initially 10mg once daily in the AM; may increase to 20mg/day after 1 week. >17yrs: 20mg once daily in the AM. Switching from Adderall immediate-release: give total daily dose of immediate-release once daily in the AM.

Also: **Amphetamine + Dextroamphetamine** CII **ADDERALL** Teva US Generics

Mixed salts of a single-entity amphetamine product (each tab contains equal parts dextroamphetamine saccharate, dextroamphetamine sulfate, amphetamine aspartate monohydrate, amphetamine sulfate); 5mg, 7.5mg, 10mg, 12.5mg, 15mg, 20mg, 30mg; double-scored tabs.

Indications: Attention deficit disorder. Narcolepsy.

Adults and Children: Avoid late evening doses; give upon awakening and 4–6 hours apart. ADHD: <3yrs: not recommended. 3–5yrs: initially 2.5mg once daily, may increase by 2.5mg weekly. ≥6yrs: initially 5mg 1–2 times daily, may increase by 5mg weekly; usual max 40mg/day in 2–3 divided doses. Narcolepsy: <12yrs: use dextroamphetamine sulfate; ≥12yrs: usual range 5–60mg/day in divided doses.

Contraindications: Advanced arteriosclerosis. Symptomatic cardiovascular disease. Moderate-to-severe hypertension. Hyperthyroidism. Glaucoma. History of drug abuse. Agitation. During or within 14 days of MAOIs. Hypersensitivity to sympathomimetics.

Warnings/Precautions: Known structural cardiac abnormalities. Cardiomyopathy. Heart rhythm abnormalities. Coronary artery disease. Hypertension. CHF. Recent MI. Arrhythmias. Tourette's syndrome. Psychosis. Bipolar disorder. Depression. Seizure disorders. Monitor HR, BP, growth in children. Reevaluate periodically. Write Rx for smallest practical amount. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Potentiated by alkalinizers (eg, thiazides), tricyclic antidepressants,

propoxyphene, norepinephrine. Potentiates meperidine, norepinephrine, tricyclic antidepressants, phenobarbital, phenytoin. Antagonized by acidifiers, chlorpromazine, haloperidol, lithium. Antagonizes adrenergic blockers, antihistamines, veratrum alkaloids, antihypertensives. May delay absorption of phenytoin, phenobarbital, ethosuximide. Convulsions with propoxyphene overdose and amphetamines. May interfere with urinary steroid tests.

Adverse reactions: Anorexia, insomnia, abdominal pain, emotional lability, vomiting, nervousness, nausea, fever, weight loss; also Adults: dry mouth, headache, anxiety, agitation, dizziness, tachycardia, diarrhea, asthenia, UTIs; serious cardiovascular events, visual disturbances.

How supplied: Caps, tabs—100

ARMODAFINIL

NUVIGIL Teva CNS

Wakefulness promoter. Armodafinil 50mg, 150mg, 250mg; tabs.

Indications: To improve wakefulness in patients with excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome (OSAHS), narcolepsy and shift work sleep disorder (SWSD). Adjunct to standard treatment for underlying airway obstruction in OSAHS.

Adults: ≥17yrs: OSAHS, narcolepsy: 150mg or 250mg once daily in the AM. SWSD: 150mg one hour before starting shift. Severe hepatic impairment: reduce dose.

Children: <17yrs: not recommended.

Warnings/Precautions: Discontinue if rash appears (unless clearly not drug-related), or if angioedema, anaphylaxis, or multi-organ hypersensitivity reaction occurs. OSAHS: treat underlying obstruction; maintain CPAP use if indicated. History of LV hypertrophy or mitral valve prolapse syndrome (eg, ischemic ECG changes, chest pain, arrhythmias associated with CNS stimulants): not recommended. Recent MI. Unstable angina. Monitor BP. Psychosis. Depression. Mania. Severe hepatic or renal impairment. Reevaluate periodically. Elderly (may need to reduce dose). Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: May antagonize hormonal contraceptives; use alternative or additional contraception during and for 1 month after. Avoid alcohol. Caution with MAOIs. Armodafinil levels may be decreased by CYP3A4 inducers (eg, carbamazepine, phenobarbital, rifampin) and increased by CYP3A4 inhibitors (eg, ketoconazole, erythromycin). May reduce levels of drugs metabolized by CYP3A4 (eg, cyclosporine). May increase levels of drugs metabolized by CYP2C9 (eg, warfarin) or CYP2C19 (eg, phenytoin, diazepam, propranolol).

Adverse reactions: Headache, insomnia, other CNS effects, GI upset; rash (may be serious, eg, Stevens-Johnson, toxic epidermal necrolysis).

How supplied: Contact supplier.

ATOMOXETINE

R

STRATTERA Lilly

SNRI (selective norepinephrine reuptake inhibitor). Atomoxetine HCl 10mg, 18mg, 25mg, 40mg, 60mg, 80mg, 100mg; caps.

Indications: Attention deficit hyperactivity disorder (ADHD).

Adults and Children: Swallow whole. Give once daily in the AM, or in 2 evenly divided doses (in AM and late afternoon/early PM). <6yrs: not recommended. Acute: ≥ 6 yrs (≤ 70 kg): initially 0.5mg/kg per day; increase after at least 3 days to 1.2mg/kg per day; max 1.4mg/kg or 100mg per day (whichever is less); (>70kg): initially 40mg/day; increase after at least 3 days to 80mg/day, then after 2–4 weeks may increase to max 100mg/day. Maintenance: 6–15yrs: continue with same dose, reevaluate periodically; see literature. Concomitant potent CYP2D6 inhibitors: titrate above initial dose at 4-week intervals only if needed. Hepatic insufficiency (moderate): reduce dose by 50%; (severe): reduce dose by 75%. May discontinue without tapering.

Contraindications: During or within 14 days of MAOIs. Narrow angle glaucoma. Pheochromocytoma or history of. Severe cardiovascular disorders that might deteriorate with clinically important increases in HR and BP.

Warnings/Precautions: Increased risk of suicidal ideation in children and adolescents. Monitor closely for clinically worsening, suicidality and unusual changes in behavior, esp. during initial therapy and dose adjustments. Severe liver injury (discontinue if jaundice or elevated liver enzymes occur; do not restart). Structural cardiac abnormalities. Assess cardiovascular status and do physical exam. Hypertension. Tachycardia. Cardiovascular disease. Psychoses. Bipolar disorder. Depression. Monitor growth, BP/pulse (esp. at baseline and after dose increases), worsening aggressive behavior or hostility. Poor metabolizers (CYP2D6). Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: MAOIs: see Contraindications. May be potentiated by potent CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine). Increased cardiovascular effects with albuterol, pressor agents (eg, dobutamine, dopamine).

Adverse reactions: GI upset, fatigue, decreased appetite, abdominal pain, somnolence, weight loss, dizziness, headache, mood swings, tachycardia, hypertension, orthostatic hypotension, mydriasis; rare: severe liver injury, priapism. Adults also: constipation, dry mouth, insomnia, sexual dysfunction, urinary retention/hesitation, dysuria, dysmenorrhea, hot flush.

How supplied: Caps–30

DEXMETHYLPHENIDATE

CII

FOCALIN XR Novartis

Stimulant. Dexmethylphenidate HCl (single-isomer methylphenidate) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg, 35mg, 40mg; ext-rel caps (contains immediate-release + e-c del-rel beads).

Indications: Attention deficit hyperactivity disorder.

Adults: Take once daily in the AM. Swallow whole or sprinkle contents onto applesauce (swallow immediately); do not crush, chew or divide beads. Initially 10mg/day; may increase by 10mg weekly. Usual dose: 20–40mg/day. Doses >40mg/day: not recommended. Switching from racemic methylphenidate: give $\frac{1}{2}$ of total daily racemic methylphenidate dose. Switching from immediate-release dexmethylphenidate: give same total daily dose.

Children: Take once daily in the AM. Swallow whole or sprinkle contents onto applesauce (swallow immediately); do not crush, chew or divide beads. <6yrs: not recommended. Individualize. ≥ 6 yrs: initially 5mg/day; may increase by 5mg weekly. Usual dose: 10–30mg/day. Doses >30mg/day: not recommended. Switching from racemic methylphenidate: give $\frac{1}{2}$ of total daily racemic methylphenidate dose. Switching from immediate-release dexmethylphenidate: give same total daily dose.

Also: Dexmethylphenidate

CII

FOCALIN

Dexmethylphenidate HCl (single-isomer methylphenidate) 2.5mg, 5mg, 10mg +; tabs; + dye-free.

Adults and Children: <6yrs: not recommended.

Individualize. ≥ 6 yrs: initially 2.5mg twice daily. Switching from racemic methylphenidate (eg, Ritalin): $\frac{1}{2}$ of racemic methylphenidate dose. Allow at least 4 hours between doses. May increase by 2.5–5mg weekly; max 20mg/day.

Contraindications: Marked anxiety, tension, agitation. Glaucoma. History of tics or Tourette's syndrome in patient or family. During or within 14 days of MAOIs.

Warnings/Precautions: History of drug dependence or alcoholism. Known structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease, or other serious cardiac disease: not recommended. Hypertension. Heart failure. Recent MI. Ventricular arrhythmia. Assess cardiovascular status prior to treatment. Psychotic disorders. Bipolar disorder. Depression. Seizure disorders (discontinue if occur). Reduce dose or discontinue if paradoxical aggravation of symptoms occur. Reevaluate periodically. Monitor for worsening of aggressive behavior or hostility. Monitor growth, blood pressure, heart rate, CBC, differential, platelet counts. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Hypertensive crisis with MAOIs. Caution with pressor agents. May potentiate coumarin anticoagulants, anticonvulsants

(eg, phenobarbital, phenytoin, primidone), tricyclics (eg, imipramine, clomipramine, desipramine), SSRIs; adjust doses. Antagonizes antihypertensives. Caps: may be affected by drugs that affect pH (eg, antacids, acid suppressants).

Adverse reactions: Dyspepsia, dry mouth, decreased appetite, headache, anxiety, anorexia, insomnia; hypertension, tachycardia, visual disturbances, tics.

How supplied: Caps, tabs—100

DEXTROAMPHETAMINE

DEXEDRINE SPANSULE Amedra

Amphetamine. Dextroamphetamine sulfate 5mg, 10mg, 15mg; sust-rel caps.

Indications: Attention deficit hyperactivity disorder. Narcolepsy.

Adults: Individualize. Narcolepsy: 5–60mg daily in divided doses.

Children: Individualize. ADHD: <6yrs: not recommended. ≥6yrs: initially 5mg 1–2 times daily; may increase by 5mg/day at weekly intervals; usual max 40mg/day. Narcolepsy: 6–12yrs: initially 5mg daily; may increase by 5mg/day at weekly intervals. ≥12yrs: initially 10mg daily; may increase by 10mg/day at weekly intervals.

Contraindications: Cardiovascular disease. Hypertension. Arteriosclerosis. Hyperthyroidism. Glaucoma. Drug or alcohol abuse. Agitation. During or within 14 days of MAOIs. Hypersensitivity to sympathomimetics.

Warnings/Precautions: Structural cardiac abnormalities: see literature. Tourette's syndrome. Psychosis. Bipolar disorder. Aspirin sensitivity. Monitor growth. Abuse potential. Prescribe limited supply to minimize overdose. Reevaluate need for therapy after drug-free interval. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated with alkalinizers, MAOIs, tricyclic antidepressants, propoxyphene. Potentiates meperidine, norepinephrine, phenobarbital, phenytoin. Antagonized with acidifiers, psychotropics, lithium. Inhibits effects of adrenergic blockers, ethosuximide.

Adverse reactions: Hypertension, tachycardia, CNS overstimulation, dry mouth, GI disorders, anorexia, urticaria, visual disturbances.

How supplied: Caps—90

GUANFACINE

INTUNIV Shire

Central alpha-2A agonist. Guanfacine (as HCl) 1mg, 2mg, 3mg, 4mg; ext-rel tabs.

Indications: Attention deficit hyperactivity disorder (ADHD), as monotherapy or as an adjunct to stimulant medications.

Adults: ≥18yrs: not established.

Children: Swallow whole with water, milk, or other liquid. Do not give with high-fat meals. <6yrs: not recommended. 6–17yrs: Initially 1mg once daily; titrate by 1mg/day at 1-week intervals; usual max

4mg once daily. Monotherapy: improvements seen at doses of 0.05–0.08mg/kg once daily; doses up to 0.12mg/kg once daily may provide additional benefit. Adjunctive therapy: optimal dosage range: 0.05–0.12mg/kg/day. Reevaluate periodically. Withdraw gradually (by 1mg every 3–7 days).

Contraindications: Concomitant use with other forms of guanfacine.

Warnings/Precautions: Do not substitute with other forms of guanfacine on a mg-mg basis. Concomitant antihypertensives, other risks for hypotension, syncope, bradycardia, cardiovascular disease. Monitor heart rate, BP. Dehydration. Elevated temperature. Renal or hepatic impairment. Pregnancy (Cat.B). Nursing mothers.

Interactions: May be potentiated by CYP3A4/5 inhibitors (eg, ketoconazole). May be antagonized by CYP3A4 inducers (eg, rifampin). May potentiate valproic acid. Additive effects with other antihypertensives, CNS depressants (eg, benzodiazepines, antipsychotics, barbiturates).

Adverse reactions: Somnolence, sedation, fatigue, nausea, lethargy, hypotension, insomnia, dizziness, abdominal pain, dry mouth, constipation; bradycardia.

How supplied: Tabs—100

METHYLPHENIDATE

CONCERTA Janssen

Stimulant. Methylphenidate HCl 18mg, 27mg, 36mg, 54mg; ext-rel tabs.

Indications: Attention deficit hyperactivity disorder.

Adults and Children: Swallow whole with liquids. Take once daily in the AM. <6yrs: not established. Methylphenidate-naïve: 6–12yrs: initially 18mg once daily, max 54mg/day; 13–17yrs: initially 18mg once daily, max 72mg daily or 2mg/kg per day (whichever is less). 18–65yrs: initially 18mg or 36mg/day; max 72mg/day. Switching from methylphenidate 5mg 2 or 3 times daily: initially Concerta 18mg once daily. Switching from methylphenidate 10mg 2 or 3 times daily: initially Concerta 36mg once daily. Switching from methylphenidate 15mg 2 or 3 times daily: initially Concerta 54mg once daily. Switching from methylphenidate 20mg 2 or 3 times daily: initially Concerta 72mg once daily. For all: may adjust in 18mg/day increments at 1-week intervals; max 54mg/day for children; max 72mg/day for adolescents and adults.

Contraindications: Marked anxiety, tension, agitation. Glaucoma. Motor tics. Tourette's syndrome in patient or family. During or within 14 days of MAOIs.

Warnings/Precautions: History of drug dependence or alcoholism; monitor for abnormal behavior. Structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease: not recommended. Hypertension. Heart failure. Recent MI. Reduce dose or discontinue if paradoxical worsening of

symptoms occurs. Reevaluate periodically. Preexisting GI narrowing. Psychosis. Bipolar disorder. Seizure disorders; discontinue if occur. May exacerbate behavior disturbances, thought disorders; monitor for worsening aggressive behavior or hostility. Monitor growth, blood pressure, CBC, differential, platelet counts, vision. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Hypertensive crisis with MAOIs. Caution with pressor agents. May increase levels of anticonvulsants, coumarin anticoagulants, tricyclics, SSRIs (eg, fluoxetine).

Adverse reactions: Decreased appetite, headache, dry mouth, nausea, insomnia, anxiety, dizziness, weight loss, irritability, hyperhidrosis, hypertension, visual disturbances; tics, possible GI obstruction.

How supplied: Tabs-100

METHYLPHENIDATE

CII

METADATE CD UCB

Stimulant. Methylphenidate HCl 10mg, 20mg, 30mg, 40mg, 50mg, 60mg; ext-rel caps (contains immediate-release + ext-rel beads).

Indications: Attention deficit hyperactivity disorder.

Adults and Children: Take before breakfast.

Swallow whole or sprinkle contents onto applesauce (swallow immediately); do not crush, chew, or divide beads. <6yrs: not recommended. ≥6yrs: initially 20mg once daily, may increase weekly by 10–20mg/day; max 60mg once daily.

Also: Methylphenidate

METADATE ER

Methylphenidate HCl 20mg; ext-rel tabs; dye-free.

Indications: Attention deficit hyperactivity disorder. Narcolepsy.

Adults and Children: Swallow whole. <6yrs: not recommended. ≥6yrs: may use Metadate ER tabs in place of immediate-release products when the 8-hour dose of Metadate ER corresponds to the titrated 8-hour dose of immediate-release product; max 60mg daily.

Contraindications: During or within 14 days of MAOIs. Marked anxiety, tension, agitation. Severe depression. Psychosis. History of aggression. Suicidal tendency. Severe hypertension. Angina. Cardiac arrhythmias. Heart failure. Recent MI. Hyperthyroidism. Thyrotoxicosis. Glaucoma. History of tics or Tourette's syndrome in patient or family.

Warnings/Precautions: Discontinue if seizures or agitation occur. Reduce dose or discontinue if paradoxical worsening of symptoms occurs. Reassess periodically. Reevaluate therapy at puberty. Hypertension. Seizure disorders. Normal fatigue states. Emotionally unstable (eg, drug or alcohol abusers). Abuse potential. May exacerbate behavior disturbances, thought disorders. Monitor growth, BP, CBC, differential, and platelet counts. Interrupt therapy if growth suppression occurs. Structural cardiac abnormalities: see literature. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Caution with pressor agents, α_2 -agonists (eg, clonidine). May increase levels of anticonvulsants, oral anticoagulants, tricyclics, SSRIs, phenylbutazone. Antagonizes guanethidine.

Adverse reactions: Headache, anorexia, abdominal pain, insomnia, nervousness, CNS overstimulation, weight loss, nausea, dizziness, dyskinesias, hypertension, tachycardia, arrhythmias, Tourette's syndrome, toxic psychosis, seizures, blood dyscrasias, rash, visual disturbances.

How supplied: CD-100; ER-100

METHYLPHENIDATE

CII

RITALIN LA Novartis

Stimulant. Methylphenidate HCl 10mg, 20mg, 30mg, 40mg; ext-rel caps (one-half as immediate-release + one-half as enteric-coated, delayed-release beads).

Indications: Attention deficit hyperactivity disorder.

Adults and Children: Swallow whole or sprinkle contents onto applesauce (swallow immediately); do not crush, chew, or divide beads. <6yrs: not recommended. ≥6yrs: initially 20mg once daily in the AM, may increase by 10mg weekly; max 60mg/day. Switching from methylphenidate immediate-release (IR) or SR: give total daily dose of IR or SR once daily in the AM.

Also: Methylphenidate

RITALIN-SR

Methylphenidate HCl 20mg; sust-rel tabs; dye free.

Indications: Attention deficit hyperactivity disorder. Narcolepsy.

Adults and Children: Swallow whole. May use Ritalin-SR tabs in place of Ritalin tabs when the 8-hr dose of Ritalin-SR corresponds to the titrated 8-hr dose of Ritalin. Max 60mg/day.

Also: Methylphenidate

RITALIN

Methylphenidate HCl 5mg, 10mg+, 20mg+; tabs; +scored.

Adults: 10–60mg daily in 2–3 divided doses preferably 30–45 minutes before meals.

Children: <6yrs: not recommended. ≥6yrs: initially 5mg twice daily before breakfast and lunch. May increase by 5–10mg weekly; max 60mg/day.

Contraindications: Marked anxiety, tension, agitation. Glaucoma. History of tics or Tourette's syndrome in patient or family. During or within 14 days of MAOIs.

Warnings/Precautions: History of drug dependence or alcoholism; monitor for abnormal behavior. Structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, coronary artery disease: not recommended. Hypertension. Heart failure. Recent MI. Reduce dose or discontinue if paradoxical worsening of symptoms occurs. Reevaluate periodically. Psychosis. Bipolar disorder. Seizure disorders; discontinue if occur. May exacerbate behavior disturbances, thought disorders;

monitor for worsening aggressive behavior or hostility. Monitor growth, BP, CBC, differential, platelet counts, vision. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Avoid alcohol. Caution with pressor agents, α_2 -agonists (eg, clonidine). May increase levels of anticonvulsants, oral anticoagulants, tricyclics, phenylbutazone, antipsychotics (eg, haloperidol). Antagonizes guanethidine, other antihypertensives. Drugs that affect GI pH may affect release of methylphenidate from caps.

Adverse reactions: Insomnia, nervousness, CNS overstimulation, anorexia, weight loss, abdominal pain, nausea, dizziness, headache, dyskinesias, hypertension, tachycardia, arrhythmias, Tourette's syndrome, toxic psychosis, seizures, blood dyscrasias, rash, visual disturbances.

How supplied: Caps, tabs—100

MODAFINIL

CIV

PROVIGIL Teva CNS

Wakefulness-promoter. Modafinil 100mg, 200mg +; tabs; + scored.

Indications: To improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS), and shift work sleep disorder (SWSD). Adjunct to standard treatment for underlying airway obstruction in OSAHS.

Adults: ≥ 16 yrs: 200mg once daily in the AM; SWSD: take dose 1hr before work. Max 400mg/day. Severe hepatic impairment: 100mg once daily in the AM. Elderly, severe renal impairment, concomitant CYP3A4 substrates or drugs eliminated by CYP2C19: see literature.

Children: < 16 yrs: not recommended.

Warnings/Precautions: OSAHS: treat underlying obstruction. History of LV hypertrophy or symptomatic mitral valve prolapse (eg, ischemic ECG changes, chest pain, arrhythmias associated with CNS stimulants): not recommended. Discontinue if rash appears (unless clearly not drug-related), or if angioedema, anaphylaxis, or multi-organ hypersensitivity reaction occurs. Recent MI. Unstable angina. Hypertension (monitor BP). Cardiovascular disease. Psychosis. Severe hepatic or renal impairment. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: May antagonize hormonal contraceptives; use alternative or additional contraceptive method during and for one month after treatment. Avoid alcohol. Caution with MAOIs. Modafinil levels may be decreased by CYP3A4 inducers (eg, carbamazepine, phenobarbital, rifampin) and increased by CYP3A4 inhibitors (eg, ketoconazole, itraconazole). May decrease levels of drugs metabolized by CYP3A4 or CYP1A2 (eg, cyclosporine), or CYP2B6. May increase levels of drugs metabolized by CYP2C9 (eg, warfarin) or CYP2C19 (eg, phenytoin, diazepam, propranolol), and

levels of tricyclics and SSRIs in patients deficient in CYP2D6 (consider dose reduction). Monitor warfarin, phenytoin.

Adverse reactions: Headache, infection, GI upset, nervousness, rhinitis, back pain, anxiety, depression, insomnia, other CNS effects, rash (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis): may be serious, life-threatening, or become permanently disabling or disfiguring.

How supplied: Tabs—100

19B Anxiety/OCD

ALPRAZOLAM

CIV

XANAX XR Pfizer

Benzodiazepine. Alprazolam 0.5mg, 1mg, 2mg, 3mg; ext-rel tabs.

Indications: Panic disorder.

Adults: Swallow whole. ≥ 18 yrs: initially 0.5–1mg once daily, preferably in the AM; increase at intervals of at least 3–4 days by up to 1mg/day. Taper no faster than by 0.5mg every 3 days. Usual range: 3–6mg/day; max 10mg/day. Elderly or debilitated: initially 0.5mg/day. Switching from immediate-release alprazolam: give total daily dose of immediate-release once daily, preferably in the AM.

Children: < 18 yrs: not recommended.

Also: Alprazolam

CIV

XANAX

Alprazolam 0.25mg, 0.5mg, 1mg, 2mg +; scored tabs (+ multi-scored).

Indications: Anxiety. Panic disorder.

Adults: Adjust at intervals of at least 3–4 days. ≥ 18 yrs: Anxiety: initially 0.25–0.5mg 3 times daily; max 4mg daily in divided doses. Elderly or debilitated: initially 0.25mg 2–3 times daily. Panic disorder: initially 0.5mg 3 times daily; usual range: 5–6mg daily in divided doses; max 10mg/day.

Children: < 18 yrs: not recommended.

Contraindications: Acute narrow-angle glaucoma. Concomitant itraconazole, ketoconazole.

Warnings/Precautions: Not for use in untreated open-angle glaucoma. Reevaluate periodically. Change dose gradually. Withdrawal symptoms on abrupt cessation or dose reduction. Suicidal ideation. Psychosis. Mania. Renal, cardiovascular, hepatic, pulmonary dysfunction (monitor). Obesity. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: See Contraindications; other azole antifungals: not recommended. Potentiates CNS depression with alcohol, psychotropics, anticonvulsants, other CNS depressants. Potentiated by CYP3A inhibitors; reduce alprazolam dose; caution with cimetidine, nefazodone, fluvoxamine; caution with weaker CYP3A inhibitors (eg, fluoxetine, propoxyphene, oral contraceptives). Antagonized by CYP3A inducers (eg, carbamazepine). May increase levels of imipramine, desipramine.

Adverse reactions: CNS depression; impaired memory, coordination, or attention; dysarthria, ataxia, arthralgia, dyspnea, paradoxical excitement, increased salivation, withdrawal seizures, tremors, decreased libido, sexual dysfunction.

How supplied: XR-60; Tabs 0.25mg, 0.5mg, 1mg-100, 500, 1000; 2mg-100, 500

BUSPIRONE

BUSPAR Teva US Generics

Azaspiron. Buspirone HCl 5mg, 10mg, 15mg +, 30mg +; scored (+bi/trisected) tabs.

Indications: Anxiety.

Adults: Take consistently with regard to food. Initially 7.5mg twice daily, may increase by 5mg/day every 2-3 days. Usual range: 20-30mg/day; max 60mg/day.

Children: <6yrs: not recommended. 6-17yrs: doses of 7.5-30mg twice daily have been used.

Contraindications: Concomitant MAOIs.

Warnings/Precautions: Severe renal or hepatic impairment: not recommended. Elderly. Labor & delivery. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Hypertensive crisis with MAOIs: see Contraindications. Avoid alcohol, large amounts of grapefruit juice. Caution with other CNS drugs. May potentiate haloperidol, diazepam, nefazodone. Potentiated by nefazodone, verapamil, diltiazem, erythromycin, itraconazole, ketoconazole, ritonavir, other CYP3A4 inhibitors (use lower initial dose).

Antagonized by rifampin, dexamethasone, phenytoin, phenobarbital, carbamazepine, other CYP3A4 inducers.

Adverse reactions: Dizziness, GI upset, headache, nervousness, CNS or emotional effects, nonspecific chest pain, tinnitus, dream disturbances.

How supplied: Contact supplier.

CHLORDIAZEPOXIDE

LIBRIUM Valeant

Benzodiazepine. Chlordiazepoxide HCl 5mg, 10mg, 25mg; caps.

Indications: Anxiety.

Adults: Mild to moderate: 5-10mg 3-4 times daily. Severe: 20-25mg 3-4 times daily. Elderly or debilitated: 5mg 2-4 times daily.

Children: <6yrs: not recommended. ≥6yrs: 5mg 2-4 times daily. May increase to 10mg 2-3 times daily.

Warnings/Precautions: Drug or alcohol abuse. Suicidal tendencies. Depression. Renal or hepatic disease. Therapy for >4 months. Porphyria. Psychosis. Epilepsy. Change dose gradually. Monitor blood counts and liver function. Elderly. Debilitated. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Variable effects with anticoagulants. Avoid other psychotropics.

Adverse reactions: Drowsiness, CNS depression, ataxia, confusion, paradoxical excitement, memory

impairment, blood dyscrasias, jaundice, rash, edema, extrapyramidal effects, abuse potential.

How supplied: Caps 5mg-100; 10mg, 25mg-100, 500

CLOMIPRAMINE

ANAFRANIL Mallinckrodt

Tricyclic. Clomipramine HCl 25mg, 50mg, 75mg; caps.

Indications: Obsessive-compulsive disorder.

Adults: Take with food. Initially 25mg/day; titrate to 100mg/day in divided doses in first 2 weeks. Adjust as needed; max 250mg/day. May give total daily maintenance dose at bedtime.

Children: <10yrs: not recommended. Others: initially with food 25mg/day. Increase gradually over first 2 wks to 3mg/kg per day or 100mg/day (in divided doses) whichever is smaller. Further increases as needed to 3mg/kg per day or 200mg/day whichever is smaller. After titration, total daily dose may be given at bedtime.

Contraindications: During or within 14 days of MAOIs. Concomitant linezolid or IV methylene blue.

Acute post-MI.

Warnings/Precautions: Glaucoma. Adrenal tumors. Urinary retention. Suicidal tendencies. Cardiovascular disease. Epilepsy or other seizure risk. Psychosis.

Mania/hypomania. Bipolar disorder. Hepatic or renal dysfunction. Hyperthyroidism. ECT. Surgery. Avoid abrupt cessation. Reevaluate periodically. Write R for smallest practical amount. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Hyperpyretic crisis, seizures, coma and death with MAOIs. Risk of serotonin syndrome with linezolid or IV methylene blue. Potentiates alcohol, other CNS depressants, anticholinergics, sympathomimetics, other protein-bound drugs. Potentiated by CYP2D6 and/or CYP1A2 inhibitors; monitor plasma levels with cimetidine, SSRIs, phenothiazines, type 1C antiarrhythmics (eg, quinidine). Antagonized by barbiturates, carbamazepine, phenytoin, other CYP450 inducers. Caution with drugs that lower seizure threshold. Blocks guanethidine, clonidine.

Adverse reactions: Seizures, male sexual dysfunction, hyperthermia, anticholinergic effects, nausea, dyspepsia, anorexia, somnolence, dizziness, nervousness, changed libido, weight gain, visual changes, blood dyscrasias, neuropsychiatric disturbances.

How supplied: Caps-30

CLONAZEPAM

KLONOPIN Roche

Benzodiazepine. Clonazepam 0.5mg +, 1mg, 2mg; tabs; + scored.

Also: Clonazepam

CLONAZEPAM ORALLY-DISINTEGRATING TABLETS (various)

Clonazepam 0.125mg, 0.25mg, 0.5mg, 1mg, 2mg; orally-disintegrating tabs.

Indications: Panic disorder.

Adults: >18yrs: initially 0.25mg twice daily; after 3 days increase to 1mg/day; then may increase every 3 days by 0.125–0.25mg twice daily; max 4mg/day. Orally-disintegrating tabs: dissolve in mouth; swallow with or without water.

Children: <18yrs: **not recommended.**

Contraindications: Significant liver disease. Acute narrow-angle glaucoma.

Warnings/Precautions: Suicidal tendencies (monitor). Chronic respiratory disease. Renal impairment. Avoid abrupt cessation. Reevaluate periodically. Monitor blood counts, liver function. Elderly. Labor & delivery, pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Adjust anticonvulsants if needed. Absence seizures with valproate. Caution with drugs that inhibit CYP3A (eg, azole antifungals). Antagonized by CYP450 inducers (eg, phenytoin, carbamazepine, phenobarbital).

Adverse reactions: CNS effects (esp. depression), hypersalivation, liver disorders, GI upset, blood dyscrasias, paradoxical reactions.

How supplied: Tabs–100; Orally-disintegrating tabs–contact supplier

DIAZEPAM

CIV

VALIUM Roche

Benzodiazepine. Diazepam 2mg, 5mg, 10mg: scored tabs.

Indications: Anxiety.

Adults: 2–10mg 2–4 times daily. Elderly, debilitated: initially 2–2.5mg 1–2 times daily; increase gradually.

Children: <6months: **not recommended.**

≥6months: initially 1–2.5mg 3–4 times daily; increase gradually.

Also: Diazepam

CIV

DIAZEPAM INJECTION

Diazepam 5mg/mL; contains propylene glycol 40%, ethyl and benzyl alcohol.

Adults: Moderate: 2–5mg. Severe: 5–10mg. Both deep IM or slow IV (5mg/min). May repeat in 3–4 hours. Do not use small vein.

Children: **Not recommended.**

Contraindications: Acute narrow-angle glaucoma.

Warnings/Precautions: Not for use in untreated open-angle glaucoma. Inj not for use in shock, coma, acute alcohol intoxication, or obstetrical conditions.

Discontinue if paradoxical reaction occurs. Drug or alcohol abuse. Depression. Suicidal tendencies. Renal or liver dysfunction. Avoid abrupt cessation. May increase tonic-clonic seizures. Reevaluate periodically. Monitor blood counts, liver function. Elderly. Debilitated. Psychosis, pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants (consider reducing opioid doses by at least ½). Increased serum levels with cimetidine. Potentiated by sertraline. Inj: hypotension, muscle weakness with narcotics, barbiturates, alcohol.

Adverse reactions: CNS depression, ataxia, memory impairment, paradoxical excitement, salivation changes, neutropenia, jaundice. Inj: apnea, cardiac arrest, venous thrombosis, phlebitis, status epilepticus (when treating petit mal).

How supplied: Tabs 2mg–100; Tabs 5mg, 10mg–100, 500; Vials (10mL)–contact supplier

DOXEPIN

R

DOXEPIN HCl CAPSULES (various)

Tricyclic. Doxepin (as HCl) 10mg, 25mg, 50mg, 75mg, 100mg, 150mg; caps.

Also: Doxepin

R

DOXEPIN HCl CONCENTRATE

Doxepin (as HCl) 10mg/mL.

Indications: Anxiety.

Adults: Soln: dilute with 4oz juice, water, or milk.

Mild: 25–50mg/day. Mild to moderate: initially 75mg/day; range 75–150mg/day. Severe: max 300mg/day. May give as single (up to 150mg) or divided doses; 150mg caps for maintenance only.

Children: **Not recommended.**

Contraindications: During or within 14 days of MAOIs. Acute post MI. Urinary retention. Glaucoma.

Warnings/Precautions: Cardiovascular disease.

Epilepsy. Suicidal tendencies. Psychosis. Diabetes. Avoid abrupt cessation. Poor metabolizers (those with reduced CYP2D6 activity). Elderly. Pregnancy. Nursing mothers.

Interactions: Hyperpyretic crisis, convulsions, death with MAOIs. Potentiates CNS depression of alcohol; cimetidine; other CYP2D6 substrates.

Antagonized by barbiturates, carbamazepine, phenytoin. Paralytic ileus, hyperpyrexia with anticholinergics. May block guanethidine.

Adverse reactions: CNS effects (eg, drowsiness, overstimulation, extrapyramidal symptoms), anticholinergic effects, hypotension, GI upset, photosensitivity, endocrine effects.

How supplied: Contact supplier.

DULOXETINE

R

CYMBALTA Lilly

Serotonin and norepinephrine reuptake inhibitor.

Duloxetine (as HCl) 20mg, 30mg, 60mg; e-c pellets in caps.

Indications: Generalized anxiety disorder (GAD).

Adults: Swallow whole. Initially 60mg once daily (may start at 30mg once daily for 1 week then increase to 60mg once daily); usual target 60mg/day (doses up to 120mg/day have been given; if needed, may increase by increments of 30mg/day). Maintenance: 60–120mg once daily.

Children: **Not recommended.**

Contraindications: Allow at least 14 days after MAOI discontinuance before starting duloxetine; allow at least 5 days after duloxetine discontinuance before starting an MAOI. Concomitant linezolid or IV methylene blue. Uncontrolled narrow-angle glaucoma.

Warnings/Precautions: Suicidal tendencies (monitor). Severe renal impairment (CrCl <30mL/min), end stage renal disease, hepatic insufficiency, evidence of chronic liver disease, or substantial alcohol use: not recommended. History of seizure or mania/hypomania. Controlled narrow-angle glaucoma. Decreased GI motility. Cardiac disease. Monitor BP prior to and during therapy. Diabetes. Avoid abrupt cessation. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; consider tapering, see literature for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant thioridazine (may cause arrhythmias): not recommended. Potentiated by CYP1A2 inhibitors; avoid (eg, cimetidine, fluvoxamine, quinolones). May potentiate or be potentiated by CYP2D6 inhibitors (eg, paroxetine, fluoxetine, quinidine) or substrates (eg, tricyclics, phenothiazines, type 1C antiarrhythmics) or other highly protein-bound drugs; caution with CYP2D6 substrates with narrow therapeutic indexes. Caution with potent CYP1A2 inhibitors, antihypertensives, other drugs that induce orthostatic hypotension. Caution with triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort; may cause serotonin syndrome. Monitor concomitant CNS-acting drugs, and with those that affect gastric pH (eg, proton pump inhibitors). Increased bleeding risk with aspirin, anticoagulants, NSAIDs.

Adverse reactions: Nausea, dry mouth, constipation, somnolence, hyperhidrosis, decreased appetite, weight changes, GI disturbances, fatigue, dizziness, increased sweating, mania/hypomania, tremor, blurred vision, insomnia, hot flushes, urinary hesitation/retention, abnormal ejaculation, genital disorders, decreased libido, increased BP, orthostatic hypotension, syncope, hepatotoxicity (eg, elevated liver transaminases, cholestatic jaundice); discontinue if occurs, hyponatremia, asthenia, others; rare: seizure.

How supplied: Caps 20mg-60; 30mg-30, 90, 1000; 60mg-30, 1000

ESCITALOPRAM

LEXAPRO Forest
SSRI. Escitalopram (as oxalate) (single-isomer citalopram) 5mg, 10mg +, 20mg +; tabs (+ scored).

Also: Escitalopram
LEXAPRO ORAL SOLUTION
Escitalopram (as oxalate) 1mg/mL; peppermint flavor; contains parabens.

Indications: Generalized anxiety disorder.

Adults: Initially 10mg once daily; may increase to 20mg once daily after 1 week. Elderly or hepatic impairment: 10mg once daily.

Children: Not recommended.

Contraindications: Concomitant pimozide, linezolid, IV methylene blue. During or within 14 days of MAOIs; do not start an MAOI during or within 14 days of escitalopram.

Warnings/Precautions: Suicidal tendencies (monitor). History of seizures or mania/hypomania. Monitor for serotonin syndrome; discontinue if occurs. Hepatic or severe renal impairment (CrCl <20mL/min). ECT. Risk of bleeding events. Conditions that affect metabolic or hemodynamic responses. Recent MI. Unstable heart disease. Avoid abrupt cessation. Reevaluate periodically. Write Rx for smallest practical amount. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; see full labeling for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Do not give with citalopram. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. Caution with drugs that affect coagulation (eg, warfarin, aspirin, NSAIDs). May be antagonized by carbamazepine. Caution with drugs metabolized by CYP2D6 or other centrally-acting drugs. Increases metoprolol levels.

Adverse reactions: Insomnia, ejaculation disorder, nausea, increased sweating, fatigue, somnolence, decreased libido, anorgasmia; hyponatremia.

How supplied: Tabs-100; Soln-240mL

FLUOXETINE

PROZAC Lilly
SSRI. Fluoxetine (as HCl) 10mg, 20mg, 40mg; caps.

Also: Fluoxetine
FLUOXETINE HCl ORAL SOLUTION (various)
Fluoxetine (as HCl) 20mg/5mL; mint flavor.

Indications: Panic disorder. Obsessive-compulsive disorder (OCD).

Adults: Panic disorder: initially 10mg/day in AM; increase after 1 week to 20mg/day; max 60mg/day. OCD: initially 20mg daily in AM; may give doses >20mg/day in 2 divided doses (AM and noon); max 80mg/day. Both: titrate over several weeks. Hepatic impairment (reduce dose); switching to or from MAOIs: see full labeling.

Children: <7yrs: not recommended. 7-17yrs: OCD: initially 10mg/day; may increase after 2 weeks to 20mg/day; range 20-60mg/day. Lower weight children: range 20-30mg/day.

Contraindications: Concomitant MAOIs during or within at least 5 weeks of discontinuing fluoxetine. Within 14 days of discontinuing an MAOI. Concomitant linezolid or IV methylene blue. Concomitant pimozide, thioridazine (may cause QTc prolongation).

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults; monitor for clinical worsening or changes. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs/symptoms; discontinue if occurs. Discontinue if unexplained allergic reaction occurs. Renal or hepatic dysfunction.

History of seizures or mania/hypomania. Recent MI. Unstable heart disease. ECT (prolonged seizures). Reevaluate periodically in long-term use. Avoid abrupt cessation. Monitor weight. Conditions that affect metabolism or hemodynamic responses. Volume depletion. Diabetes. Write $\mathbb{R}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C; avoid 3rd trimester or consider lower dose; see full labeling for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Do not start with concomitant linezolid or IV methylene blue; if treatment is necessary, discontinue fluoxetine before starting; monitor for serotonin syndrome for 5 weeks or until 24 hours after last dose of linezolid or IV methylene blue, whichever comes first. Do not start thioridazine within at least 5 weeks of discontinuing fluoxetine. Caution with concomitant triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort, linezolid, IV methylene blue; may cause serotonin syndrome. May potentiate protein-bound drugs (eg, warfarin, digoxin) and those metabolized by CYP2D6 (eg, tricyclics, vinblastine, flecainide). May potentiate carbamazepine, phenytoin. Monitor lithium, phenytoin, warfarin, tricyclics. Caution with benzodiazepines (eg, diazepam, alprazolam), antipsychotics (eg, clozapine, haloperidol), other CNS drugs. Increased risk of bleeding with NSAIDs, aspirin, warfarin, others that affect coagulation. Hyponatremia with diuretics.

Adverse reactions: Nausea, CNS stimulation (eg, anxiety, nervousness, insomnia), somnolence, headache, mania/hypomania, anorexia, weight loss, tremor, asthenia, sexual dysfunction, sweating, GI disturbances, respiratory symptoms, motor impairment, serum sickness, hypo- or hyperglycemia, rash (may be serious), urticaria, pruritus; rarely: platelet dysfunction. Children: thirst, hyperkinesia, agitation, personality disorder, epistaxis, urinary frequency, menorrhagia.

How supplied: Caps 10mg–100; 20mg–30, 100, 2000; 40mg–30; Liq–contact supplier

FLUOXAMINE

$\mathbb{R}$

FLUOXAMINE (various)
SSRI. Fluvoxamine maleate 25mg, 50mg+, 100mg+; tabs; + scored.

Indications: Obsessive-compulsive disorder.

Adults: ≥ 18 yrs: initially 50mg at bedtime, increase in 50mg increments at 4–7 day intervals; range 100–300mg/day; max 300mg/day. Divide total daily doses >100 mg into 2 doses; give larger portion at bedtime. Hepatic impairment: use lower initial dose and titrate more slowly.

Children: Females may respond to lower dose.

< 8 yrs: not recommended. 8–17 yrs: initially 25mg at bedtime, increase in 25mg increments at 4–7 day intervals; usual range 50–200mg/day. Max 8–11 yrs: 200mg/day; 12–17 yrs: 300mg/day. Divide total daily doses >50 mg into 2 doses; give larger portion at

bedtime. Hepatic impairment: use lower initial dose and titrate more slowly.

Contraindications: Concomitant alosetron, tizanidine, pimoizide, thioridazine, mesoridazine, ramelteon. During or within 14 days of MAOIs.

Warnings/Precautions: Liver dysfunction. History of seizures (discontinue if occurs), mania/hypomania, or drug abuse. ECT. Cardiac or cardiovascular disease. Diseases that affect metabolism or hemodynamic response. SIADH, edema, fluid loss, adrenal disorders, displacement syndromes (monitor electrolytes, BUN, creatinine). Reduced activity of CYP2D6. Suicidal tendencies. Write $\mathbb{R}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Prolongation of QT interval with pimoizide, thioridazine, mesoridazine. Avoid alcohol. Potentiated by other serotonergic drugs, sumatriptan, lithium, tryptophan. Potentiates diazepam (not recommended), triazolam and alprazolam (reduce their doses by at least $\frac{1}{2}$), theophylline (reduce its dose by $\frac{2}{3}$ and monitor), warfarin, carbamazepine, tricyclic antidepressants (reduce their doses and monitor), propranolol, metoprolol (reduce their doses), clozapine, methadone, tacrine, midazolam. Caution with drugs that inhibit CYP2D6 (eg, quinidine) or 3A4, phenytoin, diltiazem. Monitor mexiletine levels. Smokers may have increased metabolism.

Adverse reactions: Somnolence, insomnia, nervousness, tremor, GI upset, anorexia, dry mouth, abnormal ejaculation, asthenia, urinary frequency, sweating, decreased libido, rhinitis, anorgasmia, taste perversion. Children: also agitation, depression, dysmenorrhea, flatulence, hyperkinesia, rash, weight decrease.

How supplied: Contact supplier.

LORAZEPAM

CIV

ATIVAN Biovail

Benzodiazepine. Lorazepam 0.5mg, 1mg+, 2mg+; tabs; + scored.

Indications: Anxiety.

Adults: Give in 2 or 3 divided doses, with largest dose taken at bedtime. Initially 2–3mg daily; range: 1–10mg daily. Elderly or debilitated: initially 1–2mg daily; adjust gradually if needed.

Children: Not recommended.

Contraindications: Acute narrow-angle glaucoma.

Warnings/Precautions: Therapy for >4 months.

Avoid abrupt cessation. Change dose gradually.

Discontinue if paradoxical reactions occurs. Drug or alcohol abuse. Depression. Suicidal tendencies. Renal, hepatic, or pulmonary dysfunction. Seizure disorder. Reevaluate periodically. Monitor blood counts, liver function with long-term use. Elderly. Debilitated. Psychosis, pregnancy, nursing mothers: not recommended.

Interactions: Potentiation of CNS depression with alcohol, other CNS depressants. May be potentiated

by probenecid or valproate (reduce lorazepam dose by 50%).

Adverse reactions: CNS depression (esp. sedation), dizziness, weakness, unsteadiness, transient memory impairment, disorientation, nausea, headache, sleep disturbances, agitation, abuse potential.

How supplied: 0.5mg, 2mg-100; 1mg-100, 1000

OXAZEPAM

CIV

OXAZEPAM (various)

Benzodiazepine. Oxazepam 10mg, 15mg, 30mg; caps.

Also: Oxazepam

CIV

OXAZEPAM TABLETS

Oxazepam 15mg; tabs; contains tartrazine.

Indications: Anxiety.

Adults: Mild to moderate: 10-15mg 3-4 times daily. Severe: 15-30mg 3-4 times daily.

Children: Not recommended.

Contraindications: Psychosis.

Warnings/Precautions: Renal, cardiovascular, or liver disease. Change dose gradually. Reevaluate periodically. Aspirin sensitivity (15mg tabs only). Monitor blood counts and liver function. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants.

Adverse reactions: CNS depression, drowsiness, dizziness, memory impairment, headache, ataxia, paradoxical excitement, hypotension, rash, nausea, edema, slurred speech, jaundice, blood dyscrasias, abuse potential.

How supplied: Contact supplier.

PAROXETINE

R

PAXIL CR GlaxoSmithKline

SSRI. Paroxetine (as HCl) 12.5mg, 25mg, 37.5mg; controlled-release e-c tabs.

Indications: Panic disorder. Social anxiety disorder.

Adults: Swallow whole. Give once daily, usually in the AM, adjust by 12.5mg/day at 1-week intervals. Panic disorder: initially 12.5mg/day; max 75mg/day. Social anxiety disorder: initially 12.5mg/day; max 37.5mg/day. Elderly, debilitated, severe hepatic or renal impairment: initially 12.5mg once daily; max 50mg/day.

Children: Not recommended.

Also: Paroxetine

R

PAXIL

Paroxetine (as HCl) 10mg+, 20mg+, 30mg, 40mg; tabs; + scored.

Also: Paroxetine

R

PAXIL SUSPENSION

Paroxetine (as HCl) 10mg/5mL; orange-flavored liq.

Indications: Panic disorder. Social anxiety disorder. Obsessive-compulsive disorder (OCD). Generalized anxiety disorder (GAD). Posttraumatic stress disorder (PTSD).

Adults: Give once daily, usually in the AM, adjust by 10mg/day at 1-week intervals. Panic disorder: initially

10mg/day; usual 40mg/day; max 60mg/day. Social anxiety disorder: 20mg/day; max 60mg/day. OCD: initially 20mg/day, usual 40mg/day; max 60mg/day. GAD or PTSD: 20mg/day; max 50mg/day. Elderly, debilitated, severe renal or hepatic impairment: initially 10mg/day; max 40mg/day.

Children: Not recommended.

Contraindications: Concomitant pimozide, linezolid, IV methylene blue, thioridazine. During or within 14 days of MAOIs.

Warnings/Precautions: Suicidal tendencies (monitor). History of seizures (discontinue if occurs), mania/hypomania. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs and symptoms; discontinue if occurs. Conditions that affect metabolism or hemodynamic response. Cardiac disease. ECT. Narrow angle glaucoma. Write R for smallest practical amount. Avoid abrupt cessation; reduce dose gradually. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.D); avoid use. Nursing mothers.

Interactions: See Contraindications. Do not start MAOI until at least 2 weeks after discontinuing paroxetine. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. Potentiation with other protein bound drugs. Caution with drugs that affect coagulation (eg, warfarin, NSAIDs). Potentiated by cimetidine. Antagonized by fosamprenavir/ritonavir. May affect, or be affected by, drugs metabolized by CYP2D6, including tricyclic antidepressants, fluoxetine, phenothiazines, risperidone, atomoxetine, tamoxifen, Class 1C antiarrhythmics, quinidine. Monitor digoxin, phenytoin, phenobarbital, theophylline, warfarin. Reduce procyclidine dose if anticholinergic effects occur. Hormonal contraceptives and PMDD treatment: see literature.

Adverse reactions: GI upset, asthenia, sweating, decreased appetite, somnolence, dizziness, insomnia, nervousness, headache, decreased libido, tremor, akathisia, dry mouth, abnormal ejaculation, genital disorders, impotence, hyponatremia, abnormal bleeding, others; serious discontinuation symptoms (monitor); rare: neuroleptic malignant syndrome.

How supplied: CR-30; Tabs-30; Susp-250mL

PROCHLORPERAZINE

R

PROCHLORPERAZINE (various)

Piperazine phenothiazine. Prochlorperazine (as maleate) 5mg, 10mg; tabs.

Indications: Short-term generalized anxiety.

Adults: 5mg 3-4 times daily; max 20mg/day. Do not use >12 weeks.

Children: Not recommended.

Contraindications: Coma. CNS depression. Pediatric surgery. Children <2yrs or <20lbs.

Warnings/Precautions: Discontinue 48 hrs before to 24 hrs after myelography. Cardiovascular disease. Epilepsy. Bone marrow depression. Reye's syndrome. Glaucoma. History of breast cancer. Exposure to extreme heat. Monitor blood, liver, and ocular function. Write $\bar{x}$ using fractions rather than decimals. Children with acute illness or dehydration. Debilitated. Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Potentiates α -blockers. Levels of both drugs increased with propranolol. May potentiate phenytoin; monitor for toxicity. Adjust anticonvulsant doses. May antagonize oral anticoagulants. Hypotension potentiated with thiazide diuretics. Antagonized by anticholinergics. Decreases guanethidine effects. Monitor for neurologic toxicity with lithium; discontinue if occurs. May cause false (+) PKU test.

Adverse reactions: Drowsiness, dizziness, amenorrhea, blurred vision, other anticholinergic effects, skin reactions, hypotension, cholestatic jaundice, photosensitivity, leukopenia, agranulocytosis, neuroleptic malignant syndrome, agitation, insomnia, dystonias, extrapyramidal reactions, pseudoparkinsonism, tardive dyskinesia, may mask emetic signs of disease, lowered seizure threshold, EKG changes, aspiration, deep sleep, hyperprolactinemia, paradoxical excitement in children.

How supplied: Contact supplier.

SERTRALINE

ZOLOFT Pfizer

SSRI. Sertraline (as HCl) 25mg, 50mg, 100mg; scored tabs.

Also: Sertraline

ZOLOFT ORAL CONCENTRATE

Sertraline (as HCl) 20mg/mL; soln; contains alcohol 12%. Dilute just before administering in 4oz water, ginger ale, lemon/lime soda, lemonade, or orange juice.

Indications: Panic disorder. Posttraumatic stress disorder (PTSD). Obsessive-compulsive disorder (OCD). Social anxiety disorder.

Adults: Give once daily (AM or PM). Panic or social anxiety disorder, PTSD: initially 25mg/day, increase after 1 week to 50mg/day; titrate at intervals of at least 1 week. OCD: Initially 50mg/day; may increase at 1-week intervals. For all: max 200mg/day.

Children: <6yrs: not recommended. Give once daily (AM or PM). OCD: 6–12yrs: initially 25mg/day. 13–17yrs: initially 50mg/day. May increase at 1-week intervals; max 200mg/day.

Contraindications: Concomitant MAOIs during or within 14 days of discontinuing sertraline. Within 14 days of discontinuing an MAOI. Concomitant linezolid or IV methylene blue. Concomitant pimozide. Oral soln: concomitant disulfiram.

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents,

and young adults; monitor for clinical worsening or changes. Monitor for signs/symptoms of serotonin syndrome; discontinue if occurs. Monitor for mania/hypomania. Seizure disorders. Hepatic dysfunction (reduce dose or prolong dosing interval). Cardiac disease. Conditions that affect metabolism or hemodynamic response. History of glaucoma. Volume depleted. Monitor weight. Avoid abrupt cessation. Reevaluate periodically in long-term use. Write $\bar{x}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Do not start with concomitant linezolid or IV methylene blue; if treatment is necessary, discontinue sertraline before starting; monitor for serotonin syndrome for 2 weeks or until 24 hours after last dose of linezolid or methylene blue, whichever comes first. Risk of serotonin syndrome with concomitant serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) and with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. May potentiate or be potentiated by cimetidine, protein bound drugs (eg, warfarin, digitoxin). Caution with other CNS drugs and drugs metabolized by CYP2D6 (eg, tricyclics, flecainide, propafenone). Potentiates diazepam, tolbutamide. Monitor lithium, warfarin, tricyclics. Monitor patients on sumatriptan for serotonin syndrome (eg, weakness, incoordination, hyperreflexia). Increased risk of bleeding with NSAIDs, aspirin, warfarin, and others that affect coagulation.

Adverse reactions: Diarrhea, nausea, insomnia, sexual dysfunction, somnolence, decreased libido, anorexia, weight loss, agitation, tremor, dry mouth, sweating, hyponatremia/SIADH (esp in elderly), weak uricosuric effect. Children: also, hyperkinesia, fever, urinary incontinence, aggressiveness, sinusitis, epistaxis, purpura.

How supplied: Tabs 25mg–30, 50; 50mg, 100mg–30, 100, 500, 5000; Conc–60mL (w. dropper)

VENLAFAXINE

EFFEXOR XR Pfizer

Serotonin and norepinephrine reuptake inhibitor.

Venlafaxine (as HCl) 37.5mg, 75mg, 150mg; ext-rel caps.

Indications: Generalized anxiety disorder. Social anxiety disorder. Panic disorder.

Adults: Take with food. Swallow whole or sprinkle contents on spoonful of applesauce; do not chew. Generalized or social anxiety disorder: Initially 75mg once daily; may start at 37.5mg once daily for 4–7 days before increasing to 75mg/day; may increase by increments of up to 75mg/day at intervals of at least 4 days. Panic disorder: Initially 37.5mg once daily for 7 days, then may increase to 75mg/day; then may increase in increments of up to 75mg/day at intervals of at least 7 days. For all: usual max 225mg/day. Moderate hepatic impairment: reduce by

50%. Renal impairment: reduce by 25–50%; reduce dose by 50% in hemodialysis (hold dose until end of treatment). Withdraw gradually (reduce by 75mg/day at 1-week intervals).

Children: Not established.

Contraindications: MAOIs (see Interactions). Concomitant linezolid or IV methylene blue.

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults. Monitor BP; reduce dose or discontinue if elevated BP persists. Heart disease (eg, recent MI, heart failure). Hypercholesterolemia (consider monitoring in long-term use). Renal or hepatic dysfunction. Increased intraocular pressure. Diseases that affect metabolism or hemodynamic response (eg, hyperthyroidism). Mania. Seizure disorders. Reevaluate periodically. Write R_x for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; see literature for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Allow at least 14 days after MAOI discontinuance before starting venlafaxine; allow at least 7 days after venlafaxine discontinuance before starting an MAOI. Risk of serotonin syndrome with concomitant serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) and with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. Concomitant weight loss agents (eg, phentermine), serotonin precursors (tryptophan supplements): not recommended. Caution with other CNS drugs, cimetidine, haloperidol, diuretics, metoprolol, drugs that inhibit CYP2D6, CYP3A4. Increased risk of bleeding with NSAIDs, aspirin, warfarin. False (+) urine immunoassay screening tests for PCP and amphetamine.

Adverse reactions: GI upset, dizziness, somnolence, insomnia, headache, nervousness, asthenia, sweating, dry mouth, vasodilation, abnormal dreams or vision, tremor, hypertension, sexual dysfunction, yawn, ecchymosis, anorexia, weight changes; hyponatremia/SIADH (esp in elderly); rare: interstitial lung disease, eosinophilic pneumonia.

How supplied: Caps–15, 30, 90

19C Insomnia

ESTAZOLAM

CIV

ESTAZOLAM (various)

Benzodiazepine. Estazolam 1mg, 2mg; scored tabs.

Indications: Short-term treatment of insomnia.

Adults: Initially 1mg at bedtime. May increase to 2mg nightly. Small or debilitated elderly: initially 0.5mg.

Children: <18yrs: not recommended.

Contraindications: Concomitant ketoconazole, itraconazole. Pregnancy (Cat.X).

Warnings/Precautions: Drug or alcohol abuse. Suicidal tendencies. Depression. Renal, hepatic, or respiratory impairment. Avoid abrupt cessation after prolonged use. Elderly. Debilitated. Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Caution with CYP3A4 inhibitors (eg, nefazodone, fluvoxamine, cimetidine, diltiazem, isoniazid, other macrolides): consider dose reduction.

Adverse reactions: CNS depression, complex sleep-related behaviors (eg, sleep-driving), hypokinesia, dizziness, incoordination, confusion, constipation, anxiety, paradoxical excitement; anaphylaxis, angioedema.

How supplied: Contact supplier.

ESZOPICLONE

CIV

LUNESTA Sunovion

Pyrrolopyrazine hypnotic. Eszopiclone 1mg, 2mg, 3mg; tabs.

Indications: Insomnia (decreased sleep latency and improved sleep maintenance).

Adults: ≥18yrs: 2–3mg immediately at bedtime [take only if able to get full night's sleep (8 hours) before becoming active again]. Elderly: initially 1mg for patients with difficulty falling asleep; may give 2mg if patient has difficulty staying asleep. Severe hepatic impairment: initially 1mg; max 2mg/dose. Concomitant CYP3A4 inhibitors (see Interactions): initial max 1mg/dose; may increase to 2mg if needed. Effect delayed if taken with high-fat/heavy meals.

Children: <18yrs: not recommended.

Warnings/Precautions: Depression. Abnormal thinking and behavioral changes. Drug or alcohol abuse. Compromised respiratory function. Conditions that affect metabolism or hemodynamic response. Severe hepatic impairment. Avoid abrupt cessation. Reevaluate if unresponsive after 7–10 days of treatment. Write R_x for smallest practical amount. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants; adjust dose. Potentiated by CYP3A4 inhibitors (eg, ketoconazole). May be antagonized by CYP3A4 inducers (eg, rifampicin).

Adverse reactions: Unpleasant taste, headache, somnolence, dizziness, dry mouth, infection, pain; complex sleep-related behaviors (eg, sleep-driving); rare: anaphylaxis, angioedema, others (see literature).

How supplied: Tabs (1mg)–30; 2mg, 3mg–100

PENTOBARBITAL

CII

NEMBUTAL Lundbeck

Barbiturate. Pentobarbital sodium 50mg/mL; soln for IM or IV inj; contains alcohol.

Indications: Short-term (≤ 2 weeks) treatment of insomnia when oral route is not feasible.

Adults: IM: 150mg–200mg (max 5mL/inj) as a single deep IM inj. IV: Inject slowly (max 50mg/min).

≥70kg: initially 100mg; observe and monitor vital signs at least 1 minute, then may increase as needed in small increments to usual max 500mg. Elderly, debilitated, renal or hepatic impairment: reduce dose.

Children: IM: 2–6mg/kg as a single deep IM inj; max 100mg. IV: inject slowly; reduce adult dose proportionally (see literature).

Contraindications: Porphyria.

Warnings/Precautions: Prehepatic coma: not recommended. Avoid abrupt cessation. Acute or chronic pain. Depression. Suicidal tendencies. Drug abuser. Hepatic or renal impairment. Monitor BP, respiration, cardiac function. Avoid extravasation. Write $\mathbb{R}$ for smallest practical amount. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.D). Nursing mothers.

Interactions: Potentiated by MAOIs, valproic acid, sodium valproate (monitor). CNS depression potentiated with alcohol, other CNS depressants. Antagonizes anticoagulants, corticosteroids, other steroid hormones (eg, oral contraceptives), doxycycline. May interfere with griseofulvin absorption. Variable effects with phenytoin (monitor).

Adverse reactions: Somnolence, respiratory depression, CNS effects, bradycardia, hypotension, syncope, GI upset, headache, inj site reactions, paradoxical excitement.

How supplied: Multi-dose vials (20mL, 50mL)–1

PROMETHAZINE

PROMETHAZINE HCl INJECTION (various)

Phenothiazine. Promethazine HCl 25mg/mL, 50mg/mL; sol for IM or IV inj; contains sulfites.

Indications: For light sedation and relief of apprehension. Obstetric (during labor), pre- and post-operative sedation.

Adults: Sedation: 25–50mg IM or IV. Obstetric: 50mg IM or IV in early stages of labor; 25–75mg IM or IV when labor is established; may repeat once or twice at 4 hour intervals; max 100mg/day. Pre- and post-op: 25–50mg IM or IV.

Children: <2yrs: see Contraindications. ≥2yrs: should not exceed half that of suggested adult dose (see literature).

Contraindications: Children <2 years. Coma. Intra-arterial or subcutaneous injection.

Warnings/Precautions: Sulfite sensitivity. CNS depression. Impaired respiratory function (eg, COPD, sleep apnea). Narrow-angle glaucoma. GI or GU obstruction. Cardiovascular or liver disease. Seizure disorders. Peptic ulcer. Bone marrow depression. Elderly. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Caution with epinephrine, anticholinergics, MAOIs. May alter hCG pregnancy test results and glucose tolerance tests.

Adverse reactions: Inj site reactions, CNS depression/drowsiness, lowered seizure

threshold, cholestatic jaundice, anticholinergic and extrapyramidal effects, neuroleptic malignant syndrome, photosensitivity, hypo- or hypertension, rash, blood dyscrasias, nausea, dry mouth, paradoxical reactions; children: respiratory depression (may be fatal).

How supplied: Contact supplier.

RAMELTEON

ROZEREM Takeda

Hypnotic (melatonin agonist). Ramelteon 8mg; tabs.

Indications: Insomnia.

Adults: Take 8mg within 30min of bedtime. Do not take with high-fat/heavy meals (delays effect).

Children: Not recommended.

Contraindications: Severe hepatic impairment. Concomitant fluvoxamine.

Warnings/Precautions: Severe COPD, severe obstructive sleep apnea: not recommended. Moderate hepatic impairment. Depression. Behavioral changes. Monitor prolactin and testosterone levels if unexplained amenorrhea, galactorrhea, decreased libido, or fertility problems occur. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid alcohol. Potentiated by potent inhibitors of CYP1A2, CYP3A4 (eg, ketoconazole), CYP2C9 (eg, fluconazole).

Antagonized by potent CYP450 inducers (eg, rifampin).

Adverse reactions: Somnolence, complex sleep-related behaviors (eg, sleep-driving), dizziness, fatigue; reduced testosterone or cortisol levels, increased prolactin levels (monitor if occurs); anaphylaxis, angioedema, others (see literature).

How supplied: Tabs–30, 100, 500

TEMAZEPAM

RESTORIL Mallinckrodt

Benzodiazepine. Temazepam 7.5mg, 15mg, 22.5mg, 30mg; caps.

Indications: Short-term (7–10 days) treatment of insomnia.

Adults: 7.5mg–30mg at bedtime. Elderly or debilitated: 7.5mg. Max 1 month/ $\mathbb{R}$.

Children: <18yrs: not recommended.

Contraindications: Pregnancy (Cat.X).

Warnings/Precautions: Drug or alcohol abuse. Suicidal tendencies. Depression. Renal, hepatic, or respiratory impairment. Reevaluate if used ≥2–3 wks. Sleep disturbances after stopping drug. Avoid abrupt cessation after prolonged use. Nursing mothers.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants.

Adverse reactions: CNS depression, complex sleep-related behaviors (eg, sleep-driving), lethargy, confusion, weakness, ataxia, paradoxical excitement, euphoria; anaphylaxis, angioedema.

How supplied: 7.5mg, 22.5mg–30, 100; 15mg, 30mg–100, 500

ZALEPLON**SONATA** King

Pyrazolopyrimidine hypnotic. Zaleplon 5mg, 10mg; caps; contains tartrazine.

Indications: Short-term treatment of insomnia.**Adults:** Usually 10mg at bedtime (at least 4hrs before becoming active again); max 20mg. Mild-to-moderate hepatic impairment, elderly, debilitated, concomitant cimetidine, or low weight patients: 5mg; max 10mg. Max 1month/R. Effect delayed if taken with high-fat/heavy meals.**Children:** Not established.**Warnings/Precautions:** Severe hepatic impairment: not recommended. Compromised respiratory function, mild-to-moderate hepatic impairment, debilitated: monitor closely. Depression. Behavioral changes. Suicidal tendencies. Drug or alcohol abuse. Conditions that affect metabolism or hemodynamic response. Write R for smallest practical amount. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C), nursing mothers: not recommended.**Interactions:** Potentiates CNS depression with alcohol, other CNS depressants. Efficacy may be compromised by drug(s) that induce CYP3A4. May be potentiated by drugs that inhibit aldehyde oxidase (eg, cimetidine, possibly diphenhydramine). May be antagonized by promethazine.**Adverse reactions:** CNS effects, complex sleep-related behaviors (eg, sleep-driving), GI upset, abdominal pain, migraine; anaphylaxis, angioedema, others (see full labeling).**How supplied:** Caps-100

CIV

ZOLPIDEM**AMBIEN CR** Sanofi Aventis

Imidazopyridine hypnotic. Zolpidem tartrate 6.25mg, 12.5mg; ext-rel tabs.

Indications: Insomnia.**Adults:** Swallow whole. Use lowest effective dose. Initially 6.25mg (in women), and 6.25mg or 12.5mg (in men) at bedtime (take only if able to get 7-8hrs of sleep before becoming active again). Both: if 6.25mg dose ineffective, may increase to max 12.5mg. Elderly, debilitated, or hepatic insufficiency: 6.25mg once daily at bedtime. Effect delayed if taken with a meal.**Children:** <18yrs: not recommended.**Also: Zolpidem****AMBIEN**

Zolpidem tartrate 5mg, 10mg; tabs.

Adults: Use lowest effective dose. Initially 5mg (in women), and 5mg or 10mg (in men) at bedtime (take only if able to get 7-8hrs of sleep before becoming active again). Both: if 5mg dose ineffective, may increase to max 10mg. Elderly, debilitated, or hepatic insufficiency: 5mg once daily at bedtime. Effect delayed if taken with a meal.**Children:** <18yrs: not recommended.**Warnings/Precautions:** Increased risk of next-day psychomotor impairment. Depression. Abnormal thinking

CIV

and behavioral changes. Compromised respiratory function. Sleep apnea. Myasthenia gravis. Evaluate for co-morbid diagnoses before initiation. Reevaluate if insomnia persists after 7-10 days of use. Drug or alcohol abuse. Write R for smallest practical amount. Withdraw gradually. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant other sedative-hypnotics including other zolpidem products: not recommended. May potentiate CNS depression with alcohol, other CNS depressants (eg, benzodiazepines, opioids, tricyclics). May be potentiated by CYP3A4 inhibitors (eg, ketoconazole), sertraline. Decreased alertness with imipramine, chlorpromazine. May be antagonized by CYP3A4 inducers (eg, rifampin).**Adverse reactions:** CNS effects, complex sleep-related behaviors (eg, sleep-driving), headache, next-day somnolence, dizziness, diarrhea, dry mouth; anaphylaxis, angioedema, others (see full labeling).**How supplied:** CR tabs 6.25mg-100; 12.5mg-100, 500; tabs 5mg-100; 10mg-100, 500**19D Mood disorders****ARIPIPRAZOLE**

R

ABILIFY Bristol-Myers Squibb and Otsuka

Aripiprazole 2mg, 5mg, 10mg, 15mg, 20mg, 30mg; tabs.

Also: Aripiprazole

R

ABILIFY ORAL SOLUTION

Aripiprazole 1mg/mL; orange cream flavor; contains parabens.

Also: Aripiprazole

R

ABILIFY DISCMLT

Aripiprazole 10mg, 15mg; oral disintegrating tabs; vanilla flavor; contains phenylalanine.

Indications: Acute and maintenance treatment of manic or mixed episodes in bipolar disorder as monotherapy; or as an adjunct to lithium or valproate. Adjunct to antidepressants for major depressive disorder. Irritability associated with autistic disorder.**Adults:** Tabs and soln may be interchanged on a mg-to-mg basis up to 25mg; 30mg as tablet is equivalent to 25mg oral soln. Discmlt: Dissolve on tongue; take without liquids. Bipolar disorder: initially 15mg once daily; may increase to max 30mg/day; maintenance: 15mg/day or 30mg/day (see literature for duration of therapy). Adjunct to major depressive disorder: initially 2-5mg/day; may adjust by 5mg/day increments at intervals of ≥ 1 week; usual range: 2-15mg/day. Reduce aripiprazole dose by at least $\frac{1}{2}$ with CYP3A4 inhibitors or CYP2D6 inhibitors. Double aripiprazole dose (max 30mg/day) with CYP3A4 inducers. Adjust dose to normal range when these drugs are withdrawn.**Children:** <10yrs: not recommended. 10-17yrs: Bipolar disorder: initially 2mg/day, then increase to 5mg/day after 2 days, then increase to target dose of

10mg/day after 2 days. Subsequent dose increases may be adjusted by increments of 5mg/day; max 30mg/day. Maintenance: continue at lowest dose to maintain remission; see literature. Irritability w. autistic disorder: 6–17yrs: initially 2mg/day, then increase to 5mg/day; adjust dose by 5mg/day at ≥ 1 week intervals; usual range 5–15mg/day.

Also: Aripiprazole
ABILIFY INJECTION

Aripiprazole 7.5mg/mL; soln for IM use only.

Indications: Treatment of agitation associated with acute manic or mixed episodes in bipolar disorder.

Adults: 9.75mg IM, if 2nd dose is needed, may repeat after 2 hours; max 30mg/day. Switch to oral form as soon as possible. Reduce aripiprazole dose by at least $\frac{1}{2}$ with CYP3A4 inhibitors or CYP2D6 inhibitors. Double aripiprazole dose (max 30mg/day) with CYP3A4 inducers. Adjust dose to normal range when these drugs are withdrawn.

Children: Not recommended.

Warnings/Precautions: Cardio- or cerebrovascular disease. Risk of hypotension, aspiration pneumonia, seizures, or diabetes (do baseline fasting blood sugar). Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Exposure to extreme heat. Dehydration. Reevaluate periodically. Monitor for hyperglycemia. Exclude neuroleptic malignant syndrome if fever occurs. Suicidal tendencies. Write $\frac{1}{2}$ for smallest practical amount. Elderly (not for dementia-related psychosis). Labor & delivery. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid alcohol. Caution with other centrally-acting drugs. Potentiates antihypertensives. Levels may be reduced by CYP3A4 inducers (eg, carbamazepine). Levels may be increased by CYP3A4 inhibitors (eg, ketoconazole) or CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine). Caution with drugs that interfere with temperature regulation (eg, anticholinergics).

Adverse reactions: Headache, anxiety, insomnia, GI upset, somnolence, fatigue, akathisia, orthostatic hypotension, asthenia, blurred vision, tremor, pyrexia, salivary hypersecretion, neuroleptic malignant syndrome, tardive dyskinesia, weight gain, dyslipidemia, others. Inj: local reactions.

How supplied: Tabs 2mg–30; 5mg, 10mg, 15mg, 20mg, 30mg–30, 100; Oral soln (w. dosing cup)–150mL; Discmelt–30; Single use vials–1

BUPROPION

WELLBUTRIN XL GlaxoSmithKline
Aminoketone. Bupropion HCl 150mg, 300mg; ext-rel tabs.

Indications: Depression. Seasonal affective disorder.

Adults: Swallow whole. Avoid bedtime dosing. ≥ 18 yrs: Depression: initially 150mg once daily in

the AM for at least 3 days; if tolerated, increase to 300mg once daily at least 24 hrs apart. May increase after several weeks to max 450mg once daily. Seasonal affective disorder: start in autumn, taper and stop in early spring. 150mg once daily in AM; if tolerated, increase to 300mg once daily after 1 week. Max 300mg/day. Severe hepatic cirrhosis: max 150mg every other day. Mild-moderate hepatic cirrhosis, or renal impairment: consider reduced dose and/or dose frequency.

Children: <18yrs: not recommended.

Also: Bupropion

BUDEPRION SR Teva US Generics

WELLBUTRIN SR

Bupropion HCl 100mg, 150mg, 200mg; sust-rel tabs.

Indications: Depression.

Adults: Swallow whole. Avoid bedtime dosing.

≥ 18 yrs: initially 150mg once daily in the AM for at least 3 days; if tolerated, increase to 150mg twice daily at least 8 hrs apart. May increase after several weeks to max 200mg twice daily at least 8 hrs apart. Severe hepatic cirrhosis: max 100mg/day or 150mg every other day. Mild-moderate hepatic cirrhosis, or renal impairment: consider reduced dose and/or dose frequency.

Children: <18yrs: not recommended.

Also: Bupropion

WELLBUTRIN

Bupropion HCl 75mg, 100mg; immediate-rel tabs.

Adults: Avoid bedtime dosing. ≥ 18 yrs: initially 100mg twice daily for at least 3 days; if tolerated, increase to 100mg 3 times daily at least 6 hrs apart; max increase 100mg/day per 3-day period. May increase after several weeks to max 450mg/day in 3 divided doses; max single dose: 150mg (give 400mg/day as 100mg 4 times daily at least 4 hrs apart). Severe hepatic cirrhosis: max 75mg once daily. Mild-moderate hepatic cirrhosis, or renal impairment: consider reduced dose and/or dose frequency.

Children: <18yrs: not recommended.

Contraindications: Seizure disorders. Bulimia.

Anorexia nervosa. During or within 14 days of discontinuing MAOIs. Concomitant linezolid or IV methylene blue. Abrupt withdrawal of sedatives or alcohol. Other forms of bupropion (eg, Zyban).

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults; monitor for clinical worsening or unusual changes. History or risk of seizures; discontinue if seizure occurs; do not restart. Hepatic or renal impairment (monitor closely). Bipolar disorder. Psychosis. Unstable heart disease. CHF. Recent MI. Maintain at lowest effective dose. Write $\frac{1}{2}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Do not start with concomitant linezolid or IV methylene blue; if treatment necessary, discontinue bupropion before starting. Monitor for 2 weeks or until 24 hours after

last dose of linezolid or IV methylene blue, whichever comes first. Avoid alcohol. Levodopa, amantadine may increase toxicity. Caution with drugs that lower seizure threshold (eg, quinolones, theophylline, antidiabetics, anorectics, CNS stimulants, systemic steroids, antidepressants, antipsychotics) or factors that lower seizure threshold (eg, opiate or cocaine addiction, excessive use of alcohol or sedatives). Caution with drugs metabolized by CYP2B6 (eg, orphenadrine, cyclophosphamide, thiotepa, ticlopidine, clopidogrel) or CYP2D6 including tricyclic antidepressants, SSRIs (eg, paroxetine, fluoxetine, sertraline), antipsychotics (eg, haloperidol, risperidone, thioridazine), β -blockers (eg, metoprolol), Class 1C antiarrhythmics (eg, propafenone, flecainide); consider dose reduction. May be affected by metabolic enzyme inducers (eg, carbamazepine, phenobarbital, phenytoin), or inhibitors (eg, cimetidine). Monitor for hypertension with nicotine replacement.

Adverse reactions: CNS stimulation (eg, agitation, insomnia, seizures, tremor, dizziness), mania/hypomania, psychosis, weight change, dry mouth, headache, migraine, nausea, constipation, diarrhea, edema, rash (rarely may be serious, eg, erythema multiforme, Stevens-Johnson syndrome), palpitations, urinary frequency, sweating, tinnitus, myalgia, hypertension.

How supplied: XL tabs-30, 90; SR tabs-60; Immediate-rel tabs-100

CITALOPRAM

CELEXA Forest

SSRI. Citalopram (as HBr) 10mg, 20mg+, 40mg+; tabs (+ scored).

Also: Citalopram

CELEXA ORAL SOLUTION

Citalopram (as HBr) 2mg/mL; sugar- and alcohol-free; peppermint flavor; contains parabens.

Indications: Depression.

Adults: Initially 20mg once daily; after ≥ 1 week may increase to 40mg once daily. Doses >40 mg/day: not recommended. Elderly (>60 yrs), hepatic impairment, CYP2C19 poor metabolizers, concomitant cimetidine or other CYP2C19 inhibitors: max 20mg/day. 3rd trimester pregnant women: consider tapering dose.

Children: Not recommended.

Contraindications: Concomitant pimozide, linezolid, IV methylene blue. During or within 14 days of MAOIs; do not start an MAOI during or within 14 days of citalopram.

Warnings/Precautions: Suicidal tendencies (monitor). Congenital long QT syndrome, bradycardia, hypokalemia, hypomagnesemia, recent MI, uncompensated heart failure, or concomitant drugs that prolong the QT interval: not recommended; monitor ECG if therapy is considered. Correct hypokalemia, hypomagnesemia before starting and periodically monitor. History of seizures or mania/

hypomania. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like symptoms; discontinue if occurs. Hepatic or severe renal impairment (CrCl <20 mL/min). ECT. Risk of bleeding events. Avoid abrupt cessation. Reevaluate periodically. Write Rx for smallest practical amount. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; see full labeling for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid drugs that prolong QT interval including Class 1A (eg, quinidine, procainamide) or Class III antiarrhythmics (eg, amiodarone, sotalol), antipsychotics (eg, chlorpromazine, thioridazine), antibiotics (eg, gatifloxacin, moxifloxacin), and others (eg, pentamidine, methadone, levomethadyl acetate). Avoid alcohol. Caution with drugs that affect coagulation (eg, warfarin, aspirin, NSAIDs). May be potentiated by cimetidine, potent inhibitors of CYP2C19 or CYP3A4 (eg, azole antifungals). May be antagonized by carbamazepine. Increases metoprolol levels.

Adverse reactions: GI upset, dry mouth, somnolence, insomnia, increased sweating, anorexia, rhinitis, sexual dysfunction, agitation, fatigue, arthralgia, myalgia, hyponatremia, SIADH, abnormal bleeding; dose-dependent QT prolongation, neuroleptic malignant syndrome.

How supplied: Tabs-100; Soln-240mL

DESVENLAFAXINE

PRISTIQ Pfizer

Serotonin and norepinephrine reuptake inhibitor. Desvenlafaxine (as succinate) 50mg, 100mg; ext-rel tabs.

Indications: Major depressive disorder.

Adults: Swallow whole. 50mg once daily. Moderate renal impairment: max 50mg/day. Severe renal impairment (CrCl <30 mL/min), ESRD: 50mg every other day. Do not give supplemental dose after dialysis. Hepatic impairment: max 100mg/day. Withdraw gradually.

Children: Not recommended.

Contraindications: Allow ≥ 14 days after MAOI discontinuance before starting desvenlafaxine; allow ≥ 7 days after desvenlafaxine discontinuance before starting an MAOI. Concomitant linezolid, IV methylene blue.

Warnings/Precautions: Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs and symptoms; discontinue if occurs. Monitor BP; reduce dose or discontinue if elevated BP persists. Cardio- or cerebrovascular disease. Hypercholesterolemia. Increased intracranial pressure. Mania/hypomania. Severe renal dysfunction.

Seizure disorder. Reevaluate periodically. Suicidal ideation (monitor). Write R_x for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C; avoid in 3rd trimester; taper). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid alcohol, concomitant venlafaxine, other forms of desvenlafaxine. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Increased risk of bleeding with concomitant NSAIDs, aspirin, anticoagulants; monitor. May be potentiated by potent CYP3A4 inhibitors. May antagonize CYP3A4 substrates. May cause false (+) urine immunoassay screening tests for PCP and amphetamine.

Adverse reactions: Nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, sexual dysfunction; rare: hyponatremia/SIADH (esp in elderly), interstitial lung disease, eosinophilic pneumonia, serotonin syndrome, mydriasis.

How supplied: Tabs—14, 30, 90

DIVALPROEX

DEPAKOTE AbbVie

Divalproex sodium 125mg, 250mg, 500mg; delayed-release tabs.

Indications: Mania associated with bipolar disorder.

Adults: ≥18yrs: initially 750mg daily in divided doses; max 60mg/kg per day.

Children: <18yrs: not recommended.

Also: Divalproex

DEPAKOTE ER

Divalproex sodium 250mg, 500mg; ext-rel tabs.

Indications: Acute manic or mixed episodes in bipolar disorder.

Adults: Take once daily. Swallow whole. Initially 25mg/kg per day, max 60mg/kg per day.

Children: Not recommended.

Contraindications: Hepatic disease. Significant hepatic dysfunction. Urea cycle disorders.

Warnings/Precautions: Discontinue if hepatic dysfunction, pancreatitis, thrombocytopenia, or hyperammonemic encephalopathy occurs. History of liver disease. Increased hepatotoxicity risk with congenital metabolic disorders, multiple AEDs, severe seizure disorders with mental retardation, organic brain disorders, in children <2 years of age. Monitor liver function and symptoms (esp. 1st 6 months). Follow-up if symptoms of hyperammonemia occur. Suicidal tendencies (monitor). Depakote ER is not bioequivalent to delayed-release tabs on mg/mg basis. Avoid abrupt cessation. Monitor platelets, bleeding time (at baseline, before surgery, and in pregnancy); reevaluate periodically. May affect HIV or CMV viral

load (*in vitro*). Elderly (monitor fluid and nutritional intake, and for somnolence). Pregnancy (Cat.D): apprise females of childbearing potential of risks to fetus (eg, neural tube defects). Nursing mothers: not recommended.

Interactions: Monitor levels of valproate, ethosuximide, other anticonvulsants, and whenever an enzyme inducer is added or withdrawn. Potentiates carbamazepine, diazepam, ethosuximide, lamotrigine, phenobarbital, phenytoin, tolbutamide, warfarin, zidovudine, amitriptyline, nortriptyline. Potentiated by aspirin, felbamate. Levels reduced by rifampin, phenytoin, carbamazepine, phenobarbital, carbapenem antibiotics. CNS depression with alcohol, other CNS depressants. Clonazepam may induce absence status in patients with history of absence seizures. May interfere with urine ketone and thyroid tests. Others: see literature.

Adverse reactions: Dizziness, headache, GI upset, CNS effects (esp. somnolence), rash, cardiovascular effects, arthralgia, liver failure, acute pancreatitis, clotting abnormalities, thrombocytopenia, hyperammonemia, others.

How supplied: Tabs 125mg–100; Tabs 250mg, 500mg–100, 500; ER 250mg–60; ER 250mg, 500mg–100, 500

DOXEPIN

DOXEPIN HCl CAPSULES (various)

Tricyclic. Doxepin (as HCl) 10mg, 25mg, 50mg, 75mg, 100mg, 150mg; caps.

Also: Doxepin

DOXEPIN HCl CONCENTRATE

Doxepin (as HCl) 10mg/mL.

Indications: Depression.

Adults: Soln: dilute with 4oz juice, water, or milk.

Mild: 25–50mg/day. Mild to moderate: initially 75mg/day; range 75–150mg/day. Severe: max 300mg/day. May give as single (up to 150mg) or divided doses; 150mg caps for maintenance only.

Children: Not recommended.

Contraindications: During or within 14 days of MAOIs. Acute post MI. Urinary retention. Glaucoma.

Warnings/Precautions: Cardiovascular disease. Epilepsy. Suicidal tendencies. Psychosis. Diabetes. Avoid abrupt cessation. Poor metabolizers (those with reduced CYP2D6 activity). Elderly. Pregnancy. Nursing mothers.

Interactions: Hyperpyretic crisis, convulsions, death with MAOIs. Potentiates CNS depression of alcohol; cimetidine; other CYP2D6 substrates. Antagonized by barbiturates, carbamazepine, phenytoin. Paralytic ileus, hyperpyrexia with anticholinergics. May block guanethidine.

Adverse reactions: CNS effects (eg, drowsiness, overstimulation, extrapyramidal symptoms), anticholinergic effects, hypotension, GI upset, photosensitivity, endocrine effects.

How supplied: Contact supplier.

DULOXETINE

R

CYMBALTA Lilly

Serotonin and norepinephrine reuptake inhibitor.

Duloxetine (as HCl) 20mg, 30mg, 60mg; e-c pellets in caps.

Indications: Major depressive disorder.**Adults:** Swallow whole. Initially 40mg/day (given as 20mg twice daily) to 60mg/day (given either once daily or as 30mg twice daily); may start at 30mg once daily for 1 week, if needed; usual target 60mg once daily (doses up to 120mg/day have been given). Maintenance: 60mg once daily.**Children: Not recommended.****Contraindications:** Allow at least 14 days after MAOI discontinuance before starting duloxetine; allow at least 5 days after duloxetine discontinuance before starting an MAOI. Concomitant linezolid or IV methylene blue. Uncontrolled narrow-angle glaucoma.**Warnings/Precautions:** Suicidal tendencies (monitor). Severe renal impairment (CrCl < 30mL/min), end stage renal disease, hepatic insufficiency, evidence of chronic liver disease, or substantial alcohol use: not recommended. History of seizure or mania/hypomania. Controlled narrow-angle glaucoma. Decreased GI motility. Cardiac disease. Monitor BP prior to and during therapy. Diabetes. Avoid abrupt cessation. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; consider tapering, see literature for effects on neonate). Nursing mothers: not recommended.**Interactions:** See Contraindications. Concomitant thioridazine (may cause arrhythmias): not recommended. Potentiated by CYP1A2 inhibitors; avoid (eg, cimetidine, fluvoxamine, quinolones). May potentiate or be potentiated by CYP2D6 inhibitors (eg, paroxetine, fluoxetine, quinidine) or substrates (eg, tricyclics, phenothiazines, type 1C antiarrhythmics) or other highly protein-bound drugs; caution with CYP2D6 substrates with narrow therapeutic indexes. Caution with potent CYP1A2 inhibitors, antihypertensives, other drugs that induce orthostatic hypotension. Caution with triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort; may cause serotonin syndrome. Monitor concomitant CNS-acting drugs, and with those that affect gastric pH (eg, proton pump inhibitors). Increased bleeding risk with aspirin, anticoagulants, NSAIDs.**Adverse reactions:** Nausea, dry mouth, constipation, somnolence, hyperhidrosis, decreased appetite, weight changes, GI disturbances, fatigue, dizziness, increased sweating, mania/hypomania, tremor, blurred vision, insomnia, hot flushes, urinary hesitation/retention, abnormal ejaculation, genital disorders, decreased libido, increased BP, orthostatic hypotension, syncope, hepatotoxicity (eg, elevated liver transaminases, cholestatic jaundice); discontinue if occurs, hyponatremia, asthenia, others; rare: seizure.**How supplied:** Caps 20mg-60; 30mg-30, 90, 1000; 60mg-30, 1000**ESCITALOPRAM**

R

LEXAPRO Forest

SSRI. Escitalopram (as oxalate) (single-isomer citalopram) 5mg, 10mg+, 20mg+; tabs (+ scored).

Also: Escitalopram

R

LEXAPRO ORAL SOLUTION

Escitalopram (as oxalate) 1mg/mL; peppermint flavor; contains parabens.

Indications: Major depressive disorder.**Adults:** Initially 10mg once daily; may increase to 20mg once daily after 1 week. Elderly or hepatic impairment: 10mg once daily.**Children:** <12yrs: not recommended. 12-17yrs: initially 10mg once daily; may increase to 20mg once daily after 3 weeks.**Contraindications:** Concomitant pimozide, linezolid, IV methylene blue. During or within 14 days of MAOIs; do not start an MAOI during or within 14 days of escitalopram.**Warnings/Precautions:** Suicidal tendencies (monitor). History of seizures or mania/hypomania. Monitor for serotonin syndrome; discontinue if occurs. Hepatic or severe renal impairment (CrCl < 20mL/min). ECT. Risk of bleeding events. Conditions that affect metabolic or hemodynamic responses. Recent MI. Unstable heart disease. Avoid abrupt cessation. Reevaluate periodically. Write R for smallest practical amount. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; see full labeling for effects on neonate). Nursing mothers: not recommended.**Interactions:** See Contraindications. Do not give with citalopram. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. Caution with drugs that affect coagulation (eg, warfarin, aspirin, NSAIDs). May be antagonized by carbamazepine. Caution with drugs metabolized by CYP2D6 or other centrally-acting drugs. Increases metoprolol levels.**Adverse reactions:** Insomnia, ejaculation disorder, nausea, increased sweating, fatigue, somnolence, decreased libido, anorgasmia; hyponatremia.**How supplied:** Tabs-100; Soln-240mL**FLUOXETINE**

R

PROZAC Lilly

SSRI. Fluoxetine (as HCl) 10mg, 20mg, 40mg; caps.

Also: Fluoxetine

R

PROZAC ORAL SOLUTION (various)

Fluoxetine (as HCl) 20mg/5mL; mint flavor.

Indications: Monotherapy: major depressive disorder (MDD); or bulimia nervosa. In combination with olanzapine: depressive episodes associated with bipolar disorder, or treatment resistant depression (TRD; see full labeling).

Adults: MDD: initially 20mg daily in AM; increase if needed after several weeks. May give doses >20mg/day in 2 divided doses (AM and noon); max 80mg/day. Bulimia: 60mg once daily in the AM; may titrate to this dose. Bipolar depression: initially olanzapine 5mg + fluoxetine 20mg once daily in the PM; range: olanzapine 5–12.5mg + fluoxetine 20–50mg. TRD: initially olanzapine 5mg + fluoxetine 20mg once daily in the PM; range: olanzapine 5–20mg + fluoxetine 20–50mg. Risk of hypotension, hepatic impairment, slow metabolizers, or sensitive to olanzapine: initially olanzapine 2.5–5mg + fluoxetine 20mg; increase cautiously. Hepatic impairment (reduce dose), dose adjustments; switching to or from MAOIs: see full labeling.

Children: <8yrs: not recommended. 8–17yrs: MDD: initially 10mg or 20mg/day; if started on 10mg/day, increase after 1 week to 20mg/day. Lower weight children: start at 10mg/day; may increase after several weeks to 20mg/day.

Also: Fluoxetine

PROZAC WEEKLY

Fluoxetine (as HCl) 90mg; caps containing e-c delayed-release pellets.

Indications: Maintenance phase of depression.

Adults: 90mg once weekly. Start 7 days after last dose of fluoxetine 20mg (when switching from daily dosing).

Children: Not recommended.

Contraindications: Concomitant MAOIs during or within at least 5 weeks of discontinuing fluoxetine. Within 14 days of discontinuing an MAOI. Concomitant linezolid or IV methylene blue. Concomitant pimozone, thioridazine (may cause QTc prolongation).

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults; monitor for clinical worsening or changes. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs/symptoms; discontinue if occurs. Discontinue if unexplained allergic reaction occurs. Renal or hepatic dysfunction. History of seizures or mania/hypomania. Recent MI. Unstable heart disease. ECT (prolonged seizures). Reevaluate periodically in long-term use. Avoid abrupt cessation. Monitor weight. Conditions that affect metabolism or hemodynamic responses. Volume depletion. Diabetes. Write $\mathbb{R}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C; avoid 3rd trimester or consider lower dose; see full labeling for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Do not start with concomitant linezolid or IV methylene blue; if treatment is necessary, discontinue fluoxetine before starting; monitor for serotonin syndrome for 5 weeks or until 24 hours after last dose of linezolid or IV methylene blue, whichever comes first. Do not start thioridazine within at least 5 weeks of discontinuing fluoxetine. Caution with concomitant triptans,

tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort, linezolid, IV methylene blue; may cause serotonin syndrome. May potentiate protein-bound drugs (eg, warfarin, digoxin) and those metabolized by CYP2D6 (eg, tricyclics, vinblastine, flecainide). May potentiate carbamazepine, phenytoin. Monitor lithium, phenytoin, warfarin, tricyclics. Caution with benzodiazepines (eg, diazepam, alprazolam), antipsychotics (eg, clozapine, haloperidol), other CNS drugs. Increased risk of bleeding with NSAIDs, aspirin, warfarin, others that affect coagulation. Hyponatremia with diuretics.

Adverse reactions: Nausea, CNS stimulation (eg, anxiety, nervousness, insomnia), somnolence, headache, mania/hypomania, anorexia, weight loss, tremor, asthenia, sexual dysfunction, sweating, GI disturbances, respiratory symptoms, motor impairment, serum sickness, hypo- or hyperglycemia, rash (may be serious), urticaria, pruritus; rarely: platelet dysfunction. Children: thirst, hyperkinesia, agitation, personality disorder, epistaxis, urinary frequency, menorrhagia.

How supplied: Caps 10mg–100; 20mg–30, 100, 2000; 40mg–30; Liq-contact supplier; Weekly–4

LAMOTRIGINE

$\mathbb{R}$

LAMICTAL GlaxoSmithKline

Phenytriazine. Lamotrigine 25mg, 100mg, 150mg, 200mg; scored tabs.

Also: Lamotrigine

$\mathbb{R}$

LAMICTAL CHEWABLE DISPERSIBLE TABS

Lamotrigine 2mg, 5mg, 25mg; blackcurrant flavor.

Also: Lamotrigine

$\mathbb{R}$

LAMICTAL ODT

Lamotrigine 25mg, 50mg, 100mg, and 200mg; orally-disintegrating tabs.

Indications: Maintenance treatment of bipolar disorder.

Adults: ≥ 18 yrs: Not on enzyme-inducing antiepileptic drugs (EIAEDs, eg, phenytoin, carbamazepine, phenobarbital, primidone), or valproate: 25mg daily for 2 weeks, then 50mg daily for 2 weeks, then 100mg daily for 1 week, then to target dose of 200mg daily. Concomitant valproate: 25mg every other day for 2 weeks, then 25mg daily for 2 weeks, then 50mg daily for 1 week, then to target dose of 100mg daily. Concomitant EIAEDs and not valproate: 50mg daily for 2 weeks, then 100mg daily in divided doses for 2 weeks, then increase weekly by 100mg daily in divided doses to target dose of 400mg daily in divided doses. Discontinuing valproate: double lamotrigine dose over 2 weeks in equal weekly increments. Discontinuing EIAEDs: maintain lamotrigine dose for 1 week after discontinuing EIAEDs, then reduce lamotrigine dose by $\frac{1}{2}$ over 2 weeks in equal weekly decrements then adjust as needed. Reevaluate periodically. Concomitant estrogen-containing oral contraceptives or hormone replacement therapy: see literature. Hepatic impairment: if moderate or severe (w/o

ascites) reduce dose by 25%; if severe (w. ascites) reduce dose by 50%.

Children: <18yrs: not recommended.

Warnings/Precautions: Discontinue at first sign of rash (unless clearly not drug related); avoid rechallenge. Avoid rapid dose increases and exceeding recommended dose (may increase risk of serious rash). History of allergy or rash to other AEDs (may increase frequency of nonserious rash). Reevaluate if fever, rash, or other hypersensitivity reaction occurs; discontinue if hypersensitivity occurs. Impaired cardiac function. Moderate or severe hepatic impairment. Significant renal impairment: consider reduced dose. Suicidal tendencies (monitor). Increased risk of aseptic meningitis; evaluate and treat if signs/symptoms develop. Avoid abrupt cessation; taper over at least 2 weeks if possible. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Lamotrigine levels increased by valproate. Lamotrigine levels decreased by phenytoin, carbamazepine, phenobarbital, primidone, rifampin. Monitor with other anticonvulsants. Lamotrigine levels may be decreased by oral contraceptives and increased when they are stopped (if monotherapy: adjust dose), and may affect hormonal replacement therapy or other hormonal contraceptive efficacy. May potentiate other folate inhibitors (eg, trimethoprim). Valproate may increase risk of serious rash. Increased incidence of dizziness, diplopia, ataxia, blurred vision with carbamazepine. No apparent effect on lithium levels.

Adverse reactions: GI upset, insomnia, somnolence, dizziness, back pain, fatigue, rhinitis, non-serious rash, abdominal pain, dry mouth, headache, abnormal dreams; rare: serious rash (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis), hypersensitivity, multiorgan failure, blood dyscrasias.

Note: Register pregnant patients exposed to lamotrigine by calling (800) 336-2176.

How supplied: Tabs 25mg, 100mg-100; 150mg, 200mg-60; Chewable Dispersible tabs 2mg-30; 5mg, 25mg-100; Starter kit 25mg × 35 tabs-1; 25mg × 84 tabs + 100mg × 14 tabs-1; 25mg × 42 tabs + 100mg × 7 tabs-1; ODT Maintenance Packs-30; ODT Titration Kit 25mg × 21 tabs + 50mg × 7 tabs-1; 50mg × 42 tabs + 100mg × 14 tabs-1; 25mg × 14 tabs, 50mg × 14 tabs, 100mg × 7 tabs-1

LITHIUM CARBONATE

LITHIUM CARBONATE CAPSULES Roxane
Lithium salt. Lithium carbonate 150mg, 300mg, 600mg.

Also: Lithium carbonate

LITHIUM CARBONATE TABLETS
Lithium carbonate 300mg; scored tabs.

Also: Lithium carbonate

LITHIUM ORAL SOLUTION
Lithium ion 8mEq/5mL (equivalent to 300mg lithium carbonate); contains alcohol.

Indications: Mania in bipolar disorder.

Adults: Individualize. Acute mania: 600mg 3 times daily. Usual maintenance: 300mg 3 or 4 times daily.

Children: Not recommended.

Contraindications: Renal or cardiovascular disease, concomitant diuretics, sodium depletion, severely debilitated or dehydrated: not recommended (if necessary, use low doses, monitor serum lithium levels daily, hospitalize).

Warnings/Precautions: Seizure disorders.

Maintain adequate fluid and salt intake, esp. with fever, sweating, diarrhea, or infection. Monitor serum lithium levels frequently (toxic and therapeutic levels are close); draw blood for serum tests 8-12 hrs after previous dose. Monitor thyroid, renal function. Discontinue if diarrhea, vomiting, tremor, ataxia, drowsiness or weakness occur. Elderly. Pregnancy (Cat.D), nursing mothers: not recommended.

Interactions: See Contraindications. Lithium toxicity potentiated by diuretics, ACE inhibitors, angiotensin II receptor blockers, carbamazepine, indomethacin, piroxicam (possibly other NSAIDs, including COX-2 inhibitors), metronidazole, calcium channel blockers: monitor and adjust lithium dose, if needed. Discontinue if signs of neurologic toxicity occur with neuroleptics (eg, haloperidol). Xanthines, acetazolamide, urea, alkalinizing agents may reduce serum lithium levels. Fluoxetine has variable effects on serum lithium levels. Prolongs effects of neuromuscular blockers. Hypothyroidism with chronic iodide administration. Serotonin syndrome with SSRIs.

Adverse reactions: Polyuria, polydipsia, drowsiness, tremor, hypothyroidism, extrapyramidal symptoms, GI upset, renal toxicity, seizures, arrhythmias, hypotension, lethargy, metallic taste, dry mouth, blurred vision, pseudotumor cerebri (discontinue if occurs).

How supplied: Caps 150mg, 600mg-100; Caps 300mg-100, 1000; Tabs 300mg-100, 1000; Soln-500mL

LURASIDONE

LATUDA Sunovion

Atypical antipsychotic (benzisoisothiazol derivative).

Lurasidone HCl 20mg, 40mg, 60mg, 80mg, 120mg; tabs.

Indications: Major depressive episodes associated with bipolar I disorder as monotherapy and as adjunctive therapy with lithium or valproate.

Adults: Take with food (≥350 calories). Initially 20mg once daily. Usual range: 20-120mg/day. Max 120mg/day. Moderate (CrCl 30-50mL/min) to severe renal impairment (CrCl <30mL/min), moderate hepatic impairment (Child Pugh Score 7-9): initially 20mg; max 80mg/day. Severe hepatic impairment (Child Pugh Score 10-15): initially 20mg; max 40mg/day. Concomitant moderate CYP3A4 inhibitors (eg, diltiazem, atazanavir, erythromycin, fluconazole, verapamil): initially 20mg/day; max 80mg/day.

Concomitant moderate CYP3A4 inducers: may need to increase lurasidone dose after chronic treatment (≥ 7 days) with inducer.

Children: Not established.

Contraindications: Concomitant strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil) and inducers (eg, rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine).

Warnings/Precautions: Elderly with dementia-related psychosis (not approved use); increased risk of death or cerebrovascular events (eg, stroke, TIA). Increased risk of suicidal thoughts and behavior in children, adolescents, and young adults; monitor closely for worsening or unusual changes in behavior in all patients. Discontinue if neuroleptic malignant syndrome occurs; consider discontinuing if tardive dyskinesia occurs. Cardio- or cerebrovascular disease, risk of hypotension: monitor orthostatic vital signs. Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia, dyslipidemia, weight gain, hyperprolactinemia. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of therapy; discontinue if WBCs decline. Moderate to severe hepatic or renal impairment. History of seizures, Mania or hypomania (monitor). Dysphagia. Parkinson's disease. Dementia with Lewy Bodies. Exposure to extreme heat. Write $\mathbb{R}$ for smallest practical amount; closely supervise high-risk patients (suicidal ideation). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Adults and Contraindications. Avoid grapefruit and grapefruit juice.

Adverse reactions: Somnolence, akathisia, extrapyramidal symptoms, nausea, parkinsonism, agitation; orthostatic hypotension and syncope possible.

How supplied: Tabs-30, 90, 500, 100 (10 blister cards $\times$ 10 tabs)

MIRTAZAPINE

REMERON Merck

Tetracyclic. Mirtazapine 15mg+, 30mg+, 45mg, tabs; + scored.

Also: Mirtazapine

REMERON SOLTAB

Mirtazapine 15mg, 30mg, 45mg; orally-disintegrating tabs; orange flavor; contains phenylalanine.

Indications: Major depressive disorder.

Adults: Initially 15mg once daily at bedtime; increase at intervals of at least 1-2 weeks. Usual range: 15-45mg daily. SolTab: Dissolve on tongue and swallow with or without water.

Children: Not recommended.

Contraindications: During or within 14 days of MAOIs. Concomitant linezolid or IV methylene blue.

Warnings/Precautions: Suicidal ideation (monitor). Hepatic or moderate to severe renal dysfunction. Diseases that affect metabolism or hemodynamic response. History of mania/

hypomania. Seizure disorders. History of MI. Angina. Ischemic stroke. Hypovolemia. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs/symptoms. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Possible serious/fatal reactions with MAOIs. Concomitant diazepam: not recommended. Caution with triptans, tricyclics, fentanyl, linezolid, IV methylene blue, lithium, tramadol, tryptophan, buspirone, St. John's wort; may cause serotonin syndrome. Potentiation with alcohol, diazepam, other CNS depressants. Caution with drugs metabolized by and/or that inhibit CYP450. Monitor warfarin.

Adverse reactions: Somnolence, increased appetite, weight gain, dizziness, nausea, dry mouth, constipation, asthenia, flu syndrome, edema, CNS effects; hypo- or hypertension, elevated cholesterol, triglycerides, or transaminases; rarely; hyponatremia, agranulocytosis.

How supplied: Tabs, SolTabs-30

NEFAZODONE

NEFAZODONE (various)

Phenylpiperazine. Nefazodone HCl 50mg, 100mg+, 150mg+, 200mg, 250mg; tabs; + scored.

Indications: Depression.

Adults: ≥ 18 years: initially 200mg daily in 2 divided doses; increase in increments of 100-200mg/day in 2 divided doses at 1-week intervals; range 300-600mg/day. Debilitated: initially 100mg daily in 2 divided doses.

Children: <18yrs: not recommended.

Contraindications: Concomitant MAOIs, cisapride, carbamazepine; triazolam (see Interactions). Active liver disease. Elevated baseline serum transaminases. History of nefazodone-associated liver dysfunction.

Warnings/Precautions: Monitor for liver dysfunction; discontinue if signs of liver disease occur (eg, AST or ALT $\geq 3 \times$ ULN). Cardio- or cerebrovascular disease. Predisposition to hypotension (eg, dehydration, hypovolemia). Mania/hypomania. Suicidal patients. Seizure disorders. Hepatic cirrhosis. Discontinue and reevaluate if priapism occurs. ECT. Reevaluate periodically. Elderly. Debilitated. Pregnancy (Cat.C). Nursing mothers.

Interactions: Allow 14 days after discontinuing an MAOI before starting nefazodone; allow 7 days after discontinuing nefazodone before starting an MAOI. Avoid alcohol. Avoid concomitant triazolam (esp. in elderly); if used, reduce concomitant triazolam dose by 75%. Reduce concomitant alprazolam dose by 50%. Caution with antihypertensives, diuretics, other CNS-active drugs, oral anticoagulants, oral hypoglycemics, aspirin, other highly protein-bound drugs, drugs metabolized by CYP3A4. Risk of rhabdomyolysis with statins metabolized by CYP3A4 (eg, simvastatin, lovastatin, atorvastatin). May potentiate buspirone, haloperidol (reduce

dose); cyclosporine, tacrolimus, digoxin (monitor). Discontinue before general anesthesia.

Adverse reactions: Headache, nausea, dizziness, insomnia, asthenia, agitation, somnolence, dry mouth, constipation, blurred or abnormal vision, confusion, postural hypotension, priapism, others; rare: hepatic failure.

How supplied: Contact supplier.

NORTRIPTYLINE

R

PAMELOR Mallinckrodt

Tricyclic. Nortriptyline HCl 10mg, 25mg, 50mg, 75mg; caps.

Also: Nortriptyline

R

NORTRIPTYLINE ORAL SOLUTION (various)

Nortriptyline (as HCl) 10mg/5mL; contains alcohol 4%.

Indications: Depression.

Adults: Initially 25mg 3–4 times daily; max 150mg/day. Elderly and adolescents: 30–50mg/day in single or divided doses.

Children: Not recommended.

Contraindications: During or within 14 days of MAOIs. Concomitant linezolid or IV methylene blue. Acute post-MI.

Warnings/Precautions: Suicidal tendencies (monitor). Mania/hypomania. Bipolar disorder. Psychosis. ECT. Cardiovascular disease. Glaucoma. Urinary retention. Epilepsy. Hyperthyroidism. Diabetes. Liver disorders. Monitor plasma levels if dose >100mg/day. Elderly. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Hyperpyretic crisis, convulsions, death with MAOIs. Serotonin syndrome possible with concomitant triptans, tricyclics, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's wort, linezolid, IV methylene blue. Potentiates alcohol, sympathomimetics. CNS stimulation with reserpine. Potentiated by CYP2D6 inhibitors; monitor plasma levels with quinidine, cimetidine, SSRIs, phenothiazines, type 1C antiarrhythmics (eg, propafenone, flecainide). Antagonized by barbiturates, carbamazepine, phenytoin. Paralytic ileus, hyperpyrexia with anticholinergics. Blocks guanethidine.

Adverse reactions: Drowsiness, anticholinergic effects, CNS overstimulation, arrhythmias, extrapyramidal symptoms, hypo- or hypertension, nausea, fatigue, rash, increased perspiration, headache, changes in blood sugar, photosensitivity, edema, blood dyscrasias, jaundice.

How supplied: Caps-30; Soln-contact supplier

OLANZAPINE

R

ZYPREXA Lilly

Thienobenzodiazepine. Olanzapine 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg; tabs.

Also: Olanzapine

R

ZYPREXA ZYDIS

Olanzapine 5mg, 10mg, 15mg, 20mg; orally-disintegrating tabs; contains phenylalanine.

Indications: Bipolar disorder: as monotherapy or with lithium or valproate for short-term use in acute mixed or manic episodes, or for maintenance. In combination with fluoxetine: depressive episodes associated with bipolar disorder, or treatment resistant depression (TRD; see literature).

Adults: Bipolar disorder: Monotherapy: initially 10–15mg once daily; may increase by 5mg/day. Concomitant lithium or valproate: initially 10mg once daily. For both: max 20mg/day. Maintenance: usual range 5–20mg/day. Debilitated, risk of hypotension, slow metabolizers, or sensitive to olanzapine: initially 5mg once daily; increase cautiously. Bipolar depression: initially olanzapine 5mg + fluoxetine 20mg once daily in the PM; range: olanzapine 5–20mg + fluoxetine 20–50mg. Risk of hypotension, hepatic impairment, slow metabolizers, or sensitive to olanzapine: initially olanzapine 2.5–5mg + fluoxetine 20mg; increase cautiously. Dose adjustments: see literature. Zydys: Dissolve in mouth and swallow with or without fluids.

Children: <13yrs: not recommended. 13–17yrs: Bipolar disorder: Monotherapy: initially 2.5–5mg once daily; increase to target dose of 10mg/day, adjust by 2.5–5mg if needed; max 20mg/day. Maintenance: continue at lowest dose to maintain remission: see literature.

Also: Olanzapine

R

ZYPREXA INTRAMUSCULAR

Olanzapine 10mg/vial; IM inj after reconstitution.

Indications: Agitation due to bipolar I mania.

Adults: Give by deep IM inj. Usual range: 2.5mg–10mg/dose. Elderly: 5mg. Debilitated, risk of hypotension, or sensitive to olanzapine: 2.5mg. All: up to 3 doses daily (2–4 hrs apart); switch to oral form when appropriate. Severe orthostatic hypotension: not recommended.

Children: Not recommended.

Contraindications: Combination therapies: see other drug monographs.

Warnings/Precautions: Relprevv: post-injection delirium/sedation syndrome: monitor after each injection. Elderly (not for dementia-related psychosis; may increase risk of death). Cardio- or cerebrovascular disease. Diabetes. Monitor for hyperglycemia, hyperlipidemia; do fasting blood glucose and lipids testing at beginning, and during therapy. Monitor for weight gain. Hypovolemia. Dehydration. History of seizures. Conditions that affect metabolism or hemodynamic responses. Hepatic impairment (monitor ALT/AST). GI or GU obstruction. Narrow angle glaucoma. History of paralytic ileus or breast cancer. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Exposure to extreme heat. Reevaluate periodically. Dysphagia. Suicidal ideation (monitor). Write R for smallest practical

amount. Debilitated. Labor & delivery. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Orthostatic hypotension with antihypertensives, alcohol, benzodiazepines, others. Avoid alcohol. Caution with other CNS drugs, drugs that lower seizure threshold, anticholinergics, and with hepatotoxic agents. May antagonize levodopa, dopamine agonists. May be antagonized by rifampin, omeprazole, carbamazepine, others that induce CYP1A2 or glucuronyl transferase. May be potentiated by fluvoxamine, others that inhibit CYP1A2. Smokers may have increased metabolism.

Adverse reactions: Somnolence, sedation, dizziness, constipation, weight gain, personality disorder, akathisia, asthenia, rhinitis, postural hypotension, tachycardia, headache, fever, abdominal pain, diarrhea, vomiting, dry mouth, cough, nasopharyngitis, nervousness, joint pain, peripheral edema, hyperglycemia, tardive dyskinesia, worsening of parkinsonian symptoms, neuroleptic malignant syndrome (monitor), hyperprolactinemia, increased ALT; leukopenia, neutropenia, agranulocytosis; others.

How supplied: Tabs–30, 1000; Zydys–30; Vial–1

OLANZAPINE + FLUOXETINE

SYMBYAX Lilly

Thienobenzodiazepine + SSRI. Olanzapine, fluoxetine (as HCl); 3mg/25mg, 6mg/25mg, 6mg/50mg, 12mg/25mg, 12mg/50mg; caps.

Indications: Depressive episodes associated with bipolar disorder. Treatment-resistant depression (TRD); see full labeling.

Adults: ≥18yrs: Take once daily in the PM. Bipolar depression: initially one 6mg/25mg cap; range: 6–12mg/25–50mg. TRD: initially one 6mg/25mg cap; range: 6–18mg/25–50mg. Both: max 18mg/75mg per day. Risk of hypotension, hepatic impairment, slow metabolizers, or sensitive to olanzapine: initially 3mg/25mg to 6mg/25mg; increase cautiously. Switching to or from MAOIs: see full labeling.

Children: <18yrs: not recommended.

Contraindications: Concomitant MAOIs during or within at least 5 weeks of discontinuing olanzapine/fluoxetine. Within 14 days of discontinuing an MAOI. Concomitant linezolid or IV methylene blue. Concomitant pimozide or thioridazine (may cause QTc prolongation).

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults; monitor for clinical worsening or changes. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs/symptoms; discontinue if occurs. Cardio- or cerebrovascular disease. Hepatic impairment (monitor ALT/AST). Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during

1st few months of treatment; discontinue if WBCs decline. Hypovolemia. Dehydration. History of seizures or mania/hypomania. Conditions that affect metabolism or hemodynamic response. Diabetes. Monitor for hyperglycemia, hyperlipidemia; do fasting blood glucose and lipids testing at beginning, and during therapy. Monitor for weight gain. Narrow angle glaucoma. Prostatic hypertrophy. History of paralytic ileus or breast cancer. Exposure to extreme heat. Dysphagia. Reevaluate periodically. Write Rx for smallest practical amount. Avoid abrupt cessation. Elderly (not for dementia-related psychosis; may increase risk of death). Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to SSRIs or SNRIs exposure during 3rd-trimester pregnancy). Labor & delivery. Pregnancy (Cat.C; avoid in 3rd trimester or consider lower dose; see literature). Nursing mothers: not recommended.

Interactions: See Contraindications. Do not start with concomitant linezolid or IV methylene blue; if treatment is necessary, discontinue olanzapine/fluoxetine before starting; monitor for serotonin syndrome for 5 weeks or until 24hrs after last dose of linezolid or IV methylene blue, whichever comes first. Do not start thioridazine within at least 5 weeks of discontinuing olanzapine/fluoxetine. Concomitant SSRIs, SNRIs: not recommended. May increase phenytoin, carbamazepine, haloperidol, clozapine levels. May potentiate other protein bound drugs and those metabolized by CYP2D6 (eg, tricyclics). May be potentiated by CYP1A2 inhibitors (eg, fluvoxamine). May antagonize levodopa, dopamine agonists. May be antagonized by carbamazepine, rifampin, omeprazole, other CYP1A2 or glucuronyl transferase inducers. Increased risk of bleeding with NSAIDs, aspirin, warfarin, others that affect coagulation. Orthostatic hypotension with antihypertensives, benzodiazepines, alcohol, others. Hyponatremia with diuretics. Caution with triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, buspirone, tryptophan, St. John's wort, linezolid, IV methylene blue; may cause serotonin syndrome (eg, agitation, tachycardia, incoordination, hyperreflexia). Caution with other antipsychotics, benzodiazepines, drugs that lower seizure threshold, other CNS drugs, hepatotoxic agents, anticholinergics, other forms of olanzapine or fluoxetine. Smokers may have increased metabolism.

Adverse reactions: Disturbance in attention, dry mouth, fatigue, hypersomnia, increased appetite, peripheral edema, sedation, somnolence, tremor, blurred vision, weight gain, orthostatic hypotension; rare: neuroleptic malignant syndrome, tardive dyskinesia, hyponatremia, hyperprolactinemia, mania/hypomania, elevated liver enzymes, serotonin syndrome; severe neutropenia.

How supplied: Caps 3mg/25mg, 12mg/25mg–30 6mg/25mg, 6mg/50mg, 12mg/50mg–30, 100

PAROXETINE**PAXIL CR** GlaxoSmithKline

SSRI. Paroxetine (as HCl) 12.5mg, 25mg, 37.5mg; controlled-release e-c tabs.

Indications: Depression. Premenstrual dysphoric disorder (PMDD).**Adults:** Swallow whole. Give once daily, usually in the AM, adjust by 12.5mg/day at 1-week intervals. Depression: initially 25mg/day; max 62.5mg/day. PMDD: Give daily throughout menstrual cycle or intermittently (start 14 days before expected menses onset through 1st full day of menses): initially 12.5mg/day; usual max 25mg/day. Elderly, debilitated, severe hepatic or renal impairment: initially 12.5mg/day; max 50mg/day.**Children: Not recommended.****Also: Paroxetine****PAXIL**

Paroxetine (as HCl) 10mg+, 20mg+, 30mg, 40mg; tabs; + scored.

Also: Paroxetine**PAXIL SUSPENSION**

Paroxetine (as HCl) 10mg/5mL; orange-flavored liq.

Indications: Depression.**Adults:** Give once daily, usually in the AM, adjust by 10mg/day at 1-week intervals. Initially 20mg/day; max 50mg/day. Elderly, debilitated, severe hepatic or renal impairment: initially 10mg/day; max 40mg/day.**Children: Not recommended.****Contraindications:** Concomitant pimozide, linezolid, IV methylene blue, thioridazine. During or within 14 days of MAOIs.**Warnings/Precautions:** Suicidal tendencies (monitor). History of seizures (discontinue if occurs), mania/hypomania. Monitor for serotonin syndrome or neuroleptic malignant syndrome-like signs and symptoms; discontinue if occurs. Conditions that affect metabolism or hemodynamic response. Cardiac disease. ECT. Narrow angle glaucoma. Write R for smallest practical amount. Avoid abrupt cessation; reduce dose gradually. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.D); avoid use. Nursing mothers.**Interactions:** See Contraindications. Do not start MAOI until at least 2 weeks after discontinuing paroxetine. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. Potentiation with other protein bound drugs. Caution with drugs that affect coagulation (eg, warfarin, NSAIDs). Potentiated by cimetidine. Antagonized by fosamprenavir/ritonavir. May affect, or be affected by, drugs metabolized by CYP2D6, including tricyclic antidepressants, fluoxetine, phenothiazines, risperidone, atomoxetine, tamoxifen, Class 1C antiarrhythmics, quinidine. Monitor digoxin, phenytoin, phenobarbital, theophylline, warfarin.

R

Reduce procyclidine dose if anticholinergic effects occur. Hormonal contraceptives and PMDD treatment: see literature.

Adverse reactions: GI upset, asthenia, sweating, decreased appetite, somnolence, dizziness, insomnia, nervousness, headache, decreased libido, tremor, akathisia, dry mouth, abnormal ejaculation, genital disorders, impotence, hyponatremia, abnormal bleeding, others; serious discontinuation symptoms (monitor); rare: neuroleptic malignant syndrome.**How supplied:** CR-30; Tabs-30; Susp-250mL**QUETIAPINE**

R

SEROQUEL XR AstraZeneca

Dibenzothiazepine. Quetiapine (as fumarate) 50mg, 150mg, 200mg, 300mg, 400mg; ext-rel tabs.

R

Indications: Monotherapy for acute manic or mixed episodes in bipolar I disorder; or as an adjunct to lithium or valproate for acute manic or mixed episodes and maintenance treatment. Depressive episodes associated with bipolar disorder. Adjunct to antidepressants for major depressive disorder (MDD).

R

Adults: Swallow whole. Take on an empty stomach or with light meal. Give once daily in the PM.

Depressive episodes due to bipolar disorder: 50mg on day 1, then 100mg on day 2, then 200mg on day 3, then 300mg on day 4; max 300mg/day.

Mania: Give once daily in the PM. 300mg on day 1, then 600mg on day 2, then titrate to effective dose beginning on day 3, usually 400-800mg/day. Maintenance: usual range 400-800mg/day. Adjunct to MDD: 50mg/day on days 1 and 2, then 150mg/day on day 3, then titrate to effective dose, usual range: 150-300mg/day. Elderly, debilitated, or risk of postural hypotension: titrate more slowly to lower target dose. Elderly or hepatic impairment: initially 50mg/day; may increase at increments of 50mg/day. Concomitant CYP3A4 inhibitors or inducers, reinitiation of treatment: see full labeling.

Switching from Seroquel immediate-release: give XR at equivalent total daily dose taken once daily.

Children: Swallow whole. Take on an empty stomach or with light meal. Give once daily in the PM. <10yrs: not established. 10-17yrs: Mania: 50mg on day 1, then 100mg on day 2, then 200mg on day 3, then 300mg on day 4, then 400mg on day 5; may further increase up to target range of 400-600mg/day; max 600mg/day.**Also: Quetiapine****SEROQUEL**

R

Quetiapine (as fumarate) 25mg, 50mg, 100mg, 200mg, 300mg, 400mg; tabs.

Indications: Monotherapy for acute mania in bipolar I disorder; or as an adjunct to lithium or valproate for acute mania and maintenance treatment. Depressive episodes associated with bipolar disorder.**Adults:** ≥17yrs: Mania: 100mg/day in 2 divided doses on day 1, then increase in increments of up to 100mg/day in 2 divided doses, to target 400mg/day by day 4; then may increase in increments of up to

200mg/day to max 800mg/day in divided doses by day 6. Usual range 400–800mg/day. Maintenance: usually 400–800mg/day in two divided doses; or may continue on same stabilized dose. Depressive episodes due to bipolar disorder: Give at bedtime. 50mg on day 1, then 100mg on day 2, then 200mg on day 3, then 300mg on day 4; max 300mg/day. Elderly, debilitated, or risk of postural hypotension: titrate more slowly to lower target dose. Elderly: initially 50mg/day. Hepatic impairment: initially 25mg/day; titrate daily by 25–50mg/day to effective dose. Concomitant CYP3A4 inhibitors or inducers, reinitiation of treatment: see full labeling.

Children: <10yrs: not established. 10–17yrs: Mania: 25mg twice daily on day 1, then 50mg twice daily on day 2, then 100mg twice daily on day 3, then 150mg twice daily on day 4, then 200mg twice daily on day 5; may further increase in increments up to 100mg/day to target range of 400–600mg/day (may give 3 times daily); max: 600mg/day.

Warnings/Precautions: Elderly with dementia-related psychosis (not approved use); increased risk of death or cerebrovascular events (eg, stroke, TIA). Increased risk of suicidal thoughts and behavior in children, adolescents, and young adults; monitor closely for worsening or unusual changes in behavior in all patients. Exclude neuroleptic malignant syndrome if fever or other symptoms occur. Diabetes. Monitor for hyperglycemia, hyperlipidemia: do fasting blood glucose and lipids testing initially and during therapy. Monitor for weight gain. Cardio- or cerebrovascular disease. Monitor BP in children and adolescents initially and during therapy. Increased risk of QT prolongation (eg, family history, cardiovascular disease, elderly, CHF, heart hypertrophy). Avoid in cardiac arrhythmias (eg, bradycardia), hypokalemia, hypomagnesemia, congenital prolongation of the QT interval. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Hepatic dysfunction. Seizure risk. Risk of aspiration pneumonia. Exposure to extreme heat. Dehydration. Hypovolemia. Do eye exam initially and every 6 months. History of breast cancer. Reevaluate periodically. Avoid abrupt cessation. Write $\mathbb{R}$ for smallest practical amount. Debilitated. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid drugs that prolong QT interval including Class 1A (eg, quinidine, procainamide) or Class III antiarrhythmics (eg, amiodarone, sotalol), antipsychotics (eg, ziprasidone, chlorpromazine, thioridazine), antibiotics (eg, gatifloxacin, moxifloxacin), and others (eg, pentamidine, methadone, levomethadyl acetate). Potentiates CNS effects with alcohol (avoid), other CNS depressants. Antagonized by CYP3A4 inducers (eg, thioridazine, phenytoin, carbamazepine, phenobarbital, rifampin);

adjust dose. Potentiates antihypertensives, lorazepam. Antagonizes effects of levodopa, dopamine agonists. Caution with drugs that interfere with temperature regulation (eg, anticholinergics) and with CYP3A inhibitors (eg, azole antifungals, erythromycin).

Adverse reactions: Somnolence, dry mouth, constipation, dizziness, increased appetite, dyspepsia, weight gain, fatigue, dysarthria, nasal congestion, asthenia, abdominal pain, postural hypotension, pharyngitis, lethargy, hyperglycemia, hypothyroidism, hyperprolactinemia; increased ALT (transient), total cholesterol +/or triglycerides; leukopenia, neutropenia, agranulocytosis; rarely: tardive dyskinesia, neuroleptic malignant syndrome.

How supplied: XR-60; Tabs 25mg, 50mg, 100mg, 200mg, 400mg-100; 300mg-60

RISPERIDONE

$\mathbb{R}$

RISPERDAL CONSTA Janssen

Benzisoxazole. Risperidone 12.5mg, 25mg, 37.5mg, 50mg; per vial; pwd for long-acting IM inj after reconstitution.

Indications: Monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder.

Adults: Risperidone-naïve: rule out risperidone hypersensitivity before using injection. Give by deep deltoid or gluteal IM inj; alternate sides. Give with oral risperidone (or other antipsychotic) for 3 weeks, then stop oral form. ≥ 18 yrs: 25mg IM every 2 weeks; may adjust dose every 4 weeks. Max 50mg every 2 weeks. Renal or hepatic impairment: if total daily dose of at least 2mg of oral risperidone tolerated, may give 12.5mg or 25mg IM every 2 weeks. History of poor tolerability to psychotropic drugs or drug interactions that increase risperidone plasma levels (see literature); may use lower initial dose of 12.5mg.

Children: <18yrs: not recommended.

Warnings/Precautions: Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia. Cardio- or cerebrovascular disease. Renal or hepatic dysfunction. Orthostatic hypotension. Pre-existing low WBC count or history of leukopenia/neutropenia: monitor CBC during 1st few months of therapy; discontinue if WBCs decline. Parkinson's disease. Dementia with Lewy bodies. Diseases that affect metabolic or hemodynamic response. History of breast cancer or seizures. Dysphagia. Reevaluate periodically. Monitor for neuroleptic malignant syndrome. May have antiemetic effect. Exposure to extreme temperatures. Suicidal patients. Elderly (not for dementia-related psychosis); consider monitoring renal function and for orthostatic effects. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended (do not breastfeed until at least 12 weeks after last injection).

Interactions: Avoid alcohol. Caution with other CNS drugs. May potentiate antihypertensives. May antagonize levodopa, dopamine agonists. Clearance may be decreased by clozapine; may be increased by carbamazepine, other enzyme inducers (eg, phenytoin, rifampin, phenobarbital); adjust risperidone dose. May be potentiated by cimetidine, ranitidine. May be affected by fluoxetine, paroxetine, others that affect CYP isoenzymes. Monitor valproate.

Adverse reactions: Headache, somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, parkinsonism, dystonia, abdominal pain, anxiety, GI upset, dizziness, dry mouth, tremor, rash, akathisia; orthostatic hypotension, tardive dyskinesia, neuroleptic malignant syndrome, hyperprolactinemia, priapism, leukopenia/neutropenia, agranulocytosis, thrombotic thrombocytopenic purpura (rare).

How supplied: Inj: single-use vial-1 (pack w. diluent, supplies)

RISPERIDONE

RISPERDAL TABLETS Janssen
Benzisoxazole. Risperidone 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg.

Also: Risperidone
RISPERDAL ORAL SOLUTION
Risperidone 1mg/mL.

Also: Risperidone
RISPERDAL M-TABS
Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg; orally-disintegrating tabs; contains phenylalanine.

Indications: Monotherapy in adults and children/adolescents (10–17yrs old) for short-term treatment of acute manic or mixed episodes associated with bipolar 1 disorder, or in combination with lithium or valproate in adults. Irritability associated with autistic disorder in children/adolescents (5–16yrs old).

Adults: Initially 2–3mg once daily; may adjust at intervals of at least 24 hours by 1mg/day. Usual range: 1–6mg/day; max 6mg/day. Elderly, debilitated, hypotensive, severe renal or hepatic impairment: 0.5mg twice daily; adjust in increments of up to 0.5mg twice daily; titrate at intervals of at least 1 week if exceeding 1.5mg twice daily; may switch to once-daily dosing after titration. For all: re-evaluate periodically; withdraw gradually. Oral soln: do not give with cola, tea. M-Tabs: dissolve on tongue; swallow with or without liquid.

Children: Bipolar mania: <10yrs: not recommended. ≥10yrs: Initially 0.5mg once daily (AM or PM); may adjust at intervals of at least 24 hours by 0.5mg or 1mg/day to target dose of 2.5mg/day. Usual range: 0.5–6mg/day; max 6mg/day. If somnolence occurs: give ½ daily dose twice daily. Irritability w. autism: <5yrs: not recommended. ≥5yrs: Give as a single daily dose or ½ total daily dose twice daily. <20kg: initially 0.25mg/day; may increase to 0.5mg/day after ≥4

days. Maintain dose for ≥14 days; if no response, may increase at ≥2 week intervals in increments of 0.25mg/day. ≥20kg: initially 0.5mg/day; may increase to 1mg/day after ≥4 days. Maintain dose for ≥14 days; if no response, may increase at ≥2 week intervals in increments of 0.5mg/day. If somnolence occurs, give once daily dose at bedtime, or ½ daily dose twice daily, or reduce dose. <15kg: use cautiously. For all: re-evaluate periodically.

Warnings/Precautions: Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia. Cardio- or cerebrovascular disease. Renal or hepatic dysfunction. Orthostatic hypotension. Pre-existing low WBC count or history of leukopenia/neutropenia: monitor CBC during 1st few months of therapy; discontinue if WBCs decline. Parkinson's disease. Dementia with Lewy bodies. Diseases that affect metabolic or hemodynamic response. History of breast cancer or seizures. Dysphagia. Reevaluate periodically. Monitor for neuroleptic malignant syndrome. May have antiemetic effect. Exposure to extreme temperatures. Suicidal patients. Elderly (not for dementia-related psychosis); consider monitoring renal function and for orthostatic effects. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid alcohol. Caution with other CNS drugs. May potentiate antihypertensives. May antagonize levodopa, dopamine agonists. Clearance may be decreased by clozapine; may be increased by carbamazepine, other enzyme inducers (eg, phenytoin, rifampin, phenobarbital); adjust risperidone dose. May be potentiated by cimetidine, ranitidine. May be affected by fluoxetine, paroxetine, others that affect CYP isoenzymes. Monitor valproate.

Adverse reactions: Headache, somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, parkinsonism, dystonia, abdominal pain, anxiety, GI upset, dizziness, dry mouth, tremor, rash, akathisia; orthostatic hypotension, tardive dyskinesia, neuroleptic malignant syndrome, hyperprolactinemia, priapism, leukopenia/neutropenia, agranulocytosis, thrombotic thrombocytopenic purpura (rare).

How supplied: Tabs 0.25mg, 0.5mg, 1mg, 2mg, 3mg–60, 500; 4mg–60; Oral soln–30mL (w. pipette); M-Tabs–28

SERTRALINE

ZOLOFT Pfizer
SSRI. Sertraline (as HCl) 25mg, 50mg, 100mg; scored tabs.

Also: Sertraline
ZOLOFT ORAL CONCENTRATE
Sertraline (as HCl) 20mg/mL; soln; contains alcohol 12%. Dilute just before administering in 4oz water, ginger ale, lemon/lime soda, lemonade, or orange juice.

Indications: Depression. Premenstrual dysphoric disorder (PMDD).

Adults: Give once daily (AM or PM). Depression: initially 50mg/day, may increase at 1-week intervals; max 200mg/day. PMDD: give either for entire menstrual cycle or only during luteal phase. Luteal phase dosing: initially 50mg/day; if no response, may increase to 100mg/day, starting each cycle at 50mg/day for 3 days. Entire cycle dosing: initially 50mg/day, if no response, may increase by 50mg/cycle to max 150mg/day.

Children: Not recommended.

Contraindications: Concomitant MAOIs during or within 14 days of discontinuing sertraline. Within 14 days of discontinuing an MAOI. Concomitant linezolid or IV methylene blue. Concomitant pimozide. Oral soln: concomitant disulfiram.

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults; monitor for clinical worsening or changes. Monitor for signs/symptoms of serotonin syndrome; discontinue if occurs. Monitor for mania/hypomania. Seizure disorders. Hepatic dysfunction (reduce dose or prolong dosing interval). Cardiac disease. Conditions that affect metabolism or hemodynamic response. History of glaucoma. Volume depleted. Monitor weight. Avoid abrupt cessation. Reevaluate periodically in long-term use. Write $\mathbb{R}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Do not start with concomitant linezolid or IV methylene blue; if treatment is necessary, discontinue sertraline before starting; monitor for serotonin syndrome for 2 weeks or until 24 hours after last dose of linezolid or methylene blue, whichever comes first. Risk of serotonin syndrome with concomitant serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) and with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. May potentiate or be potentiated by cimetidine, protein bound drugs (eg, warfarin, digitoxin). Caution with other CNS drugs and drugs metabolized by CYP2D6 (eg, tricyclics, flecainide, propafenone). Potentiates diazepam, tolbutamide. Monitor lithium, warfarin, tricyclics. Monitor patients on sumatriptan for serotonin syndrome (eg, weakness, incoordination, hyperreflexia). Increased risk of bleeding with NSAIDs, aspirin, warfarin, and others that affect coagulation.

Adverse reactions: Diarrhea, nausea, insomnia, somnolence, sexual dysfunction, tremor, dry mouth, sweating, anorexia, weight loss, anxiety, decreased libido, hyponatremia, weak uricosuric effect.

How supplied: Tabs 25mg-30, 50; 50mg, 100mg-30, 100, 500, 5000; Conc-60mL (w. dropper)

TRAZODONE

$\mathbb{R}$

TRAZODONE (various)
Triazolopyridine. Trazodone HCl 50mg, 100mg, 150mg+, 300mg+; scored (+bi/trisected) tabs.

Indications: Depression.

Adults: ≥ 18 yrs: initially 150mg/day in divided doses with food. May increase by 50mg/day at 3-4 day intervals; max 400mg/day (outpatients) or 600mg/day (inpatients) in divided doses; give most of dose at bedtime.

Children: <18 yrs: not recommended.

Contraindications: Acute post MI.

Warnings/Precautions: Avoid ECT. Urinary retention. Cardiovascular disease. Suicidal tendencies. Bipolar disorder. Mania/hypomania. Psychosis. Discontinue if priapism occurs. Epilepsy. Liver disorders. Write $\mathbb{R}$ for smallest practical amount. Reevaluate periodically. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates alcohol, other CNS depressants, digoxin, phenytoin, antihypertensives. Potentiated by potent CYP3A4 inhibitors (eg, nefazodone, ritonavir, indinavir, ketoconazole, itraconazole); consider reducing trazodone dose. Antagonized by potent CYP3A4 inducers (eg, carbamazepine); may need dose adjustments. Caution if starting trazodone during or after MAOI therapy. May affect anticoagulants. Discontinue before general anesthetics, if possible.

Adverse reactions: Drowsiness, dizziness, anticholinergic effects (rare), CNS overstimulation, arrhythmias, extrapyramidal symptoms, hypotension, GI upset, fatigue, headache, leukopenia, priapism, impotence, seizures, altered liver function tests.

How supplied: Contact supplier.

VENLAFAXINE

$\mathbb{R}$

EFFEXOR XR Pfizer

Serotonin and norepinephrine reuptake inhibitor. Venlafaxine (as HCl) 37.5mg, 75mg, 150mg; ext-rel caps.

Indications: Major depressive disorder.

Adults: Take with food. Swallow whole or sprinkle contents on spoonful of applesauce; do not chew. Transferring from immediate-release: give total daily dose on once-daily basis. Initially 75mg once daily; may start at 37.5mg once daily for 4-7 days before increasing to 75mg/day; may increase by increments of up to 75mg/day at intervals of at least 4 days; usual max 225mg/day. Moderate hepatic impairment: reduce by 50%. Renal impairment: reduce by 25-50%; reduce dose by 50% in hemodialysis (hold dose until end of treatment). Withdraw gradually (reduce by 75mg/day at 1-week intervals).

Children: Not established.

Also: *Venlafaxine*

$\mathbb{R}$

EFFEXOR

Venlafaxine (as HCl) 25mg, 37.5mg, 50mg, 75mg, 100mg; scored tabs.

Adults: Take with food. ≥ 18 yrs: Initially 75mg/day in 2–3 divided doses; may increase at 4-day intervals in 75mg/day increments to 150mg/day; max 375mg/day, in 3 divided doses. Hepatic impairment: reduce by at least 50%. Mild-to-moderate renal impairment: reduce by at least 25%; hemodialysis: reduce by 50% (hold dose until end of dialysis treatment). Withdraw gradually (over 2 weeks).

Children: < 18 yrs: not established.

Contraindications: MAOIs (see Interactions). Concomitant linezolid or IV methylene blue.

Warnings/Precautions: Increased risk of suicidal thinking and behavior in children, adolescents, and young adults. Monitor BP; reduce dose or discontinue if elevated BP persists. Heart disease (eg, recent MI, heart failure). Hypercholesterolemia (consider monitoring in long-term use). Renal or hepatic dysfunction. Increased intraocular pressure. Diseases that affect metabolism or hemodynamic response (eg, hyperthyroidism). Mania. Seizure disorders. Reevaluate periodically. Write $\mathbb{R}$ for smallest practical amount. Elderly. Labor & delivery. Pregnancy (Cat.C) (avoid 3rd trimester; see literature for effects on neonate). Nursing mothers: not recommended.

Interactions: See Contraindications. Allow at least 14 days after MAOI discontinuance before starting venlafaxine; allow at least 7 days after venlafaxine discontinuance before starting an MAOI. Risk of serotonin syndrome with concomitant serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) and with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Avoid alcohol. Concomitant weight loss agents (eg, phentermine), serotonin precursors (tryptophan supplements): not recommended. Caution with other CNS drugs, cimetidine, haloperidol, diuretics, metoprolol, drugs that inhibit CYP2D6, CYP3A4. Increased risk of bleeding with NSAIDs, aspirin, warfarin. False (+) urine immunoassay screening tests for PCP and amphetamine.

Adverse reactions: GI upset, dizziness, somnolence, insomnia, sexual dysfunction, sweating, dry mouth, nervousness, asthenia, tremor, vasodilation, hypertension, abnormal dreams or vision, yawn, paresthesia, agitation, ecchymosis, anorexia, weight changes; hyponatremia/SIADH (esp in elderly); rare: interstitial lung disease; eosinophilic pneumonia.

How supplied: Caps–15, 30, 90; Tabs 25mg, 37.5mg–60; 50mg, 75mg–30; 100mg–20

VILAZODONE

$\mathbb{R}$

VIIBRYD Forest

Selective serotonin reuptake inhibitor + 5-HT_{1A} receptor partial agonist. Vilazodone HCl 10mg, 20mg, 40mg; tabs.

Indications: Major depressive disorder.

Adults: Take with food. Initially 10mg once daily for 7 days, then 20mg once daily for 7 days, then

increase to 40mg once daily. Concomitant strong CYP3A4 inhibitors (eg, ketoconazole) or moderate CYP3A4 inhibitors (eg, erythromycin) with intolerable adverse events: reduce to 20mg once daily. Reevaluate periodically.

Children: Not recommended.

Contraindications: Concomitant MAOIs within 14 days of discontinuing vilazodone. Within 14 days of discontinuing MAOIs. Concomitant linezolid or IV methylene blue.

Warnings/Precautions: Monitor for clinical worsening, suicidality, or unusual changes in behavior. Activation of mania/hypomania; screen patients for bipolar disorder. Seizure disorder. Severe hepatic impairment. Avoid abrupt cessation. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Contraindications. Increased risk of serotonin syndrome with other serotonergic drugs (eg, triptans, tricyclic antidepressants, fentanyl, lithium, tramadol, tryptophan, buspirone, St. John's Wort) or with drugs that impair serotonin metabolism (eg, MAOIs, linezolid, IV methylene blue). Increased risk of bleeding with concomitant aspirin, NSAIDs, warfarin (monitor), other anticoagulants. Potentiated by CYP3A4 inhibitors. Antagonized by CYP3A4 inducers. Caution with other highly protein bound drugs.

Adverse reactions: GI upset, insomnia; hyponatremia (esp in elderly); possible neuroleptic malignant syndrome (monitor; discontinue if occurs).

How supplied: Tabs–30; Patient Starter Kit (7 $\times$ 10mg tabs, 7 $\times$ 20mg tabs, 16 $\times$ 40mg tabs)–30

ZIPRASIDONE

$\mathbb{R}$

GEODON Pfizer

Serotonin and dopamine antagonist. Ziprasidone HCl 20mg, 40mg, 60mg, 80mg; caps.

Indications: Acute and maintenance treatment of manic or mixed episodes in bipolar disorder as monotherapy; or as an adjunct to lithium or valproate.

Adults: Take with food. Initially 40mg twice daily; may increase on day 2 to 60mg or 80mg twice daily; usual range 40–80mg twice daily. Elderly: consider lower initial dose, slower titration.

Children: Not recommended.

Contraindications: History of QT prolongation.

Congenital long QT syndrome. Recent acute MI. Uncompensated heart failure. Concomitant drugs that cause QT prolongation, including dofetilide, sotalol, quinidine, other Class Ia and III antiarrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl, dolasetron, probucol, tacrolimus.

Warnings/Precautions: Increased mortality in elderly with dementia-related psychosis (not approved use). Concomitant use of oral and IM forms: not recommended. Renal (IM form) or hepatic impairment (both forms). Discontinue if

QTc >500 msec persists, neuroleptic malignant syndrome, or unexplained rash occurs; consider discontinuing if tardive dyskinesia occurs. Conditions that increase risk of torsade de pointes (eg, bradycardia, hypokalemia, hypomagnesemia). Monitor potassium, magnesium, others if risk of electrolyte disturbances (eg, diarrhea); correct imbalance before starting. Avoid in significant cardiovascular disease (eg, arrhythmias). Evaluate cardiac function if symptoms of torsade de pointes occur (eg, dizziness, palpitations, syncope). Cardio- or cerebrovascular disease. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Diabetes; monitor for hyperglycemia. Risk of hypotension or seizures. History of breast cancer. Dysphagia. Exposure to extreme heat. Reevaluate periodically. Write **Rx** for smallest practical amount. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. May potentiate CNS drugs, antihypertensives. Antagonizes levodopa, dopamine agonists. Extent of absorption and/or plasma levels may be affected by CYP3A4 inducers (eg, carbamazepine) or inhibitors (eg, ketoconazole). Correct hypokalemia, hypomagnesemia due to diuretics.

Adverse reactions: Somnolence, extrapyramidal syndrome, respiratory disorder, dizziness, akathisia, abnormal vision, asthenia, vomiting, rash, dystonia, tachycardia, myalgia, postural hypotension, QTc prolongation, headache, weight gain, hyperprolactinemia; rare: priapism.

How supplied: Caps-60

19E Psychosis

ARIPIRAZOLE

ABILIFY Bristol-Myers Squibb and Otsuka
Aripiprazole 2mg, 5mg, 10mg, 15mg, 20mg, 30mg; tabs.

Also: Aripiprazole

ABILIFY ORAL SOLUTION

Aripiprazole 1mg/mL; orange cream flavor; contains parabens.

Also: Aripiprazole

ABILIFY DISCMELT

Aripiprazole 10mg, 15mg; oral disintegrating tabs; vanilla flavor; contains phenylalanine.

Indications: Schizophrenia.

Adults: Tabs and soln may be interchanged on a mg-to-mg basis up to 25mg; 30mg as tablet is equivalent to 25mg oral soln. Discmelt: Dissolve on tongue; take without liquids. Initially 10mg or 15mg once daily; may increase at intervals of at least 2 weeks; usual maintenance 15mg/day; max

30mg/day. Reduce aripiprazole dose by at least ½ with CYP3A4 inhibitors or CYP2D6 inhibitors. Double aripiprazole dose (max 30mg/day) with CYP3A4 inducers. Adjust dose to normal range when these drugs are withdrawn.

Children: <13yrs: not recommended. 13–17yrs: initially 2mg daily, then increase to 5mg after 2 days, then increase to target dose of 10mg after 2 days. Subsequent doses may be adjusted by increments of 5mg/day; max 30mg/day. Maintenance: continue at lowest dose to maintain remission; see literature.

Also: Aripiprazole

ABILIFY MAINTENA

Aripiprazole extended-release injectable suspension 300mg, 400mg; per vial.

Adults: Treatment-naïve: establish tolerability with oral form first. Give by IM inj into the gluteal muscle. Initial and maintenance: 400mg once monthly (no sooner than 26 days after the previous inj); may consider reducing to 300mg once monthly if adverse reactions occur. After first Maintenance dose, continue with concurrent oral aripiprazole (10mg or 20mg) or other antipsychotic for 14 consecutive days. Dose adjustments for missed dose, CYP3A4 poor metabolizers, concomitant CYP2D6 inhibitors, CYP3A4 inhibitors or inducers for >14 days: see full labeling.

Children: <18yrs: not recommended.

Also: Aripiprazole

ABILIFY INJECTION

Aripiprazole 7.5mg/mL; soln for IM use only.

Indications: Treatment of agitation associated with schizophrenia.

Adults: 9.75mg IM, if 2nd dose is needed, may repeat after 2 hours; max 30mg/day. Switch to oral form as soon as possible. Reduce aripiprazole dose by at least ½ with CYP3A4 inhibitors or CYP2D6 inhibitors. Double aripiprazole dose (max 30mg/day) with CYP3A4 inducers. Adjust dose to normal range when these drugs are withdrawn.

Children: Not recommended.

Warnings/Precautions: Cardio- or cerebrovascular disease. Risk of hypotension, aspiration pneumonia, seizures, or diabetes (do baseline fasting blood sugar). Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Exposure to extreme heat. Dehydration. Reevaluate periodically. Monitor for hyperglycemia. Exclude neuroleptic malignant syndrome if fever occurs. Suicidal tendencies. Write **Rx** for smallest practical amount. Elderly (not for dementia-related psychosis). Labor & delivery. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid alcohol. Caution with other centrally-acting drugs. Potentiates antihypertensives. Levels may be reduced by CYP3A4 inducers (eg, carbamazepine). Levels may be increased by CYP3A4

inhibitors (eg, ketoconazole) or CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine). Caution with drugs that interfere with temperature regulation (eg, anticholinergics).

Adverse reactions: Headache, anxiety, insomnia, GI upset, somnolence, fatigue, akathisia, orthostatic hypotension, asthenia, blurred vision, tremor, pyrexia, salivary hypersecretion, neuroleptic malignant syndrome, tardive dyskinesia, weight gain, dyslipidemia, others. Inj: local reactions.

How supplied: Tabs 2mg–30; 5mg, 10mg, 15mg, 20mg, 30mg–30, 100; Oral soln (w. dosing cup)—150mL; Discmelt–30; Maintena Kit–1 (w. supplies); Single use vials–1

CHLORPROMAZINE

R

CHLORPROMAZINE (various)

Aliphatic phenothiazine. Chlorpromazine HCl 10mg, 25mg, 50mg, 100mg, 200mg; tabs; contains parabens.

Indications: Psychosis. Mania. Intractable hiccups. Severe childhood behavior problems. Tetany.

Adults: Psychosis: initially 10mg 3–4 (or 25mg 2–3) times daily; may increase semiweekly by 25–50mg daily. Hiccups: 25–50mg 3–4 times daily. Severe psychosis: initially 25mg 3 times daily; may increase semiweekly by 20–50mg/day.

Children: <6months: not recommended. ≥6 months: initially 0.25mg/lb every 4–6 hrs as needed.

Also: Chlorpromazine

R

CHLORPROMAZINE INJECTION

Chlorpromazine HCl 25mg/mL; for IV inj after dilution or IM inj; contains sulfites; multidose vials contain benzyl alcohol.

Indications: Rapid control of severe psychotic symptoms. Severe childhood behavior disorders. Adjunct in tetanus.

Adults: Psychosis: 25mg IM; may repeat in 1 hour, then switch to oral forms. Tetanus: 25–50mg IM 3–4 times daily or 25–50mg IV (see literature).

Children: <6months: not recommended. ≥6months: Severe behavior disorders: 0.25mg/lb IM every 6–8 hrs if needed. Tetanus: 0.25mg/lb IM or IV (see literature) every 6–8 hrs. Both: <5yrs or <50lbs: max 40mg/day; ≥5yrs or 50–100lbs: usual max 75mg/day.

Contraindications: Coma. CNS or bone marrow depression. Reye's syndrome.

Warnings/Precautions: Discontinue 48 hrs before to 24 hrs after myelography. Cardiovascular, respiratory, renal, or liver disease. Epilepsy. Glaucoma. History of breast cancer. Exposure to extreme heat or organophosphates. Asthma (inj). Monitor blood, liver, and ocular function. Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates phenytoin, alcohol, other CNS depressants, propranolol. Potentiated by propranolol. Antagonized by anticholinergics. Atropine. Decreased guanethidine, anticoagulant effects.

Adverse reactions: Tardive dyskinesia, drowsiness, jaundice, blood dyscrasias, hypotension,

retinopathy, may mask emetic signs of disease, lowered seizure threshold, rash, skin pigmentation, anticholinergic effects, insomnia, extrapyramidal reactions, neuroleptic malignant syndrome.

How supplied: Contact supplier.

CLOZAPINE

R

CLOZARIL Novartis

Atypical antipsychotic. Clozapine 25mg, 100mg; scored tabs.

Indications: Refractory severe schizophrenia. To reduce risk of recurrent suicidal behavior in schizoaffective disorders.

Adults: Initially 12.5mg 1–2 times daily; then usually given in divided doses; may increase by 25–50mg/day to 300–450mg/day by the end of 2 weeks. Then may increase once or twice weekly in increments of up to 100mg; max 900mg/day. Reevaluate periodically. Reduce gradually over 1–2 weeks if discontinuing; may discontinue abruptly if necessary (eg, leukopenia, myocarditis; may cause relapse or cholinergic rebound). Retitrate if stopped for ≥2 days. Caution when rechallenging (see full labeling). Suicidal behavior: usually 300mg/day; range 12.5mg–900mg/day; treat for at least 2 years.

Children: Not established.

Contraindications: Concomitant bone marrow suppressants or other agranulocytosis-causing agents. Myeloproliferative disorders. Uncontrolled epilepsy. Severe or history of clozapine-induced agranulocytosis, or granulocytopenia. Paralytic ileus. Severe CNS depression. Coma.

Warnings/Precautions: See full labeling. Increased mortality in elderly with dementia-related psychosis (not approved use). Significant risk of agranulocytosis. Monitor WBC and absolute neutrophil count (ANC) at baseline, weekly for 1st 6 months and for 4 weeks after discontinuing; if acceptable WBC and ANC maintained, may reduce monitoring to every 2 weeks after 6 months, then every 4 weeks after 12 months. History of seizures. Monitor for myocarditis if tachycardia occurs in 1st month; discontinue if myocarditis suspected. Increased risk of QT prolongation. Recent MI. Uncompensated heart failure. Arrhythmias. Cardio- or cerebrovascular disease. Pulmonary disease. Renal or hepatic impairment; discontinued if jaundice or significant increases in liver enzymes occur. Monitor for hyperglycemia. Diabetes or risk factors thereof. Glaucoma. GI or GU obstruction. Poor metabolizers. Surgery. Exclude infection, agranulocytosis, neuroleptic malignant syndrome if fever occurs. Tardive dyskinesia. Correct electrolyte abnormalities prior to starting; monitor at baseline and periodically thereafter. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd trimester pregnancy). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Caution with general anesthetics, benzodiazepines,

psychotropics (possible respiratory/cardiac arrest), fluvoxamine, paroxetine, sertraline. Caution with concomitant drugs known to prolong the QT interval (eg, quinidine, procainamide, amiodarone, sotalol), certain antipsychotics (eg, ziprasidone, iloperidone, chlorpromazine, thioridazine, mesoridazine, droperidol, pimozide), antibiotics (eg, gatifloxacin, moxifloxacin, sparfloxacin), and others (eg, pentamidine, levomethadyl acetate, methadone, halofantrine, mefloquine, dolasetron mesylate, probucol, tacrolimus). Caution with drugs that can cause electrolyte imbalance (eg, diuretics). May potentiate alcohol, CNS drugs, antihypertensives, anticholinergics. Caution with drugs that affect or are affected by CYP2D6, 3A4, 1A2; clozapine levels increased by CYP450 inhibitors (eg, citalopram, cimetidine, erythromycin); clozapine levels decreased by CYP450 inducers (eg, rifampin, phenytoin, nicotine). May potentiate or be potentiated by protein-bound drugs. Do not use epinephrine to reverse hypotension.

Adverse reactions: Sedation, dizziness, salivation, anticholinergic toxicity (eg, GI paralysis), agranulocytosis, seizures, tachycardia, orthostatic hypotension, syncope, weight gain, hyperglycemia, fever, myocarditis, eosinophilia, CHF, cardiomyopathy, neuroleptic malignant syndrome, thrombosis, pulmonary embolism.

Note: To register patients call National Registry at (800) 448-5938.

How supplied: Tabs-100, 500

CLOZAPINE

FAZACLO Jazz

Atypical. Clozapine 12.5mg, 25mg, 100mg, 150mg, 200mg; orally-disintegrating tabs; contains phenylalanine (0.87mg/12.5mg tab, 1.74mg/25mg tab, 6.96mg/100mg tab, 10.44mg/150mg tab, 13.92mg/200mg tab).

Indications: Refractory severe schizophrenia. To reduce risk of recurrent suicidal behavior in schizoaffective disorders.

Adults: Dissolve tablet in mouth. Initially 12.5mg 1–2 times daily; may increase by 25–50mg/day to 300–450mg/day in divided doses by the end of 2 weeks. Then may increase once or twice weekly in increments of up to 100mg; max 900mg/day. Reevaluate periodically. Reduce gradually over 1–2 weeks if discontinuing; may discontinue abruptly if necessary (eg, leukopenia, myocarditis; may cause relapse or cholinergic rebound). Retitrate if stopped for ≥ 2 days. Caution when rechallenging (see literature). Suicidal behavior: usually 300mg/day; range 12.5mg–900mg/day; treat for at least 2 years.

Children: Not recommended.

Contraindications: Concomitant bone marrow suppressants or other agranulocytosis-causing agents. Myeloproliferative disorders. Uncontrolled epilepsy. Severe or history of clozapine-induced agranulocytosis, granulocytopenia, or myocarditis. Paralytic ileus. Severe CNS depression. Coma.

Warnings/Precautions: See literature. Monitor WBC and absolute neutrophil count (ANC) at baseline, weekly for 1st 6 months and for 4 weeks after discontinuing; if acceptable WBC and ANC maintained, may reduce monitoring to every 2 weeks after 6 months, then every 4 weeks after 12 months. Monitor for myocarditis if tachycardia occurs in 1st month; discontinue if myocarditis suspected. Hypokalemia, hypomagnesemia, recent MI, uncompensated heart failure, arrhythmias, CV disease, congenital QT prolongation: avoid (risk of torsades de pointes/sudden death). Monitor electrolytes esp. K^+ , Mg^{++} . Monitor for hyperglycemia. Diabetes. Seizures. Cardio- or cerebrovascular, pulmonary, renal, or hepatic disease (discontinued if jaundice or significant increases in liver enzymes occur). Glaucoma. GI or GU obstruction. Surgery. Exclude infection, agranulocytosis, neuroleptic malignant syndrome if fever occurs. Elderly (not for dementia-related psychosis).

Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Caution with general anesthetics, benzodiazepines, psychotropics (possible respiratory/cardiac arrest), fluvoxamine, paroxetine, drugs that cause QT prolongation (eg, quinidine, amiodarone, sotalol, procainamide, chlorpromazine, thioridazine, moxifloxacin, methadone), drugs that can cause electrolyte imbalance (eg, diuretics). May potentiate alcohol, CNS drugs, antihypertensives, anticholinergics. Caution with drugs that affect or are affected by CYP2D6, 3A4, 1A2; clozapine levels increased by CYP450 inhibitors (eg, caffeine, cimetidine, erythromycin); clozapine levels decreased by CYP450 inducers (eg, rifampin, carbamazepine, phenytoin, nicotine). Do not use epinephrine to reverse hypotension.

Adverse reactions: Sedation, dizziness, headache, tremor, salivation, sweating, dry mouth, visual disturbances, tachycardia, orthostatic hypotension, syncope, GI upset, fever, anticholinergic toxicity (eg, GI paralysis), agranulocytosis, seizures, weight gain, hyperglycemia, myocarditis, eosinophilia, neuroleptic malignant syndrome, thrombosis, pulmonary embolism.

Note: To register patients call FazaClo Patient Registry at (877) 329-2256.

How supplied: Orally-disintegrating tabs-100

FLUPHENAZINE

FLUPHENAZINE (various)

Piperazine phenothiazine. Fluphenazine HCl 1mg, 2.5mg, 5mg +, 10mg; tabs; + contains tartrazine.

Also: Fluphenazine

FLUPHENAZINE CONCENTRATE

Fluphenazine HCl 5mg/mL; alcohol 14%. Dilute just before administration.

Also: Fluphenazine**FLUPHENAZINE ELIXIR**

Fluphenazine HCl 0.5mg/mL; alcohol 14%.

Indications: Psychosis.

Adults: Initially: 2.5–10mg daily in 3–4 divided doses; max 40mg daily.

Children: Not recommended.

Elderly: Initially 1–2.5mg daily in 3–4 divided doses; max 40mg daily.

Also: Fluphenazine**FLUPHENAZINE INJECTION**

Fluphenazine HCl 2.5 mg/mL; vial.

Adults: Initially: 1.25mg IM every 6–8 hrs; max 10mg daily.

Children: Not recommended.

Also: Fluphenazine**FLUPHENAZINE DECANOATE INJECTION**

Fluphenazine decanoate 25mg/mL; syringe; vial; contains benzyl alcohol.

Indications: Depot parenteral for psychosis.

Adults: Initially: 12.5–25mg IM or SC every 4–6 wks; max 100mg/dose.

Children: Not recommended.

Contraindications: Coma. CNS or bone marrow depression. Liver disease. Subcortical brain damage. Blood dyscrasias.

Warnings/Precautions: Cardiovascular or renal disease. Pheochromocytoma. Seizures. Glaucoma. History of breast cancer. Exposure to extreme heat or organophosphates. Gradually reduce to lowest effective maintenance dose. Monitor blood, liver, renal, and ocular function. Mental retardation. Surgery. Pregnancy. Nursing mothers.

Interactions: Potentiates anticholinergics, CNS depression with alcohol and other CNS depressants; both drugs with propranolol. Antagonized by anticholinergics. Decreased guanethidine effects. May cause false (+) pregnancy test.

Adverse reactions: Drowsiness, anticholinergic and other autonomic effects, insomnia, restlessness, rash, photosensitivity, tardive dyskinesia, blood dyscrasias, jaundice, pneumonia, hypertension, retinopathy, lowered seizure threshold, extrapyramidal reactions, neuroleptic malignant syndrome, weight changes, endocrine effects.

How supplied: Contact supplier.

HALOPERIDOL

HALDOL INJECTION Janssen

Butyrophenone. Haloperidol (as lactate) 5mg/mL; for IM inj.

Indications: Schizophrenia. Tourette's disorder.

Adults: Individualize. 2–5mg IM every 4–8 hrs or up to hourly if needed. Switch to oral form 12–24 hrs after last injection.

Children: Not recommended.

Also: Haloperidol**HALDOL DECANOATE INJECTION**

Haloperidol (as decanoate) 50mg/mL, 100mg/mL; for IM inj; contains benzyl alcohol.

Indications: Treatment of schizophrenia when prolonged parenteral therapy required.

Adults: Individualize. Administer by deep IM every 4 weeks. Initial therapy: switching from oral form: initially 10–20 times previous daily dose of oral haloperidol. Stabilized on low daily oral dose, elderly, or debilitated: 10–15 times previous daily dose of oral haloperidol. Maintained on high dose antipsychotics, risk of relapse, or if tolerant: consider 20 times previous daily oral dose; then titrate downward subsequently. Max initial dose: 100mg; if conversion requires >100mg, then give balance in 3–7 days. Maintenance therapy: usual range: 10–15 times previous daily dose of oral haloperidol based on response. Max: 450mg/month.

Children: Not recommended.

Contraindications: Severe CNS depression. Coma. Parkinsonism.

Warnings/Precautions: Elderly (not for dementia-related psychosis): increased risk of death. Risk of QT prolongation: electrolyte disturbances (eg, hypokalemia, hypomagnesemia), underlying cardiac abnormalities, hypothyroidism, familial long QT-syndrome, concomitant drugs known to prolong the QT interval. Seizures. Thyrotoxicosis. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Severe cardiovascular disorders. Mania. Avoid abrupt cessation. Dehydrated. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: CNS depression potentiated with alcohol, other CNS depressants. Possible neurotoxicity with lithium: monitor, discontinue if occurs.

Caution with drugs that prolong the QT interval (eg, ketoconazole, paroxetine). May be potentiated by CYP3A4 inhibitors/substrates or CYP2D6 enzymes (eg, itraconazole, nefazodone, buspirone, venlafaxine, alprazolam, fluvoxamine, quinidine, fluoxetine, sertraline, chlorpromazine, promethazine). May be antagonized by CYP3A4 inducers (eg, rifampin, carbamazepine); monitor and adjust doses. May increase intraocular pressure with anticholinergics, antiparkinson agents. Monitor anticoagulants.

Adverse reactions: Tardive dyskinesia, neuroleptic malignant syndrome, extrapyramidal symptoms, hyperpyrexia, heat stroke, bronchopneumonia, cardiovascular effects, hematological effects, GI upset, anticholinergic effects; QT prolongation, Torsades de Pointes, dystonia.

How supplied: Inj (1mL amps)–10

Decanoate 50 (1mL amps)–3

Decanoate 100 (1mL amps)–5

HALOPERIDOL

HALOPERIDOL TABLETS (various)

Butyrophenone. Haloperidol 0.5mg, 1mg, 2mg, 5mg, 10mg, 20mg; scored tabs.

Indications: Psychosis. Tourette's disorder.

For severe behavior disorders or as a short-term

treatment for hyperactivity in children who are refractory to psychotherapy or other medications.

Adults: Individualize. Initially: Moderate symptoms: 0.5mg–2mg 2–3 times daily. Severe, chronic, or resistant symptoms: 3mg–5mg 2–3 times daily. Debilitated: 0.5mg–2mg 2–3 times daily. Max: 100mg/day.

Children: <3yrs: not recommended. Total dose may be divided, to be given 2–3 times daily. ≥3yrs: Initially 0.5mg daily, may increase at increments of 0.5mg at 5–7 day intervals. Psychosis: 0.05mg/kg/day–0.15mg/kg/day. Nonpsychotic behavior and Tourette s: 0.05mg/kg/day–0.075mg/kg/day. Max 6mg/day.

Elderly: Initially 0.5mg–2mg 2–3 times daily.

Contraindications: Severe CNS depression. Coma. Parkinsonism.

Warnings/Precautions: Elderly (not for dementia-related psychosis): increased risk of death. Risk of QT prolongation: electrolyte disturbances (eg, hypokalemia, hypomagnesemia), underlying cardiac abnormalities, hypothyroidism, familial long QT-syndrome, concomitant drugs known to prolong the QT interval. Seizures. Thyrotoxicosis. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Severe cardiovascular disorders. Mania. Avoid abrupt cessation. Debilitated. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy. Nursing mothers: not recommended.

Interactions: CNS depression potentiated with alcohol, other CNS depressants. Possible neurotoxicity with lithium: monitor, discontinue if occurs. Caution with drugs that prolong the QT interval (eg, ketoconazole, paroxetine). May be potentiated by CYP3A4 inhibitors/substrates or CYP2D6 enzymes (eg, itraconazole, nefazodone, bupropion, venlafaxine, alprazolam, fluvoxamine, quinidine, fluoxetine, sertraline, chlorpromazine, promethazine. May be antagonized by CYP3A4 inducers (eg, rifampin, carbamazepine); monitor and adjust doses. May increase intraocular pressure with anticholinergics. Monitor anticoagulants.

Adverse reactions: Tardive dyskinesia, extrapyramidal symptoms, CNS effects, GI upset, cardiovascular effects, bronchopneumonia, neuroleptic malignant syndrome.

How supplied: Contact supplier.

ILOPERIDONE

FANAPT Novartis

Piperidyl-benzisoxazole atypical. Iloperidone 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg; tabs.

Indications: Acute treatment of schizophrenia.

Adults: ≥18yrs: 1mg twice daily on day 1, 2mg twice daily on day 2, 4mg twice daily on day 3, 6mg twice daily on day 4, 8mg twice daily on day 5, 10mg twice daily on day 6, 12mg twice daily

on day 7; target range 6–12mg twice daily; max 24mg/day. Reduce dose by ½ with concomitant strong CYP2D6/CYP3A4 inhibitors, or poor metabolizers of CYP2D6. Retitrate if therapy suspended >3 days. Reassess periodically.

Children: <18yrs: not recommended.

Warnings/Precautions: Increased mortality in elderly patients with dementia-related psychosis (not approved use). Bradycardia, hypokalemia, hypomagnesemia, congenital QT prolongation, recent MI, uncompensated heart failure, arrhythmias: avoid (risk of torsades de pointes/sudden death). Cardio- or cerebrovascular disease. Monitor electrolytes esp. K⁺, Mg⁺⁺. Hepatic impairment: not recommended. Diabetes or risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia, weight changes. History of breast cancer or seizures. Orthostatic hypotension. Preexisting low WBC count or history of leukopenia/neutropenia: monitor CBC during 1st few months of therapy; discontinue if WBCs decline. Exposure to extreme heat. Dehydration. Suicidal tendencies. Write Rx for the smallest practical amount. Monitor for neuroleptic malignant syndrome. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid other drugs that cause QT prolongation (eg, quinidine, amiodarone, sotalol, procainamide, chlorpromazine, thioridazine, moxifloxacin, methadone). May potentiate antihypertensives. Caution with alcohol, CNS depressants. Potentiated by inhibitors of CYP2D6 (eg, fluoxetine, paroxetine) or CYP3A4 (eg, clarithromycin, ketoconazole).

Adverse reactions: Dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, increased weight; QT prolongation (discontinue if QTc >500msec persists), priapism, neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia, dyslipidemia, dysphagia, hyperprolactinemia.

How supplied: Tabs–60; Titration pack–8 (2 × 1mg, 2 × 2mg, 2 × 4mg, 2 × 6mg)

LURASIDONE

R

LATUDA Sunovion

Atypical antipsychotic (benziso-thiazol derivative).

Lurasidone HCl 20mg, 40mg, 60mg, 80mg, 120mg; tabs.

Indications: Schizophrenia.

Adults: Take with food (≥350 calories). Initially 40mg once daily. Usual range: 40–160mg/day. Max 160mg/day. Moderate (CrCl 30–50mL/min) to severe renal impairment (CrCl <30mL/min), moderate hepatic impairment (Child Pugh Score 7–9): initially 20mg; max 80mg/day. Severe hepatic impairment (Child Pugh Score 10–15): initially 20mg; max 40mg/day. Concomitant moderate CYP3A4 inhibitors (eg, diltiazem, atazanavir, erythromycin, fluconazole, verapamil): initially 20mg/day; max 80mg/day.

Concomitant moderate CYP3A4 inducers: may need to increase lurasidone dose after chronic treatment (≥ 7 days) with inducer.

Children: Not established.

Contraindications: Concomitant strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil) and inducers (eg, rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine).

Warnings/Precautions: Elderly with dementia-related psychosis (not approved use); increased risk of death or cerebrovascular events (eg, stroke, TIA). Increased risk of suicidal thoughts and behavior in children, adolescents, and young adults; monitor closely for worsening or unusual changes in behavior in all patients. Discontinue if neuroleptic malignant syndrome occurs; consider discontinuing if tardive dyskinesia occurs. Cardio- or cerebrovascular disease, risk of hypotension: monitor orthostatic vital signs. Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia, dyslipidemia, weight gain, hyperprolactinemia. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of therapy; discontinue if WBCs decline. Moderate to severe hepatic or renal impairment. History of seizures, Mania or hypomania (monitor). Dysphagia. Parkinson's disease. Dementia with Lewy Bodies. Exposure to extreme heat. Write R for smallest practical amount; closely supervise high-risk patients (suicidal ideation). Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Adults and Contraindications. Avoid grapefruit and grapefruit juice.

Adverse reactions: Somnolence, akathisia, extrapyramidal symptoms, nausea, parkinsonism, agitation; orthostatic hypotension and syncope possible.

How supplied: Tabs-30, 90, 500, 100 (10 blister cards $\times$ 10 tabs)

OLANZAPINE

ZYPREXA Lilly

Thienobenzodiazepine. Olanzapine 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg; tabs.

Also: Olanzapine

ZYPREXA ZYDIS

Olanzapine 5mg, 10mg, 15mg, 20mg; orally-disintegrating tabs; contains phenylalanine.

Indications: Schizophrenia.

Adults: Initially 5–10mg once daily; increase to 10mg once daily within several days, adjust by 5mg/day at intervals of 1 week; max 20mg/day. Maintenance: usual range 10–20mg/day. Debilitated, risk of hypotension, slow metabolizers, or sensitive to olanzapine: initially 5mg once daily; increase cautiously. Zydys: Dissolve in mouth and swallow with or without fluids.

Children: <13yrs: not recommended. 13–17yrs: initially 2.5–5mg once daily; increase to target dose of 10mg/day, adjust by 2.5–5mg if needed; max 20mg/day. Maintenance: continue at lowest dose to maintain remission: see literature.

Also: Olanzapine

ZYPREXA INTRAMUSCULAR

Olanzapine 10mg/vial; IM inj after reconstitution.

Indications: Agitation due to schizophrenia.

Adults: Give by deep IM inj. Usual range:

2.5mg–10mg/dose. Elderly: 5mg. Debilitated, risk

of hypotension, or sensitive to olanzapine: 2.5mg.

All: up to 3 doses daily (2–4 hrs apart); switch to oral form when appropriate. Severe orthostatic hypotension: not recommended.

Children: Not recommended.

Warnings/Precautions: Relprev: post-injection delirium/sedation syndrome: monitor after each injection. Elderly (not for dementia-related psychosis; may increase risk of death). Cardio- or cerebrovascular disease. Diabetes. Monitor for hyperglycemia, hyperlipidemia; do fasting blood glucose and lipids testing at beginning, and during therapy. Monitor for weight gain. Hypovolemia. Dehydration. History of seizures. Conditions that affect metabolism or hemodynamic responses. Hepatic impairment (monitor ALT/AST). GI or GU obstruction. Narrow angle glaucoma. History of paralytic ileus or breast cancer. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Exposure to extreme heat. Reevaluate periodically. Dysphagia. Suicidal ideation (monitor). Write R for smallest practical amount. Debilitated. Labor & delivery. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Orthostatic hypotension with antihypertensives, alcohol, benzodiazepines, others. Avoid alcohol. Caution with other CNS drugs, drugs that lower seizure threshold, anticholinergics, and with hepatotoxic agents. May antagonize levodopa, dopamine agonists. May be antagonized by rifampin, omeprazole, carbamazepine, others that induce CYP1A2 or glucuronyl transferase. May be potentiated by fluvoxamine, others that inhibit CYP1A2. Smokers may have increased metabolism.

Adverse reactions: Somnolence, sedation, dizziness, constipation, weight gain, personality disorder, akathisia, asthenia, rhinitis, postural hypotension, tachycardia, headache, fever, abdominal pain, diarrhea, vomiting, dry mouth, cough, nasopharyngitis, nervousness, joint pain, peripheral edema, hyperglycemia, tardive dyskinesia, worsening of parkinsonian symptoms, neuroleptic malignant syndrome (monitor), hyperprolactinemia, increased ALT; leukopenia, neutropenia, agranulocytosis; others.

How supplied: Tabs-30, 1000; Zydys-30; Vial-1

PALIPERIDONE

INVEGA Janssen

Benzisoxazole. Paliperidone 1.5mg, 3mg, 6mg, 9mg; ext-rel tabs.

Indications: Acute and maintenance treatment of schizophrenia in adults. Acute treatment of

schizoaffective disorder in adults, as monotherapy or as an adjunct to mood stabilizer and/or antidepressants. Treatment of schizophrenia in adolescents 12–17yrs of age.

Adults: Swallow whole. ≥ 18 yrs: 6mg once daily in AM; may increase in increments of 3mg/day at intervals of > 4 days (for schizoaffective disorder) or > 5 days (for schizophrenia) if needed. Usual range: 3–12mg/day. Max 12mg/day. Maintenance: use lowest effective dose. Renal impairment: CrCl ≥ 50 – < 80 mL/min: max 6mg/day; CrCl 10– < 50 mL/min: max 3mg/day.

Children: Schizoaffective disorder: < 18 yrs: not recommended. Schizophrenia: < 12 yrs: not recommended. 12–17yrs: (< 51 kg): initially 3mg once daily in AM; usual range: 3–6mg/day; max 6mg/day; (≥ 51 kg): initially 3mg once daily in AM; usual range: 3–12mg/day; max 12mg/day. Both: may increase in increments of 3mg/day at intervals of > 5 days if needed.

Warnings/Precautions: Elderly (not for dementia-related psychosis): increased risk of death. Avoid in congenital long QT syndrome, cardiac arrhythmias. Discontinue if neuroleptic malignant syndrome (NMS) occurs; consider discontinuing if tardive dyskinesia occurs. Diabetes risk factors (obtain baseline fasting blood sugar). Cardio- or cerebrovascular disease; risks may be increased due to metabolic changes (eg, hyperglycemia, dyslipidemia, weight gain); monitor. Pre-existing low WBCs or history of leukopenia/neutropenia: monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Orthostatic hypotension. Parkinson's disease. Dementia with Lewy bodies. History of seizures. Patients at risk for aspiration pneumonia. Renal insufficiency. Severe hepatic impairment. Exposure to extreme temperatures. May have antiemetic effect. Suicidal patients. Tabs: Pre-existing severe GI narrowing: not recommended. Reevaluate periodically. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid alcohol, drugs that prolong QT interval (eg, Class 1A and Class III antiarrhythmics, chlorpromazine, thioridazine, gatifloxacin, moxifloxacin). Caution with other CNS drugs, drugs that may cause orthostatic hypotension. May be antagonized by carbamazepine; adjust dose. May antagonize levodopa, other dopamine agonists. May be potentiated by divalproex sodium; consider dose reduction.

Adverse reactions: Extrapyramidal symptoms, akathisia, somnolence, tremor, dystonia, cogwheel rigidity, anxiety, weight gain, tachycardia, dyspepsia, constipation, nasopharyngitis; may cause NMS, tardive dyskinesia, QT prolongation, hyperglycemia, dyslipidemia, orthostatic hypotension, syncope, hyperprolactinemia, priapism.

How supplied: Tabs–30

PALIPERIDONE

R

INVEGA SUSTENNA Janssen

Benzisoxazole. Paliperidone (as palmitate) 39mg, 78mg, 117mg, 156mg, 234mg; ext-rel susp for IM inj.

Indications: Acute and maintenance treatment of schizophrenia.

Adults: Establish tolerability with oral paliperidone or oral risperidone prior to initiating. Give by deep deltoid IM inj, initially 234mg on day 1, then 156mg one week later. Maintenance: Give by deep deltoid or gluteal IM inj once monthly. 117mg; may increase or decrease in the range of 39–234mg. Renal impairment: mild (CrCl ≥ 50 mL/min– < 80 mL/min): initially 156mg on day 1, then 117mg one week later, then 78mg monthly; moderate to severe (CrCl < 50 mL/min): not recommended. Missed doses or switching from other antipsychotics: see literature.

Children: < 18 yrs: not recommended.

Warnings/Precautions: Avoid in congenital long QT syndrome, cardiac arrhythmias. Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia. Cardio- or cerebrovascular disease. Pre-existing low WBCs or history of leukopenia/neutropenia: monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Orthostatic hypotension. Parkinson's disease. Dementia with Lewy bodies. History of seizures. Patients at risk for aspiration pneumonia. Renal insufficiency. Severe hepatic impairment. Exposure to extreme temperatures. May have antiemetic effect. Suicidal patients. Reevaluate periodically. Elderly (not for dementia-related psychosis); consider monitoring renal function and for orthostatic effects. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid alcohol, drugs that prolong QT interval (eg, Class 1A and Class III antiarrhythmics, chlorpromazine, thioridazine, gatifloxacin, moxifloxacin). Caution with other CNS drugs, drugs that may cause orthostatic hypotension. May be antagonized by carbamazepine; adjust dose. May antagonize levodopa, other dopamine agonists.

Adverse reactions: Inj site reactions, somnolence/sedation, dizziness, akathisia, extrapyramidal disorder; may cause neuroleptic malignant syndrome, tardive dyskinesia, QT prolongation, hyperglycemia, orthostatic hypotension, syncope, hyperprolactinemia, priapism.

How supplied: Kit–1 (prefilled syringe + needles)

PERPHENAZINE

R

PERPHENAZINE (various)

Piperaziny phenothiazine. Perphenazine 2mg, 4mg, 8mg, 16mg; tabs.

Indications: Manifestations of psychotic disorders.

Adults: Nonhospitalized: initially 4–8mg 3 times daily; then reduce to lowest effective dose.

Hospitalized: 8–16mg 2–4 times daily; max 64mg per day.

Children: Not recommended.

Contraindications: Coma. Concomitant large doses of CNS depressants. Blood dyscrasias. Bone marrow depression. Liver damage. Subcortical brain damage.

Warnings/Precautions: CNS depression. Epilepsy. Cardiovascular disease. Respiratory disorders. History of breast cancer. Pheochromocytoma. Avoid sun, exposure to extreme heat or phosphorus insecticides. Surgery: consider lower anesthetic dose. Monitor blood, hepatic, and renal function. Write $\mathbb{R}$ for smallest practical amounts. Reevaluate periodically. Debilitated. Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Adjust anticonvulsant doses. Additive anticholinergic effects with atropine or related drugs.

Adverse reactions: Tardive dyskinesia, drowsiness, jaundice, blood dyscrasias, hypotension, ECG changes, retinopathy, may mask emetic signs of disease, lowered seizure threshold, rash, skin pigmentation, anticholinergic effects, insomnia, adynamic ileus, hyperprolactinemia, extrapyramidal reactions, neuroleptic malignant syndrome.

How supplied: Contact supplier.

PIMOZIDE

$\mathbb{R}$

ORAP Teva US Generics

Antipsychotic. Pimozide 1mg, 2mg; scored tabs.

Indications: Motor and phonic tics of Tourette's disorder unresponsive to standard treatment that severely compromise development or daily life function.

Adults: Initially 1–2mg/day in divided doses; may increase every other day to max 0.2mg/kg per day not to exceed 10mg/day.

Children: <12yrs: not recommended. ≥ 12 yrs: Initially 0.05mg/kg once daily at bedtime; may increase every third day to max 0.2mg/kg, not to exceed 10mg/day.

Contraindications: Simple tics or tics not associated with Tourette's disorder. Drugs that may cause tics (eg, pemoline, methylphenidate, amphetamines) or prolong the QT interval (eg, phenothiazines, tricyclic antidepressants, antiarrhythmics, dofetilide, sotalol, quinidine, other Class IA or III antiarrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, tacrolimus, ziprasidone, others). Congenital long QT syndrome. History of cardiac arrhythmias. Hypokalemia. Hypomagnesemia. Severe CNS depression or comatose states. Concomitant CYP3A4 inhibitors (eg, macrolides antibiotics, azole antifungals, protease inhibitors, nefazodone, zileuton, fluvoxamine, sertraline), citalopram, escitalopram.

Warnings/Precautions: Renal or hepatic impairment. Pre-existing low WBCs or history of

leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. History of seizures or EEG abnormalities. Monitor ECG at baseline and periodically (esp. during dose adjustment). Correct hypokalemia before starting. Avoid abrupt cessation. May have tumorigenic potential. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. May be potentiated by CYP1A2 inhibitors. Potentiates CNS depression with alcohol, analgesics, other CNS depressants. Caution with anticonvulsants. Avoid grapefruit juice.

Adverse reactions: Sedation, anticholinergic effects, extrapyramidal symptoms, tardive dyskinesia, ECG changes, neuroleptic malignant syndrome, hyperpyrexia; leukopenia/neutropenia.

How supplied: Tabs–100

PROCHLORPERAZINE

$\mathbb{R}$

PROCHLORPERAZINE (various)

Piperazine phenothiazine. Prochlorperazine (as maleate) 5mg, 10mg; tabs.

Indications: Schizophrenia.

Adults: Mild conditions: 5–10mg 3–4 times daily. Moderate-to-severe conditions (closely supervised): Initially 10mg 3–4 times daily, may increase gradually every 2–3 days; usual range 50–75mg/day. Severe conditions: usual range 100–150mg daily.

Children: <2yrs or <20lbs: not recommended. 2yrs–5yrs: Initially 2.5mg 2–3 times daily; max 10mg first day, then max 20mg/day. 6–12yrs: Initially 2.5mg 2–3 times daily; max 10mg first day, then max 25mg/day.

Contraindications: Coma. CNS depression. Pediatric surgery. Children <2yrs or <20lbs.

Warnings/Precautions: Discontinue 48 hrs before to 24 hrs after myelography. Cardiovascular disease. Epilepsy. Bone marrow depression. Reye's syndrome. Glaucoma. History of breast cancer. Exposure to extreme heat. Monitor blood, liver, and ocular function. Write $\mathbb{R}$ using fractions rather than decimals. Children with acute illness or dehydration. Debilitated. Elderly. Pregnancy, nursing mothers: not recommended.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Potentiates α -blockers. Levels of both drugs increased with propranolol. May potentiate phenytoin; monitor for toxicity. Adjust anticonvulsant doses. May antagonize oral anticoagulants. Hypotension potentiated with thiazide diuretics. Antagonized by anticholinergics. Decreases guanethidine effects. Monitor for neurologic toxicity with lithium; discontinue if occurs. May cause false (+) PKU test.

Adverse reactions: Drowsiness, dizziness, amenorrhea, blurred vision, other anticholinergic effects, skin reactions, hypotension, cholestatic

jaundice, photosensitivity, leukopenia, agranulocytosis, neuroleptic malignant syndrome, agitation, insomnia, dystonias, extrapyramidal reactions, pseudoparkinsonism, tardive dyskinesia, may mask emetic signs of disease, lowered seizure threshold, EKG changes, aspiration, deep sleep, hyperprolactinemia, paradoxical excitement in children.

How supplied: Contact supplier.

QUETIAPINE

R

SEROQUEL XR AstraZeneca

Dibenzothiazepine. Quetiapine (as fumarate) 50mg, 150mg, 200mg, 300mg, 400mg; ext-rel tabs.

Indications: Schizophrenia.

Adults: Swallow whole. Take on an empty stomach or with light meal. Initially 300mg once daily in the PM; may increase at 1-day intervals in increments of up to 300mg/day. Usual range: 400–800mg/day; max 800mg/day. Maintenance: 400–800mg/day. Elderly, debilitated, or risk of postural hypotension: titrate more slowly to lower target dose. Elderly or hepatic impairment: initially 50mg/day; may increase in increments of 50mg/day. Concomitant CYP3A4 inhibitors or inducers, reinitiation of treatment: see full labeling. Switching from Seroquel immediate-release: give XR at equivalent total daily dose taken once daily.

Children: Swallow whole. Take on an empty stomach or with light meal. Give once daily in the PM. <13yrs: not established. 13–17yrs: 50mg on day 1, then 100mg on day 2, then 200mg on day 3, then 300mg on day 4, then 400mg on day 5; may further increase up to target range of 400–800mg/day; max 800mg/day.

Also: Quetiapine

R

SEROQUEL

Quetiapine (as fumarate) 25mg, 50mg, 100mg, 200mg, 300mg, 400mg; tabs.

Adults: ≥17yrs: 25mg twice daily on day 1; increase by 25–50mg 2–3 times daily on days 2 and 3; target 300–400mg/day in 2–3 divided doses by day 4; may adjust at 2-day intervals by 25–50mg twice daily. Usual range 150–750mg/day; max 750mg/day. Maintenance: 400–800mg/day; max 800mg/day. Elderly, debilitated, or risk of postural hypotension: titrate more slowly to lower target dose. Elderly: initially 50mg/day. Hepatic impairment: initially 25mg/day; titrate daily by 25–50mg/day to effective dose. Concomitant CYP3A4 inhibitors or inducers, reinitiation of treatment: see full labeling.

Children: <13yrs: not established. 13–17yrs: 25mg twice daily on day 1, then 50mg twice daily on day 2, then 100mg twice daily on day 3, then 150mg twice daily on day 4, then 200mg twice daily on day 5; may further increase in increments up to 100mg/day to target range of 400–800mg/day (may give 3 times daily); max: 800mg/day.

Warnings/Precautions: Elderly with dementia-related psychosis (not approved use); increased risk of death or cerebrovascular events (eg, stroke, TIA). Increased risk of suicidal thoughts and behavior in

children, adolescents, and young adults; monitor closely for worsening or unusual changes in behavior in all patients. Exclude neuroleptic malignant syndrome if fever or other symptoms occur. Diabetes. Monitor for hyperglycemia, hyperlipidemia: do fasting blood glucose and lipids testing initially and during therapy. Monitor for weight gain. Cardio- or cerebrovascular disease. Monitor BP in children and adolescents initially and during therapy. Increased risk of QT prolongation (eg, family history, cardiovascular disease, elderly, CHF, heart hypertrophy). Avoid in cardiac arrhythmias (eg, bradycardia), hypokalemia, hypomagnesemia, congenital prolongation of the QT interval. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Hepatic dysfunction. Seizure risk. Risk of aspiration pneumonia. Exposure to extreme heat. Dehydration. Hypovolemia. Do eye exam initially and every 6 months. History of breast cancer. Reevaluate periodically. Avoid abrupt cessation. Write Rx for smallest practical amount. Debilitated. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid drugs that prolong QT interval including Class 1A (eg, quinidine, procainamide) or Class III antiarrhythmics (eg, amiodarone, sotalol), antipsychotics (eg, ziprasidone, chlorpromazine, thioridazine), antibiotics (eg, gatifloxacin, moxifloxacin), and others (eg, pentamidine, methadone, levomethadyl acetate). Potentiates CNS effects with alcohol (avoid), other CNS depressants. Antagonized by CYP3A inducers (eg, thioridazine, phenytoin, carbamazepine, phenobarbital, rifampin); adjust dose. Potentiates antihypertensives, lorazepam. Antagonizes effects of levodopa, dopamine agonists. Caution with drugs that interfere with temperature regulation (eg, anticholinergics) and with CYP3A inhibitors (eg, azole antifungals, erythromycin).

Adverse reactions: Somnolence, dry mouth, constipation, dizziness, increased appetite, dyspepsia, weight gain, fatigue, dysarthria, nasal congestion, asthenia, abdominal pain, postural hypotension, pharyngitis, lethargy, hyperglycemia, hypothyroidism, hyperprolactinemia; increased ALT (transient), total cholesterol +/or triglycerides; leukopenia, neutropenia, agranulocytosis; rarely: tardive dyskinesia, neuroleptic malignant syndrome. **How supplied:** XR-60; Tabs 25mg, 50mg, 100mg, 200mg, 400mg-100; 300mg-60

RISPERIDONE

R

RISPERDAL CONSTA Janssen

Benzisoxazole. Risperidone 12.5mg, 25mg, 37.5mg, 50mg; per vial; pwd for long-acting IM inj after reconstitution.

Indications: Schizophrenia.

Adults: Risperidone-naïve: rule out risperidone hypersensitivity before using injection. Give by deep

deltoid or gluteal IM inj; alternate sides. Give with oral risperidone (or other antipsychotic) for 3 weeks, then stop oral form. ≥ 18 yrs: 25mg IM every 2 weeks; may adjust dose every 4 weeks. Max 50mg every 2 weeks. Renal or hepatic impairment: if total daily dose of at least 2mg of oral risperidone tolerated, may give 12.5mg or 25mg IM every 2 weeks. History of poor tolerability to psychotropic drugs or drug interactions that increase risperidone plasma levels (see literature): may use lower initial dose of 12.5mg.

Children: <18yrs: not recommended.

Warnings/Precautions: Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia. Cardio- or cerebrovascular disease. Renal or hepatic dysfunction. Orthostatic hypotension. Pre-existing low WBC count or history of leukopenia/neutropenia: monitor CBC during 1st few months of therapy; discontinue if WBCs decline. Parkinson's disease. Dementia with Lewy bodies. Diseases that affect metabolic or hemodynamic response. History of breast cancer or seizures. Dysphagia. Reevaluate periodically. Monitor for neuroleptic malignant syndrome. May have antiemetic effect. Exposure to extreme temperatures. Suicidal patients. Elderly (not for dementia-related psychosis); consider monitoring renal function and for orthostatic effects. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended (do not breastfeed until at least 12 weeks after last injection).

Interactions: Avoid alcohol. Caution with other CNS drugs. May potentiate antihypertensives. May antagonize levodopa, dopamine agonists. Clearance may be decreased by clozapine; may be increased by carbamazepine, other enzyme inducers (eg, phenytoin, rifampin, phenobarbital); adjust risperidone dose. May be potentiated by cimetidine, ranitidine. May be affected by fluoxetine, paroxetine, others that affect CYP isoenzymes. Monitor valproate.

Adverse reactions: Headache, somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, parkinsonism, dystonia, abdominal pain, anxiety, GI upset, dizziness, dry mouth, tremor, rash, akathisia; orthostatic hypotension, tardive dyskinesia, neuroleptic malignant syndrome, hyperprolactinemia, priapism, leukopenia/neutropenia, agranulocytosis, thrombotic thrombocytopenic purpura (rare).

How supplied: Inj: single-use vial-1 (pack w. diluent, supplies)

RISPERIDONE

RISPERDAL TABLETS Janssen
Benzisoxazole. Risperidone 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg.

Also: Risperidone
RISPERDAL ORAL SOLUTION
Risperidone 1mg/mL.

Also: Risperidone

RISPERDAL M-TABS

Risperidone 0.5mg, 1mg, 2mg, 3mg, 4mg; orally-disintegrating tabs; contains phenylalanine.

Indications: Schizophrenia.

Adults: Give once daily or in 2 divided doses.

Initially 2mg/day; may adjust at intervals of at least 24 hours by 1-2mg/day to target dose of 4-8mg/day. Usual range: 4-16mg/day; max 16mg/day. Elderly, debilitated, hypotensive, severe renal or hepatic impairment: 0.5mg twice daily; adjust in increments of up to 0.5mg twice daily; titrate at intervals of at least 1 week if exceeding 1.5mg twice daily; may switch to once-daily dosing after titration. For all: reassess periodically; withdraw gradually. Oral soln: do not give with cola, tea. M-Tabs: dissolve on tongue; swallow with or without liquid.

Children: <13yrs: not recommended. ≥ 13 yrs: initially 0.5mg once daily (AM or PM); may adjust at intervals of at least 24 hours by 0.5mg or 1mg per day to target dose of 3mg/day. Usual range: 1-6mg/day; max 6mg/day. If somnolence occurs: give $\frac{1}{2}$ daily dose twice daily.

Warnings/Precautions: Diabetes risk factors (obtain baseline fasting blood sugar). Monitor for hyperglycemia. Cardio- or cerebrovascular disease. Renal or hepatic dysfunction. Orthostatic hypotension. Pre-existing low WBC count or history of leukopenia/neutropenia: monitor CBC during 1st few months of therapy; discontinue if WBCs decline. Parkinson's disease. Dementia with Lewy bodies. Diseases that affect metabolic or hemodynamic response. History of breast cancer or seizures. Dysphagia. Reevaluate periodically. Monitor for neuroleptic malignant syndrome. May have antiemetic effect. Exposure to extreme temperatures. Suicidal patients. Elderly (not for dementia-related psychosis); consider monitoring renal function and for orthostatic effects. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during 3rd-trimester pregnancy). Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid alcohol. Caution with other CNS drugs. May potentiate antihypertensives. May antagonize levodopa, dopamine agonists. Clearance may be decreased by clozapine; may be increased by carbamazepine, other enzyme inducers (eg, phenytoin, rifampin, phenobarbital); adjust risperidone dose. May be potentiated by cimetidine, ranitidine. May be affected by fluoxetine, paroxetine, others that affect CYP isoenzymes. Monitor valproate.

Adverse reactions: Headache, somnolence, increased appetite, fatigue, rhinitis, upper respiratory tract infection, vomiting, coughing, urinary incontinence, increased saliva, constipation, fever, parkinsonism, dystonia, abdominal pain, anxiety, GI upset, dizziness, dry mouth, tremor, rash, akathisia; orthostatic hypotension, tardive dyskinesia, neuroleptic malignant syndrome, hyperprolactinemia,

priapism, leukopenia/neutropenia, agranulocytosis, thrombotic thrombocytopenic purpura (rare).

How supplied: Tabs 0.25mg, 0.5mg, 1mg, 2mg, 3mg–60, 500; 4mg–60; Oral soln–30mL (w. pipette); M-Tabs–28

ZIPRASIDONE

R

GEODON Pfizer

Serotonin and dopamine antagonist. Ziprasidone HCl 20mg, 40mg, 60mg, 80mg; caps.

Indications: Schizophrenia.

Adults: Take with food. Initially 20mg twice daily; may increase at intervals of at least 2 days; max 80mg twice daily. Elderly: consider lower initial dose, slower titration.

Children: Not recommended.

Also: Ziprasidone

R

GEODON FOR INJECTION

Ziprasidone (as mesylate) 20mg/mL; pwd for IM inj after reconstitution; preservative-free.

Indications: Rapid control of acute agitation.

Adults: 10–20mg IM as needed, max 40mg/day (10mg every 2 hours; or 20mg every 4 hours); usual max 3 days. Switch to oral form as soon as possible.

Children: Not recommended.

Contraindications: History of QT prolongation. Congenital long QT syndrome. Recent acute MI. Uncompensated heart failure. Concomitant drugs that cause QT prolongation, including dofetilide, sotalol, quinidine, other Class Ia and III antiarrhythmics, mesoridazine, thioridazine, chlorpromazine, droperidol, pimozide, sparfloxacin, gatifloxacin, moxifloxacin, halofantrine, mefloquine, pentamidine, arsenic trioxide, levomethadyl, dolasetron, probucol, tacrolimus.

Warnings/Precautions: Increased mortality in elderly with dementia-related psychosis (not approved use). Concomitant use of oral and IM forms: not recommended. Renal (IM form) or hepatic impairment (both forms). Discontinue if QTc >500 msec persists, neuroleptic malignant syndrome, or unexplained rash occurs; consider discontinuing if tardive dyskinesia occurs. Conditions that increase risk of torsade de pointes (eg, bradycardia, hypokalemia, hypomagnesemia). Monitor potassium, magnesium, others if risk of electrolyte disturbances (eg, diarrhea); correct imbalance before starting. Avoid in significant cardiovascular disease (eg, arrhythmias). Evaluate cardiac function if symptoms of torsade de pointes occur (eg, dizziness, palpitations, syncope). Cardio- or cerebrovascular disease. Pre-existing low WBCs or history of leukopenia/neutropenia; monitor CBCs during 1st few months of treatment; discontinue if WBCs decline. Diabetes; monitor for hyperglycemia. Risk of hypotension or seizures. History of breast cancer. Dysphagia. Exposure to extreme heat. Reevaluate periodically. Write R for smallest practical amount. Neonates: risk of extrapyramidal and/or withdrawal symptoms post delivery (due to exposure during

3rd-trimester pregnancy). Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. May potentiate CNS drugs, antihypertensives. Antagonizes levodopa, dopamine agonists. Extent of absorption and/or plasma levels may be affected by CYP3A4 inducers (eg, carbamazepine) or inhibitors (eg, ketoconazole). Correct hypokalemia, hypomagnesemia due to diuretics.

Adverse reactions: Somnolence, extrapyramidal syndrome, respiratory disorder, dizziness, akathisia, abnormal vision, asthenia, vomiting, rash, dystonia, tachycardia, myalgia, postural hypotension, QTc prolongation, headache, weight gain, inj site reactions, hyperprolactinemia; rare: priapism.

How supplied: Caps–60; Inj (single-use vials)–1

SECTION 20:

RESPIRATORY DISORDERS 20A Asthma/COPD

ACLIDINIUM BROMIDE

R

TUDORZA PRESSAIR Forest

Anticholinergic. Acclidinium bromide 400mcg/actuation; dry powder for oral inhalation.

Indications: Long-term, maintenance treatment of bronchospasm associated with COPD, including chronic bronchitis and emphysema.

Adults: 400mcg twice daily.

Children: Not established.

Warnings/Precautions: Not for initial treatment of acute episodes of bronchospasm. Narrow-angle glaucoma. Urinary retention. Milk protein sensitivity. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid concomitant anticholinergic agents.

Adverse reactions: Headache, nasopharyngitis, cough; hypersensitivity reactions (discontinue if occurs), paradoxical bronchospasm possible.

How supplied: Dry powder inhaler–60 doses

ALBUTEROL

R

ALBUTEROL INHALATION SOLUTION (various)
beta-2 agonist. Albuterol (as sulfate) 0.5%.

Also: Albuterol

R

ALBUTEROL NEBULES

Albuterol (as sulfate) 0.083%; soln for inh.

Indications: Bronchospasm.

Adults: By nebulizer: 2.5mg (0.5mL of 0.5% diluted to 3mL with sterile normal saline, or 3mL of 0.083%) 3–4 times daily.

Children: Use other forms.

Also: Albuterol

R

ALBUTEROL INHALATION AEROSOL

Albuterol 90mcg/inh; metered-dose aerosol.

Adults and Children: <4yrs: not recommended. ≥4yrs: 2 inh every 4–6 hrs as needed; 1 inh every

4 hrs may suffice. Exercise-induced bronchospasm: 2 inh 15 minutes before exercise.

Also: **Albuterol**

ALBUTEROL SYRUP

Albuterol (as sulfate) 2mg/5mL; strawberry flavor.

Adults: 2–4mg 3–4 times daily, may increase gradually; max 8mg 4 times daily. Elderly: initially 2mg 3–4 times daily, may increase gradually; max 8mg 4 times daily.

Children: <2yrs: not recommended. 2–6yrs: 0.1mg/kg 3 times daily; max initially 2mg 3 times daily; may increase gradually to 0.2mg/kg 3 times daily; max 4mg 3 times daily. 6–12yrs: 2mg 3–4 times daily; may increase gradually; max 6mg 4 times daily.

Warnings/Precautions: Avoid excessive use.

Sensitivity to sympathomimetics. Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Cardiovascular disease (eg, coronary insufficiency, arrhythmias, hypertension). Diabetes. Hyperthyroidism. Seizure disorders. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid MAOIs, tricyclics within 14 days (increased cardiovascular effects). Oral sympathomimetics: not recommended. Antagonized by β -blockers. Monitor digoxin. Caution with other drugs that may lower serum potassium (eg, diuretics).

Adverse reactions: Tremor, nervousness, headache, dizziness, hyperactivity, insomnia, weakness, tachycardia, epistaxis, hypokalemia, throat irritation (inh), paradoxical bronchospasm; immediate hypersensitivity reactions (eg, rash, urticaria, angioedema).

How supplied: Contact supplier.

ALBUTEROL

PROAIR HFA Teva Respiratory

beta-2 agonist. Albuterol 90mcg/inh; metered-dose aerosol with a dose counter; CFC-free.

Indications: Bronchospasm.

Adults and Children: <4yrs: not recommended. $\geq$ 4yrs: 2 inh every 4–6 hrs as needed; 1 inh every 4 hrs may suffice. Exercise-induced bronchospasm: 2 inh 15–30 minutes before exercise.

Warnings/Precautions: Avoid excessive use.

Sensitivity to sympathomimetics. Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Cardiovascular disease (eg, coronary insufficiency, arrhythmias, hypertension). Diabetes. Hyperthyroidism. Seizure disorders. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid MAOIs, tricyclics within 14 days (increased cardiovascular effects). Oral sympathomimetics: not recommended. Antagonized by β -blockers. Monitor digoxin. Caution with other drugs that may lower serum potassium (eg, diuretics).

Adverse reactions: Tremor, nervousness, headache, dizziness, excitement, insomnia, weakness, pharyngitis, rhinitis, tachycardia,

epistaxis, hypokalemia, local irritation, paradoxical bronchospasm; immediate hypersensitivity reactions (eg, rash, urticaria, angioedema).

How supplied: Inhalation aerosol (w. dose counter)–8.5g (200 inh)

ALBUTEROL

PROVENTIL HFA Merck

beta-2 agonist. Albuterol 90mcg/inh; metered-dose aerosol; contains hydrofluoroalkane; CFC-free.

Indications: Bronchospasm.

Adults and Children: <4yrs: Use other forms. $\geq$ 4yrs: 2 inh every 4–6hrs as needed; 1 inh every 4hrs may suffice. Exercise-induced bronchospasm: 2 inh 15–30 minutes before exercise.

Warnings/Precautions: Avoid excessive use.

Sensitivity to sympathomimetics. Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Cardiovascular disease (eg, coronary insufficiency, arrhythmias, hypertension). Diabetes. Ketoacidosis. Hyperthyroidism. Seizure disorders. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid MAOIs, tricyclics within 14 days (increased cardiovascular effects). Oral sympathomimetics: not recommended. Antagonized by β -blockers. Monitor digoxin. Caution with other drugs that may lower serum potassium (eg, diuretics).

Adverse reactions: Tremor, nervousness, headache, dizziness, excitement, insomnia, weakness, tachycardia, epistaxis, hypokalemia, local irritation, paradoxical bronchospasm; immediate hypersensitivity reactions (eg, rash, urticaria, angioedema); rare; metabolic acidosis.

How supplied: Inhalation aerosol–6.7g (200 inh)

ALBUTEROL

VENTOLIN HFA GlaxoSmithKline

beta-2 agonist. Albuterol 90mcg/inh; metered-dose aerosol; contains hydrofluoroalkane; CFC-free.

Indications: Bronchospasm.

Adults and Children: <4yrs: not established.

$\geq$ 4yrs: 2 inh every 4–6hrs as needed; 1 inh every 4hrs may suffice. Exercise-induced bronchospasm: 2 inh 15–30 minutes before exercise.

Warnings/Precautions: Avoid excessive use.

Sensitivity to sympathomimetics. Discontinue if paradoxical bronchospasm, immediate hypersensitivity reactions, or cardiovascular effects occur. Cardiovascular disease (eg, coronary insufficiency, arrhythmias, hypertension). Diabetes. Hyperthyroidism. Seizure disorders. Reevaluate periodically. Elderly. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid MAOIs, tricyclics within 14 days (increased cardiovascular effects). Oral sympathomimetics: not recommended. Antagonized by β -blockers. Monitor digoxin. Caution with other drugs that may lower serum potassium (eg, diuretics).

Adverse reactions: Throat irritation, viral respiratory infections, upper respiratory inflammation, cough, musculoskeletal pain; hypokalemia, paradoxical bronchospasm, cardiovascular effects, hypersensitivity reactions (eg, rash, urticaria, angioedema).

How supplied: Inhalation aerosol (w. dose counter)—8g (60 inh), 18g (200 inh)

BECLOMETHASONE

R

QVAR Teva Respiratory

Steroid. Beclomethasone dipropionate 40mcg/inh, 80mcg/inh; metered dose inhaler; CFC-free.

Indications: Maintenance treatment of asthma as prophylactic therapy. Asthma requiring systemic corticosteroid therapy, to reduce need for systemic corticosteroids.

Adults: Previously on bronchodilators alone: initially 40–80mcg twice daily; max 320mcg twice daily. Previously on inhaled corticosteroids: initially 40–160mcg twice daily; max 320mcg twice daily. Rinse mouth after use.

Children: <5yrs: not recommended. 5–11yrs: initially 40mcg twice daily; max 80mcg twice daily. Rinse mouth after use.

Contraindications: Not for treatment of acute attacks.

Warnings/Precautions: Maintain regular regimen. Infections. If exposed to chickenpox or measles, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with inhaled corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude). Monitor for growth suppression in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually). Transferring from systemic corticosteroids: see literature. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Adverse reactions: Headache, pharyngitis, rhinitis, pain; rare: hypersensitivity reactions, psychiatric events and behavioral changes (esp in children).

How supplied: Inhaler—8.7g (120 inh)

BUDESONIDE

R

PULMICORT FLEXHALER AstraZeneca

Steroid. Budesonide (micronized) 90mcg/inh, 180mcg/inh; dry pwd for inhalation.

Indications: Maintenance treatment of asthma as prophylactic therapy. Asthma requiring systemic corticosteroid therapy, to reduce need for systemic corticosteroids.

Adults: ≥18yrs: Initially 360mcg twice daily; may consider starting at 180mcg twice daily, if appropriate. Max 720mcg twice daily. Rinse mouth after use.

Children: <6yrs: not recommended. ≥6yrs: Initially 180mcg twice daily; may consider starting at 360mcg twice daily, if appropriate. Max 360mcg twice daily. Rinse mouth after use.

Also: Budesonide

R

PULMICORT RESPULES

Budesonide (micronized) 0.25mg/2mL, 0.5mg/2mL, 1mg/2mL; susp for inhalation.

Indications: Maintenance treatment of asthma and as prophylactic therapy.

Adults: Use Flexhaler.

Children: Use jet nebulizer; do not mix with other drugs. <6months: not recommended. 6–12months: see literature. 12months–8yrs: Previously on bronchodilators alone: 0.5mg/day once daily or in 2 divided doses (if symptomatic and unresponsive to nonsteroidal therapy, may start at 0.25mg once daily). Previously on inhaled corticosteroids: 0.5mg/day once daily or in 2 divided doses; max 1mg/day. Previously on oral corticosteroids: 1mg/day once daily or in 2 divided doses. Rinse mouth and face (if face mask used) after use.

Contraindications: Not for primary treatment of acute attack.

Warnings/Precautions: Maintain regular regimen.

Infections. If exposed to chickenpox or measles, consider anti-infective prophylactic therapy. Adrenal insufficiency may occur when transferring patients from systemic corticosteroids to inhaled corticosteroids: see literature. Monitor for growth suppression in children. Post-op or during stress: monitor adrenal response. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually). Transferring from oral corticosteroids: see literature. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Caution with CYP3A4 inhibitors (eg, ketoconazole).

Adverse reactions: Pulmicort Flexhaler: nasal congestion, allergic rhinitis, viral upper respiratory tract infection, oral candidiasis, viral gastroenteritis, nausea, bronchospasm (rare). Pulmicort Respules: Respiratory or other infection, GI upset, moniliasis, fatigue, cough, dysphonia, rash, epistaxis, hypersensitivity reactions (discontinue if occurs).

How supplied: Flexhaler (90mcg/dose)—1 (60 inh); Flexhaler (180mcg/dose)—1 (120 inh); Respules—30

BUDESONIDE + FORMOTEROL

R

SYMBICORT 160/4.5 AstraZeneca

Corticosteroid + long-acting beta-2 agonist. Budesonide 160mcg, formoterol fumarate dihydrate 4.5mcg; per inh; pressurized metered-dose inhaler.

Indications: Long-term maintenance treatment of asthma in patients ≥12yrs old not adequately controlled on other asthma-controller medications (eg, low-medium dose inhaled corticosteroids) or those whose disease severity clearly warrants starting treatment with two maintenance therapies. Maintenance treatment of airflow obstruction in COPD, including chronic bronchitis and emphysema.

Also: Budesonide + Formoterol

R

SYMBICORT 80/4.5

Budesonide 80mcg, formoterol fumarate dihydrate 4.5mcg; per inh; pressurized metered-dose inhaler.

Indications: Long-term maintenance treatment of asthma in patients ≥ 12 yrs old not adequately controlled on other asthma-controller medications (eg, low-medium dose inhaled corticosteroids) or those whose disease severity clearly warrants starting treatment with two maintenance therapies.

Adults: Allow approximately 12 hours between doses. Asthma: Base initial dose on asthma severity. 2 inh of 80/4.5 or 160/4.5 twice daily (AM & PM). If insufficient response after 1–2 weeks using 80/4.5 strength, may switch to 160/4.5 strength. Max 2 inh of 160/4.5 twice daily. Titrate to lowest effective strength after adequate response. COPD: 2 inh of 160/4.5 twice daily. Rinse mouth after use.

Children: Not established (see literature).

Contraindications: Not for primary treatment of acute attacks of asthma or COPD where intensive measures required.

Warnings/Precautions: Increased risk of asthma-related deaths and hospitalizations. Reevaluate periodically. Do not exceed recommended dose. Not for use with other long-acting β_2 -agonists or for transferring from oral steroids. Do not initiate in rapidly or acutely deteriorating asthma or COPD. Not for relief of acute bronchospasm. Cardiovascular disease (esp. coronary insufficiency, arrhythmias, hypertension). Convulsive disorders. Thyrotoxicosis. Hyperresponsiveness to sympathomimetics. Hepatic impairment (monitor). Diabetes. Ketoacidosis. Hypokalemia. Hyperglycemia. Immunosuppressed. Eosinophilic conditions. Tuberculosis. COPD: monitor for pneumonia. Untreated infections. Ocular herpes simplex. If exposed to chickenpox or measles, consider immune globulin or antiviral prophylactic therapies. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with inhaled corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude). Prescribe a short-acting β_2 -agonist for acute symptoms; monitor for increased need. Monitor potassium, intraocular pressure, bone mineral density if other osteoporosis risk factors exist; and for growth suppression in adolescents; hypercorticism and HPA axis suppression. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Caution with long-term ketoconazole and other potent CYP3A4 inhibitors (eg, ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin), during and within 2 weeks of MAOIs and tricyclic antidepressants; β -blockers, K^+ -depleting diuretics, long-term ketoconazole, other potent CYP3A4 inhibitors.

Adverse reactions: Nasopharyngitis, pharyngolaryngeal pain, sinusitis, congestion, oral candidiasis, headache, upper respiratory infection, flu, back pain, GI upset; rarely: paradoxical bronchospasm (discontinue if occurs), hypersensitivity reactions; severe asthma episodes; increased risk of asthma-related death. COPD: bronchitis.

How supplied: Inhaler–10.2g (120 inh)

CROMOLYN

R

CROMOLYN SODIUM INHALATION SOLUTION

(various)

Mast cell stabilizer. Cromolyn sodium 20mg/2mL; soln for inhalation.

Indications: Asthma prophylaxis. Prevention of bronchoconstriction before exposure to a known precipitant (eg, exercise).

Adults and Children: < 2 years: not recommended. ≥ 2 years: 20mg administered by power-operated nebulizer 4 times a day. Bronchoconstriction prevention: contents of 1 amp inhaled up to 60 minutes before precipitant.

Warnings/Precautions: Not for treatment of acute attack. Impaired renal or hepatic function: reduce dose. Reevaluate if no improvement after 4 weeks. Avoid abrupt cessation. Discontinue if eosinophilic pneumonia occurs. Coronary artery disease or arrhythmias (Inhaler). Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid use with isoproterenol during pregnancy.

Adverse reactions: Bronchospasm, throat irritation, bad taste, cough, wheezing, nasal congestion, anaphylaxis.

How supplied: Contact supplier.

FLUTICASONE

R

FLOVENT HFA GlaxoSmithKline

Steroid. Fluticasone propionate 44mcg/inh, 110mcg/inh, 220mcg/inh; metered dose inhaler; CFC-free.

Indications: Maintenance treatment of asthma as prophylactic therapy. Asthma requiring systemic corticosteroid therapy, to reduce need for oral systemic corticosteroids.

Adults: Previously on bronchodilators alone: initially 88mcg twice daily; max 440mcg twice daily. Previously on inhaled corticosteroids: initially 88–220mcg twice daily; max 440mcg twice daily. Previously on oral corticosteroids (wean gradually): initially 440mcg twice daily; max 880mcg twice daily. Rinse mouth after use.

Children: < 4 yrs: not recommended. 4–11 yrs: 88mcg twice daily. Rinse mouth after use.

Contraindications: Not for primary treatment of acute attack.

Warnings/Precautions: Maintain regular regimen. Infections. If exposed to chickenpox or measles, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with inhaled corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude). Monitor for growth suppression in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually). Hepatic impairment (monitor). Transferring from oral corticosteroids: see literature. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid ritonavir. Caution with potent CYP3A4 inhibitors (eg, ketoconazole).

Adverse reactions: Local effects (pharyngitis, nasal congestion/discharge, rhinitis, dysphonia, sinusitis, oral candidiasis), upper respiratory infection, headache, influenza, bronchospasm.

How supplied: Inhaler w. actuator (44mcg)–10.6g (120 inh); 110mcg, 220mcg–12g (120 inh)

FLUTICASONE + SALMETEROL R

ADVAIR DISKUS 100/50 GlaxoSmithKline
Steroid + long-acting β_2 agonist. Fluticasone propionate 100mcg, salmeterol (as xinafoate) 50mcg; per inh; dry pwd for inh.

Also: Fluticasone + Salmeterol R
ADVAIR DISKUS 500/50

Fluticasone propionate 500mcg, salmeterol (as xinafoate) 50mcg; per inh; dry pwd for inh.

Indications: Maintenance treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, inhaled corticosteroid) or whose disease severity warrants initiation of 2 maintenance therapies.

Also: Fluticasone + Salmeterol R
ADVAIR DISKUS 250/50

Fluticasone propionate 250mcg, salmeterol (as xinafoate) 50mcg; per inh; dry pwd for inh.

Indications: Maintenance treatment of asthma in patients not adequately controlled on other asthma-controller medications (eg, inhaled corticosteroid) or whose disease severity warrants initiation of 2 maintenance therapies. Maintenance treatment of COPD, including chronic bronchitis and/or emphysema. To reduce exacerbations of COPD in patients with a history of exacerbations.

Adults: Allow approximately 12hrs between doses. Asthma: ≥ 12 yrs: not previously on inhaled steroid: 1 inh of 100/50 or 250/50 twice daily; already on inhaled steroid: see literature. If insufficient response after 2wks, use next higher strength. Max 1 inh of 500/50 twice daily. COPD: 1 inh of 250/50 twice daily. Rinse mouth after use.

Children: <4 yrs: not recommended. Allow approximately 12hrs between doses. Asthma: 4–11 yrs: 1 inh of 100/50 twice daily. Rinse mouth after use.

Contraindications: Primary treatment of status asthmaticus or other acute episodes of asthma or COPD requiring intensive measures. Concomitant with other forms of salmeterol or formoterol. Severe milk protein hypersensitivity.

Warnings/Precautions: Increased risk of asthma-related deaths and hospitalizations. Do not initiate in rapidly or acutely deteriorating asthma. Not for relief of acute bronchospasm. Not for use with other long-acting β_2 -agonists or for transferring from systemic steroids. Reevaluate periodically. Do not exceed recommended dose. Cardiovascular disease (esp. coronary insufficiency, arrhythmias, hypertension). Convulsive disorders. Thyrotoxicosis. Hyperresponsiveness to sympathomimetics.

Diabetes. Ketoacidosis. Hypokalemia. Hyperglycemia. Hepatic impairment (monitor). Tuberculosis. Untreated infections. Ocular herpes simplex. Eosinophilic conditions. Immunosuppressed. If exposed to chickenpox or measles, consider immune globulin prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with inhaled corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude). Prescribe a short-acting, inhaled β_2 -agonist for acute symptoms; monitor for increased need. Monitor potassium, intraocular pressure; bone mineral density if other osteoporosis risk factors exist; and for growth suppression in children; hypercorticism and HPA axis suppression (if occurs, discontinue gradually). Do not use with spacers. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Concomitant strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, ritonavir, atazanavir, clarithromycin, indinavir, nefazodone, nelfinavir, saquinavir, telithromycin): not recommended. Caution with other sympathomimetics (except short-acting bronchodilators), during or within 2 weeks of MAOIs, tricyclic antidepressants (increased cardiac effects), K^+ -depleting diuretics. Antagonized by β -blockers.

Adverse reactions: Upper respiratory tract infection or inflammation, pharyngitis, pneumonia, laryngeal spasm or swelling, headache, dizziness, hoarseness, dysphonia, sinusitis, pain, GI upset, oral candidiasis, bronchitis, cough, paradoxical bronchospasm (discontinue if occurs), musculoskeletal pain; rarely: serious asthma episode, asthma-related death. Children: also epistaxis.

How supplied: Diskus (60 blisters)–1

FLUTICASONE + VILANTEROL R

BREO ELLIPTA GlaxoSmithKline
Corticosteroid + long-acting β_2 agonist. Fluticasone furoate 100mcg, vilanterol 25mcg; per inhalation; dry pwd for oral inhalation.

Indications: Long term maintenance treatment of airflow obstruction in COPD, including chronic bronchitis and/or emphysema. To reduce exacerbations of COPD in patients with a history of exacerbations. Limitations of use: not indicated for relief of acute bronchospasm or for treatment of asthma.

Adults: 1 inhalation once daily. Rinse mouth after use.

Children: Not established.

Contraindications: Severe hypersensitivity to milk proteins.

Warnings/Precautions: Increased risk of asthma-related deaths. Do not initiate in rapidly or acutely deteriorating COPD. Not for relief of acute bronchospasm. Not for use with other long-acting β_2 -agonists. Do not exceed recommended dose. Prescribe a short-acting, inhaled β_2 -agonist for acute symptoms; monitor for increased need. Monitor for

signs/symptoms of pneumonia. Immunosuppressed. Tuberculosis. Systemic infections. Ocular herpes simplex. If exposed to chickenpox or measles, consider immune globulin or antiviral prophylactic therapies. Monitor for adrenal insufficiency when transferring from systemic steroids. Reevaluate periodically. Monitor for hypercorticism and HPA axis suppression (if occurs, discontinue gradually), intraocular pressure, glaucoma, or cataracts. Discontinue if paradoxical bronchospasm occurs; use alternative therapy. Cardiovascular disease (esp. coronary insufficiency, arrhythmias, hypertension). Convulsive disorders. Thyrotoxicosis. Hyperresponsiveness to sympathomimetics. Diabetes. Ketoacidosis. Hypokalemia. Hyperglycemia. Moderate or severe hepatic impairment; monitor. Assess bone mineral density if risk factors exist (eg, osteoporosis, postmenopausal). Labor and delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with concomitant strong CYP3A4 inhibitors (eg, ketoconazole, ritonavir, clarithromycin, conivaptan, indinavir, itraconazole, lopinavir, nefazodone, nelfinavir, saquinavir, telithromycin, toleandomycin, voriconazole). Caution with concomitant MAOIs, tricyclic antidepressants, or drugs known to prolong the QT interval or within 2 weeks of discontinuing such agents (increased cardiac effects), K⁺-depleting diuretics. Antagonized by β -blockers.

Adverse reactions: Nasopharyngitis, upper respiratory tract infection, headache, oral candidiasis; risk of asthma-related death.

How supplied: Dry pwd inhaler—30 doses

FORMOTEROL

FORADIL AEROLIZER Merck

Long-acting beta-2 agonist. Formoterol fumarate 12mcg/inh; dry pwd in caps for inhalation; with inhaler device.

Indications: As an adjunct (see literature): For the maintenance treatment of asthma and in the prevention of bronchospasm in reversible obstructive airway disease (including nocturnal asthma). Maintenance treatment of COPD-associated bronchospasm. Prevention of exercise-induced bronchospasm (EIB).

Adults and Children: <5yrs: not recommended. ≥ 5 yrs: 1 inh (12mcg) every 12 hours; max 2 doses/day. Prevention of EIB: 1 inh at least 15 minutes before exercise (do not use additional doses for EIB if already using regular dosing for asthma).

Contraindications: For asthma: without concomitant use of a long-term asthma control drug (eg, inhaled corticosteroid). Primary treatment of status asthmaticus or other acute episodes of asthma or COPD where intensive measures are required.

Warnings/Precautions: Increased risk of asthma-related deaths and hospitalizations. Prescribe for asthma only as additional therapy with an inhaled corticosteroid. Do not initiate in significantly

worsening or acutely deteriorating asthma. Formoterol is not a substitute for steroids. Do not exceed recommended dose. Cardiovascular disease (esp. hypertension, coronary insufficiency, arrhythmias, aneurysm, pheochromocytoma). Convulsive disorders. Thyrotoxicosis. Hyperresponsiveness to sympathomimetics. Diabetes. Ketoacidosis. Hypokalemia. Blood glucose changes. Evaluate response before altering steroid doses (may still need an antiinflammatory). Prescribe a short-acting, inhaled β_2 -agonist for acute symptoms; monitor for increased need. Allergy to milk proteins. Do not use with spacers. Labor & delivery. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid MAOIs, tricyclic antidepressants, drugs that prolong QTc interval. Not for use with other long-acting β_2 -agonists. Hypokalemia potentiated by xanthines, steroids, or diuretics. Antagonized by β -blockers. Sympathetic effects potentiated by additional adrenergics (caution). Risk of arrhythmias with concomitant anesthesia with halogenated hydrocarbons.

Adverse reactions: Infection, bronchitis, tremor (skeletal muscle), dizziness, insomnia, dysphonia, tonsillitis, paradoxical bronchospasm (discontinue if occurs), β_2 -agonist effects (eg, hypo- or hypertension, angina, tachycardia, arrhythmias, nervousness, hypokalemia, hyperglycemia, metabolic acidosis); rarely: serious asthma episode, asthma-related death.

How supplied: Caps—12, 60

INDACATEROL

ARCAPTA NEOHALER Novartis

Long-acting beta-2 agonist (LABA). Indacaterol 75mcg; inhalation pwd hard capsules for use with Neohaler device.

Indications: Long-term maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and/or emphysema.

Adults: For oral inhalation use only with Neohaler device; do not swallow caps. Remove cap from blister pack immediately before use. Inhale contents of one 75mcg cap daily.

Children: Not established.

Contraindications: LABA use in asthma patients without use of long-term control medication.

Warnings/Precautions: LABA increase risk of asthma-related death. Not recommended for treating asthma or acute deteriorations of COPD. Do not exceed recommended dose. Not for primary treatment of acute symptoms. Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Cardiovascular disease (esp. coronary insufficiency, arrhythmias, hypertension). Convulsive disorders. Severe hepatic impairment. Thyrotoxicosis. Hypokalemia. Hyperglycemia. Hyperresponsiveness to sympathomimetics. Diabetes. Ketoacidosis. Prescribe a short-acting β_2 -agonist for acute symptoms; monitor for increased need. Pregnancy (Cat.C). Labor & delivery. Nursing mothers.

Interactions: See Contraindications. Avoid other sympathomimetics (except short-acting bronchodilators). Extreme caution with MAOIs, tricyclics, others that prolong QTc interval. Antagonized by β -blockers. K^+ -depleting diuretics, theophylline, aminophylline, steroids may potentiate hypokalemia.

Adverse reactions: Cough, oropharyngeal pain, nasopharyngitis, headache, nausea; hypersensitivity reactions (discontinue immediately and use alternative therapy).

How supplied: Caps-30 (5 blister cards $\times$ 6 caps) + one Neohaler inhaler

IPRATROPIUM

R

ATROVENT HFA Boehringer Ingelheim
Anticholinergic. Ipratropium bromide 17micrograms/
inh; metered dose inhaler; CFC-free.

Indications: Bronchospasm associated with chronic bronchitis and emphysema.

Adults: 2 inh 4 times daily; max 12 inh/day.

Children: Not established.

Also: Ipratropium

R

IPRATROPIUM BROMIDE INHALATION SOLUTION
(various)

Ipratropium bromide 0.02% (500mcg in 2.5mL); for oral inhalation; preservative-free.

Adults: 500mcg orally by nebulization 3–4 times daily; separate doses by 6–8 hours.

Children: Not established.

Contraindications: Allergy to atropine or its derivatives.

Warnings/Precautions: Not for primary treatment of acute attack. Avoid eyes. Narrow-angle glaucoma. GU obstruction. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with other anticholinergics.

Adverse reactions: Bronchitis, COPD exacerbation, dyspnea, headache, anticholinergic effects; paradoxical bronchospasm, hypersensitivity reactions.

How supplied: Inhaler-12.9g (200 inh); inhalation soln-contact supplier

IPRATROPIUM + ALBUTEROL

R

COMBIVENT RESPIMAT Boehringer Ingelheim
Anticholinergic + beta-2 agonist. Ipratropium bromide 20mcg, albuterol 100mcg (equivalent to 120mcg albuterol sulfate); per actuation; inhalation spray; CFC-free.

Indications: COPD when a second aerosol bronchodilator is needed.

Adults: 1 inh 4 times daily; max 6 inh/day.

Children: Not established.

Contraindications: Atropine allergy.

Warnings/Precautions: Avoid excessive use. Discontinue if paradoxical bronchospasm occurs. Cardiovascular disorders. Arrhythmias. Hypertension. Diabetes. Hyperthyroidism. Seizure disorders. Sensitivity to sympathomimetic amines. Narrow angle glaucoma. GI or GU obstruction. Hepatic or renal

disease. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Extreme caution within 2 weeks of MAOIs or tricyclic antidepressants (increased cardiovascular effects). Caution with other anticholinergics, sympathomimetics, drugs that lower serum potassium. Antagonized by beta-blockers.

Adverse reactions: Upper respiratory infection, nasopharyngitis, cough, bronchitis, headache, dyspnea; paradoxical bronchospasm, urinary retention, hypokalemia, hypersensitivity reactions, ocular effects.

How supplied: Inhaler-4g (120 inh)

IPRATROPIUM + ALBUTEROL

R

DUONEB DEY

Anticholinergic + beta-2 agonist. Ipratropium bromide 0.5 mg/3 mL (0.017%), albuterol (as sulfate) 2.5 mg/3 mL (0.083%); soln for inh.

Indications: COPD when a second aerosol bronchodilator is needed.

Adults: ≥ 18 yrs: 1 vial by nebulizer 4–6 times daily.

Children: <18 yrs: not recommended.

Contraindications: Atropine allergy.

Warnings/Precautions: Not for primary treatment of acute attack. Avoid excessive use. Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Cardiovascular disease (eg, coronary insufficiency, arrhythmias, hypertension). Hyperthyroidism. Diabetes. Seizure disorders. Narrow angle glaucoma. GI or GU obstruction. Hepatic or renal disease. Avoid eyes. Pregnancy (Cat.C). Labor & delivery. Nursing mothers: not recommended.

Interactions: Avoid MAOIs, tricyclics within 14 days (increased cardiovascular effects). Caution with other anticholinergics, sympathomimetics, drugs that lower potassium. Monitor digoxin. Antagonized by β -blockers.

Adverse reactions: Lung disorders, pharyngitis, chest pain, GI disturbances, bronchitis, UTI, leg cramps, pain, voice changes, anticholinergic effects, nervousness, headache, dizziness, insomnia, tachycardia, hypokalemia, paradoxical bronchospasm.

How supplied: Vials (3 mL)-25

LEVALBUTEROL

R

XOPENEX HFA Sunovion

beta-2 agonist. Levalbuterol (as tartrate) (single-isomer albuterol) 45mcg/inh; metered dose inhaler; CFC-free.

Indications: Bronchospasm.

Adults and Children: <4 yrs: not established.

≥ 4 yrs: 2 inh every 4–6 hrs; or 1 inh every 4 hrs may suffice.

Also: Levalbuterol

R

XOPENEX

Levalbuterol (as HCl) (single-isomer albuterol) 0.31mg/3mL, 0.63mg/3mL, 1.25mg/3mL; per vial; inhalation soln; preservative-free.

Adults: Initially 0.63mg by nebulization 3 times daily at 6–8 hr intervals; may increase to 1.25mg 3 times daily.

Children: <6 years: not recommended. 6–11 years: 0.31mg by nebulization 3 times daily; max 0.63mg 3 times daily.

Also: Levalbuterol

XOPENEX CONCENTRATE

Levalbuterol (as HCl) (single-isomer albuterol) 1.25mg/0.5mL; per vial; soln for inhalation via nebulization after dilution; preservative-free.

Adults: Initially 0.63mg by nebulization 3 times daily at 6–8 hr intervals; may increase to 1.25mg 3 times daily.

Children: <6yrs: not established. 6–11yrs: 0.31mg by nebulization 3 times daily; max 0.63mg 3 times daily.

Warnings/Precautions: Do not exceed recommended dose; monitor for increased need. Sensitivity to sympathomimetics. Discontinue if paradoxical bronchospasm or cardiovascular effects occur. Cardiovascular disease (esp. coronary insufficiency, arrhythmias, hypertension). Seizure disorders. Diabetes. Hyperthyroidism. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Avoid within 2 weeks of MAOIs, tricyclic antidepressants. Avoid other short-acting sympathomimetic aerosol bronchodilators, epinephrine. Antagonized by β -blockers. Monitor digoxin. Caution with other drugs that may lower serum potassium (eg, diuretics).

Adverse reactions: Accidental injury, bronchitis, dizziness, nervousness, tremor, pain, pharyngitis, rhinitis, vomiting; paradoxical bronchospasm, hypersensitivity reactions, cardiovascular effects, hypokalemia.

How supplied: Inhaler w. actuator (80inh)–8.4g, (200 inh)–15g; Soln 0.31mg/3mL, 0.63mg/3mL, 1.25mg/3mL–24 vials; Concentrate 1.25mg/0.5mL–30 vials

MOMETASONE

ASMANEX TWISTHALER Merck

Steroid. Mometasone furoate 110mcg/inh, 220mcg/inh; pwd for oral inhalation, metered-dose inhaler.

Indications: Maintenance treatment of asthma as prophylactic therapy.

Adults: Previously on bronchodilators alone or inhaled corticosteroids: initially 220mcg once in the PM; max 440mcg daily (either as 220mcg twice daily or 440mcg once daily). Previously on oral corticosteroids (wean gradually): initially 440mcg twice daily; max 880mcg daily. Rinse mouth after use.

Children: <4yrs: not recommended. 4–11yrs: 110mcg once in the PM; max 110mcg daily. Rinse mouth after use.

Contraindications: Not for treatment of acute attacks. Milk protein allergy.

Warnings/Precautions: Maintain regular regimen. Infections. If exposed to chickenpox or measles,

consider anti-infective prophylactic therapy. Monitor intraocular pressure; bone mineral density if other osteoporosis risk factors exist; and for growth suppression in children; hypercorticism and HPA axis suppression (if occurs, discontinue gradually). If adrenal insufficiency exists following systemic corticosteroids, replacement with inhaled steroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude). Prescribe a short-acting, inhaled β_2 -agonist for acute symptoms; monitor for increased need. Pregnancy (Cat.C). Nursing mothers.

Interactions: Caution with potent CYP3A4 inhibitors (eg, ketoconazole).

Adverse reactions: Headache, respiratory or other infection, oral candidiasis, dysmenorrhea, musculoskeletal pain, GI upset, allergic rhinitis, sinus congestion, sinusitis, depression, fatigue, pain, bronchospasm (discontinue if occurs). Children: fever, bruise.

How supplied: Twisthaler 110mcg (30 inh)–1; 220mcg (30 inh, 60 inh, 120 inh)–1

MONTELUKAST

SINGULAIR Merck

Leukotriene receptor antagonist. Montelukast (as sodium) 10mg; tabs.

Indications: Prophylaxis and chronic treatment of asthma (for patients ≥ 12 months old). Prevention of exercise-induced bronchoconstriction (EIB) (for patients ≥ 6 yrs old).

Adults and Children: Take granules by mouth within 15 minutes of opening packet; may dissolve in 5mL of cold or room temperature baby formula or breast milk, or mix in spoonful of soft applesauce, carrots, rice, or ice cream. <12months w/asthma or <6yrs w/EIB: not established. 12–23months: one 4mg granule packet. 2–5yrs: one 4mg chew tab or granule packet. 6–14yrs: one 5mg chew tab. ≥ 15 yrs: 10mg. For asthma: take once daily in the PM. For EIB: Take at least 2 hours before exercise (max 1 dose/day). Do not take an additional dose within 24hrs of a previous dose or if already taking a daily dose for another indication.

Also: Montelukast

SINGULAIR CHEWABLE

Montelukast (as sodium) 4mg, 5mg; tabs; cherry flavor; contains phenylalanine.

Indications: Prophylaxis and chronic treatment of asthma (for patients ≥ 12 months old). Prevention of exercise-induced bronchoconstriction (EIB) (for patients ≥ 15 yrs old).

Adults and Children: Take granules by mouth within 15 minutes of opening packet; may dissolve in 5mL of cold or room temperature baby formula or breast milk, or mix in spoonful of soft applesauce, carrots, rice, or ice cream. <12months: not recommended. 12–23months: one 4mg granule packet. 2–5yrs: one 4mg chew tab or granule packet. 6–14yrs: 5mg chew tab. ≥ 15 yrs: 10mg. For asthma: take once daily in the PM. For EIB: Take at least 2 hours before exercise (max 1 dose/day).

Also: Montelukast**SINGULAIR ORAL GRANULES**

Montelukast (as sodium) 4mg; per packet.

Adults and Children: Take granules by mouth within 15 minutes of opening packet; may dissolve in 5mL of cold or room temperature baby formula or breast milk, or mix in spoonful of soft applesauce, carrots, rice, or ice cream. <12months: not established. 12–23months: one 4mg granule packet. 2–5yrs: one 4mg chew tab or granule packet. 6–14yrs: 5mg chew tab. ≥15yrs: 10mg. For asthma: take once daily in the PM. For EIB: Take at least 2 hours before exercise (max 1 dose/day).

Warnings/Precautions: Not for primary treatment of acute attack. Eosinophilic conditions. Caution when withdrawing from oral steroids. Aspirin sensitivity. Pregnancy (Cat.B). Nursing mothers.

Interactions: Monitor with potent CYP450 inducers (eg, phenobarbital, rifampin).

Adverse reactions: Upper respiratory infection, fever, headache, pharyngitis, cough, abdominal pain, diarrhea, otitis media, influenza, rhinorrhea, sinusitis; neuropsychiatric events (monitor).

How supplied: Tabs, chew tabs–30, 90; Oral granules–30

R

a history of exacerbations. Not for the relief of acute bronchospasm.

Adults: 500mcg once daily.

Children: Not recommended.

Contraindications: Moderate-to-severe liver impairment (Child-Pugh Class B or C).

Warnings/Precautions: Depression. Suicidal ideation. Mild liver impairment (Child-Pugh Class A). Monitor for insomnia, anxiety, depression, suicidal ideation, other mood changes; reevaluate if occurs. Monitor weight regularly; consider discontinuing if unexplained or significant weight loss occurs. Pregnancy (Cat.C). Labor & delivery, nursing mothers: not recommended.

Interactions: Concomitant strong CYP450 inducers (eg, rifampicin, phenobarbital, carbamazepine, phenytoin): not recommended. Potentiated by CYP3A4 and CYP1A2 inhibitors (eg, erythromycin, ketoconazole, fluvoxamine, enoxacin, cimetidine), and by oral contraceptives containing gestodene + ethinyl estradiol (possible increased adverse effects).

Adverse reactions: GI upset, weight decrease, headache, back pain, influenza, dizziness, decreased appetite; psychiatric effects (eg, insomnia, anxiety, depression).

How supplied: Tabs–30

OMALIZUMAB

R

XOLAIR Genentech and Novartis

Antiasthmatic (IgE blocker). Omalizumab 150mg/vial; pwd for SC inj after reconstitution; preservative-free.

Indications: Moderate to severe persistent asthma in patients with a (+) skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled by inhaled corticosteroids.

Adults: Base dose and frequency on baseline serum total IgE level and body weight; see literature. Give by SC inj over 5–10 seconds; max 150mg per inj site. 150–375mg every 2 or 4 weeks. Reevaluate periodically.

Children: Not recommended.

Warnings/Precautions: Not for treating acute attacks. Have medications for treating anaphylaxis available, monitor for at least 2 hours after inj; may have delayed reaction. Elevated serum IgE levels may persist for up to 1 year after stopping therapy. Patients at risk of malignancy. Pregnancy (Cat.B). Nursing mothers.

Adverse reactions: Inj site reactions, viral infections, upper respiratory tract infections (eg, sinusitis, pharyngitis), headache; hypersensitivity reactions (discontinue if severe), anaphylaxis (may be fatal), antibody formation, malignancies.

How supplied: Single-use vial–1

ROFLUMILAST

R

DALIRESP Forest

Selective phosphodiesterase 4 (PDE4) inhibitor.

Roflumilast 500mcg; tablets.

Indications: To reduce risk of COPD exacerbations in severe COPD patients with chronic bronchitis and

SALMETEROL

R

SEREVENT DISKUS GlaxoSmithKline

Long-acting beta-2 agonist. Salmeterol (as xinafoate) 50mcg/inh; dry pwd for inhalation; device with drug in blisters.

Indications: As an adjunct (see literature): For the maintenance treatment of asthma and in the prevention of bronchospasm in reversible obstructive airway disease (including nocturnal asthma). Maintenance treatment of COPD-associated bronchospasm. Prevention of exercise-induced bronchospasm (EIB).

Adults and Children: <4yrs: not recommended. ≥4yrs: 1 inh every 12 hours. EIB prevention: 1 inh at least 30 minutes before exercise. Max 2 doses/day. Do not use additional doses for EIB if already using regular dosing for asthma. COPD-associated bronchospasm: 1 inh every 12 hours.

Contraindications: For asthma: without concomitant use of a long-term asthma control drug (eg, inhaled corticosteroid). Primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures. Allergy to milk proteins.

Warnings/Precautions: Increased risk of asthma-related deaths and hospitalizations. Prescribe for asthma only as additional therapy with an inhaled corticosteroid. Do not initiate in rapidly or acutely deteriorating asthma or COPD. Not for relief of acute bronchospasm. Salmeterol is not a substitute for steroids. Not for use with other long-acting β_2 -agonists. Do not exceed recommended dose. Cardiovascular disease (esp. coronary

insufficiency, arrhythmias, hypertension). Convulsive disorders. Thyrotoxicosis. Hyperresponsiveness to sympathomimetics. Diabetes. Ketoacidosis. Hypokalemia. Hyperglycemia. Hepatic impairment (monitor). Evaluate response before altering steroid doses. Prescribe an additional short-acting, inhaled β_2 -agonist for acute symptoms; monitor for increased need. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Concomitant strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, ritonavir, atazanavir, clarithromycin, indinavir, nefazodone, nelfinavir, saquinavir, telithromycin): not recommended. Caution during or within 2 weeks of MAOIs or tricyclic antidepressants (increased cardiovascular effects). Antagonized by β -blockers. Caution with K^+ -depleting diuretics.

Adverse reactions: Headache, influenza, nasal/sinus congestion, pharyngitis, rhinitis, tracheitis/bronchitis, cough, musculoskeletal pain, throat irritation, viral respiratory infection; paradoxical bronchospasm (discontinue if occurs); rarely: serious asthma episode, asthma-related death.

How supplied: Diskus (w. 60 blisters)–1

TERBUTALINE

TERBUTALINE SULFATE TABLETS (various) β_2 -agonist. Terbutaline sulfate 2.5mg, 5mg; scored tabs.

Indications: Asthma. Chronic bronchitis. Emphysema.

Adults: 12–15yrs: 2.5mg 3 times daily at 6 hour intervals. >15yrs: 2.5–5mg 3 times daily at 6 hour intervals.

Children: Not recommended.

Also: Terbutaline

TERBUTALINE SULFATE INJECTION

Terbutaline sulfate 1mg/mL.

Adults: 0.25mg SC into lateral deltoid area; may repeat after 15–30 minutes; max 0.5mg/4 hours.

Children: Not recommended.

Warnings/Precautions: Not for management of preterm labor. Avoid excessive use. Diabetes. Cardiac disease. Hypertension. Hyperthyroidism. Seizure disorders. If subject to hypokalemia, monitor potassium. Pregnancy (Cat.B). Nursing mothers.

Interactions: Avoid other sympathomimetics (except aerosol bronchodilators), MAOIs, tricyclics. Antagonized by β -blockers.

Adverse reactions: Tachycardia, palpitations, nervousness, tremor, headache, drowsiness, nausea.

How supplied: Contact supplier.

TIOTROPIUM

SPIRIVA HANDIHALER Boehringer Ingelheim Long-acting anticholinergic. Tiotropium (as bromide monohydrate) 18mcg/cap; dry pwd in caps for oral inhalation; with inhaler device.

Indications: Long-term maintenance treatment of bronchospasm due to COPD, including chronic

bronchitis and emphysema. To reduce exacerbations of COPD.

Adults: 2 inh of one capsule contents (18mcg) once daily, using HandiHaler inhalation device. Do not swallow caps.

Children: Not recommended.

Contraindications: Allergy to atropine or its derivatives (eg, ipratropium). Not for primary treatment of acute attack.

Warnings/Precautions: Discontinue if immediate hypersensitivity reactions (eg, angioedema) or paradoxical bronchospasm occurs; consider alternative therapy. Avoid getting powder into eyes. Monitor for signs/symptoms of worsening narrow-angle glaucoma; or worsening GI or GU obstruction. Renal impairment (CrCl $\leq$ 50mL/min); monitor for anticholinergic effects. Allergy to milk proteins. Pregnancy (Cat.C). Labor and delivery. Nursing mothers.

Interactions: Avoid other anticholinergics.

Adverse reactions: Upper respiratory tract infection, dry mouth, sinusitis, pharyngitis, non-specific chest pain, urinary tract infection, dyspepsia, rhinitis, other anticholinergic effects (eg, urinary retention/difficulty, constipation, increased heart rate, blurred vision, glaucoma), GI upset, epistaxis, rash, arthritis, cough, flu-like symptoms, paradoxical bronchospasm, angioedema.

How supplied: Caps (w. inh device)–5, 30, 90

20B Cough and cold

BENZONATATE

TESSALON Forest

Antitussive. Benzonatate 100mg perles, 200mg caps.

Indications: Cough.

Adults and Children: Swallow whole; do not suck or chew. <10yrs: not recommended. $\geq$ 10yrs: 100–200mg 3 times daily.

Warnings/Precautions: Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Drowsiness, headache, dizziness, GI upset, pruritus, skin eruptions; confusion, hallucinations (rare).

How supplied: Perles, caps–100, 500

CODEINE + PROMETHAZINE

PROMETHAZINE W. CODEINE (various)

Antitussive + antihistamine. Codeine phosphate 10mg, promethazine HCl 6.25mg; per 5mL; syrup; contains alcohol 7%.

Indications: Nonproductive cough.

Adults: 5mL every 4–6hrs; max 30mL/day.

Children: <6yrs: see Contraindications. 6–12yrs: 2.5–5mL every 4–6hrs; max 30mL/day.

Contraindications: Children <6 years old. Asthma. Lower respiratory disorders. Coma. Post-op pain management in children who have undergone tonsillectomy and/or adenoidectomy.

Warnings/Precautions: Risk of respiratory depression and death related to ultra-rapid metabolizers of codeine (esp. children in post-op tonsillectomy and/or adenoidectomy). Asthma. Compromised respiratory function (eg, COPD, sleep apnea): avoid. Increased intracranial pressure. Acute abdomen. Head injury. Cardiovascular disease. Hypothyroidism. Narrow-angle glaucoma. Peptic ulcer. Bone marrow depression. Acute febrile illness. GI or GU obstruction. Ulcerative colitis. Recent GI or urinary tract surgery. Seizure disorders. Monitor for neuroleptic malignant syndrome. Impaired hepatic or renal function. Addison's disease. History of drug abuse. Dehydration. Avoid prolonged sun exposure. Use lowest effective dose for shortest duration. Elderly. Debilitated. Children ≥ 6 years. Atopic children. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Additive respiratory effects with concomitant other respiratory depressants (esp. in children). Concomitant epinephrine: not recommended. Increased extrapyramidal effects with MAOIs. Potentiates alcohol, other CNS depressants. Concomitant narcotics, local anesthetics: may lower seizure threshold. Caution with anticholinergics. May alter hCG pregnancy test and glucose tolerance test results.

Adverse reactions: CNS or respiratory depression (may be fatal in children), anticholinergic effects, orthostatic hypotension, photosensitivity, paradoxical excitement, changes in blood pressure, convulsions, jaundice, blood dyscrasias.

How supplied: Contact supplier.

DES Loratadine + Pseudoephedrine

CLARINEX-D 24 HOUR Merck
Antihistamine + sympathomimetic. Desloratadine 5mg, pseudoephedrine sulfate 240mg; ext-rel tabs.

Indications: Seasonal allergic rhinitis with nasal congestion.

Adults: Swallow whole. 1 tab once daily. Renal impairment: 1 tab every other day.

Children: Not recommended.

Also: Desloratadine + Pseudoephedrine
CLARINEX-D 12 HOUR

Desloratadine 2.5mg, pseudoephedrine sulfate 120mg; ext-rel tabs.

Adults: Swallow whole. 1 tab twice daily. Renal impairment: 1 tab once daily.

Children: Not recommended.

Contraindications: Narrow-angle glaucoma. Urinary retention. Severe hypertension or coronary artery disease. During or within 14 days of MAOIs.

Warnings/Precautions: Hepatic impairment: not recommended. Renal impairment: reduce dose. Hypertension. Ischemic heart disease. Increased intraocular pressure. Thyroid disease. GI or GU obstruction. Diabetes. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications.

Pseudoephedrine: Antagonizes antihypertensives. Increased ectopic pacemaker activity with digitalis.

Adverse reactions: Dry mouth, headache, insomnia, fatigue, pharyngitis, somnolence, nausea, dizziness, nervousness, hyperactivity, anorexia.

How supplied: Tabs-100

Fexofenadine + Pseudoephedrine

OTC

ALLEGRA-D 24 HOUR Sanofi Aventis
Antihistamine + sympathomimetic. Fexofenadine HCl 180mg, pseudoephedrine HCl 240mg; ext-rel tabs.

Indications: Seasonal allergic rhinitis with nasal congestion.

Adults: Swallow whole. Take on an empty stomach. 1 tab once daily. Renal insufficiency: not recommended.

Children: Not recommended.

Also: Fexofenadine + Pseudoephedrine OTC

ALLEGRA-D 12 HOUR
Fexofenadine HCl 60mg, pseudoephedrine HCl 120mg; ext-rel tabs.

Adults: Swallow whole. Take on an empty stomach. 1 tab twice daily. Renal impairment: initially 1 tab once daily.

Children: Not recommended.

Contraindications: Narrow-angle glaucoma. Urinary retention. Severe hypertension or coronary artery disease. During or within 14 days of stopping MAOIs.

Warnings/Precautions: Hypertension. Diabetes. Ischemic heart disease. Increased intraocular pressure. Hyperthyroidism. Renal impairment. GI or GU obstruction. Seizure disorders. Elderly. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: See Contraindications. Avoid concomitant aluminum- or magnesium-containing antacids. Pseudoephedrine: Antagonizes antihypertensives. Increased ectopic pacemaker activity with digitalis. Avoid other sympathomimetics. Fruit juices (eg, grapefruit, orange, apple) may reduce plasma levels.

Adverse reactions: Headache, insomnia, nausea, dry mouth, dyspepsia, throat irritation, dizziness, agitation, back or abdominal pain, palpitations, nervousness, anxiety, upper respiratory infection.

How supplied: Tabs 24hr-100; 12hr-100, 500

Hydrocodone + Chlorpheniramine

CIII

TISSUONEX UCB

Antitussive + antihistamine. Hydrocodone bitartrate 10mg, chlorpheniramine maleate 8mg; per 5mL; as polistirex; ext-rel susp.

Indications: Cough and upper respiratory symptoms.

Adults: Use accurate measuring device. 5mL every 12 hrs.

Children: Use accurate measuring device. <6yrs: see Contraindications. 6-11yrs: 2.5mL every 12 hrs.

Contraindications: Children <6yrs of age (risk of fatal respiratory depression).

Warnings/Precautions: Respiratory impairment. Post-op. Head injury. Increased intracranial pressure. Glaucoma. Asthma. GI or GU obstruction. Acute abdomen. Hepatic or renal impairment. Thyroid disorders. Elderly. Debilitated. Labor & delivery. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Additive CNS depression with alcohol, other CNS depressants, tricyclic antidepressants, MAOIs. Paralytic ileus with concurrent anticholinergics.

Adverse reactions: CNS and respiratory depression, abuse potential, GI upset, anticholinergic effects.

How supplied: Susp-473mL

HYDROCODONE + HOMATROPINE CIII

HYDROCODONE BITARTRATE/HOMATROPINE METHYLBROMIDE TABLETS (various)

Antitussive. Hydrocodone bitartrate 5mg, homatropine methylbromide 1.5mg; tabs.

Indications: Cough.

Adults: 1 tab every 4-6 hrs.

Children: <6 yrs: not recommended. 6-12 yrs: ½ tab every 4-6 hrs; max 3 tabs daily.

Also: Homatropine + Hydrocodone CIII

HYDROCODONE BITARTRATE/HOMATROPINE METHYLBROMIDE SYRUP

Hydrocodone bitartrate 5mg, homatropine methylbromide 1.5mg; per 5mL.

Adults: 5mL every 4-6 hrs.

Children: <6 yrs: not recommended. 6-12 yrs: 2.5mL every 4-6 hrs; max 15mL daily.

Contraindications: Glaucoma. Increased intracranial pressure. Head injury. Respiratory impairment. Labor & delivery. Nursing mothers.

Warnings/Precautions: Drug abusers. Elderly. Debilitated. GI or urinary obstruction. Acute abdomen. Hepatic or renal dysfunction. Hypothyroidism. Pregnancy (Cat.C).

Interactions: Potentiates alcohol, CNS depressants. Increased toxicity of MAOIs, tricyclics.

Adverse reactions: Respiratory depression, abuse potential, drowsiness, hypertension, orthostatic hypotension, palpitations, anticholinergic effects, sedation, anxiety, nausea, rash, pruritus.

How supplied: Contact supplier.

20C Lung surfactants/ mucolytics

BERACTANT R

SURVANTA Abbott Nutrition

Lung surfactant. Beractant (as phospholipids) 25mg/mL; susp for intratracheal administration; preservative-free.

Indications: Prevention and treatment of respiratory distress syndrome (RDS) in premature infants.

Children: See literature for dosing chart, administration, and additional support procedures. 100mg of phospholipids (4mL/kg birth weight per dose, by intratracheal administration; max 4 doses, at 6 hour intervals in the first 48 hours after birth. Rescue: give 1st dose as soon as possible after infant is placed on mechanical ventilation for treatment of RDS. Prevention: give 1st dose as soon as possible after birth, preferably within 15 minutes. Avoid suctioning for 1 hour after treatment, unless significant airway obstruction occurs. Retreatment is determined by continued respiratory distress. Get radiographic confirmation of RDS in those infants given preventative dose before giving additional doses.

Warnings/Precautions: Interrupt dosing if bradycardia or oxygen desaturation occurs; treat; resume after stabilization. Monitor oxygenation, carbon dioxide, and clinical condition frequently and carefully.

Adverse reactions: Dosing procedure reactions including oxygen desaturation and bradycardia, rales, moist breath sounds, sepsis, intracranial hemorrhage.

How supplied: Vials (4mL, 8mL)-1

CALFACTANT R

INFASURF Forest

Lung surfactant. Calfactant (as phospholipids 35mg/mL and 0.65mg proteins/mL); susp for intratracheal administration; preservative-free.

Indications: Prevention and treatment of respiratory distress syndrome (RDS) in premature infants.

Adults: Not applicable.

Children: See literature. Give by intratracheal administration through an endotracheal tube. 3mL/kg birth weight per dose (as 2 aliquots of 1.5mL/kg each) every 12 hours for 3 doses.

Warnings/Precautions: Interrupt dosing if reflux of product into endotracheal tube, cyanosis, bradycardia, airway obstruction, hypoventilation, or endotracheal tube dislodgement occurs; treat; resume after stabilization. Monitor respiratory status and clinical condition frequently and carefully.

Adverse reactions: Cyanosis, airway obstruction, bradycardia, reflux of surfactant into endotracheal tube, requirement for mechanical ventilation, reintubation, others.

How supplied: Single-use vials (6mL)-1

DORNASE ALFA R

PULMOZYME Genentech

Dornase alfa (recombinant human DNase) 1mg/mL; soln for inh; preservative-free.

Indications: Management of cystic fibrosis in conjunction with standard therapies to improve pulmonary function.

Adults and Children: <3months: not recommended. Use appropriate nebulizer. Do not dilute. >5yrs: 2.5mg once daily via nebulization; may increase to 2.5mg twice daily (see literature).

Warnings/Precautions: For patients <5yrs of age, use only if there is a potential for benefit in pulmonary function or in risk of respiratory tract infection. Use only with recommended nebulizers. Pregnancy (Cat.B). Nursing mothers.

Interactions: Do not mix with other drugs in nebulizer.

Adverse reactions: Pharyngitis, voice alteration, laryngitis, rash, chest pain, conjunctivitis.

How supplied: Amps (2.5mL)–30

PORACTANT

R

CUROSURF DEY

Lung surfactant. Poractant alfa (as phospholipids 80mg/mL and proteins 1mg/mL); susp for intratracheal administration; preservative-free.

Indications: Treatment ("rescue") of respiratory distress syndrome (RDS) in premature infants.

Adults: Not applicable.

Children: See literature. Give by intratracheal administration through an endotracheal tube. Each dose should be administered as 2 aliquots. Initial dose of 2.5mL/kg birth weight; may give 2 more doses of 1.25mL/kg birth weight at 12-hour intervals.

Warnings/Precautions: Interrupt dosing if reflux of product into endotracheal tube, cyanosis, bradycardia, airway obstruction, hypoventilation, or endotracheal tube dislodgement occurs; treat; resume after stabilization. Monitor respiratory status and clinical condition frequently and carefully.

Adverse reactions: Bradycardia, hypotension, reflux of surfactant into endotracheal tube, others.

How supplied: Single-use vials (1.5mL, 3mL)–1

20D Respiratory stimulants

CAFFEINE CITRATE

R

CAFCIT INJECTION Mead Johnson

Xanthine. Caffeine citrate 20mg/mL (equivalent to caffeine base 10mg/mL); soln for IV infusion; preservative-free.

Indications: Short-term treatment of apnea of prematurity in infants 28 to <33 weeks gestational age.

Adults: Not applicable.

Children: Use a syringe infusion pump when infusing. Loading dose: 20mg/kg caffeine citrate by IV infusion once (over 30 minutes); then, beginning 24 hours after loading dose: maintenance 5mg/kg caffeine citrate by IV infusion every 24 hours (over 10 minutes). Adjust based on response and serum caffeine levels.

Also: *Caffeine citrate*

CAFCIT ORAL SOLUTION Boehringer Ingelheim
Caffeine citrate 20mg/mL (equivalent to caffeine base 10mg/mL); preservative-free.

Adults: Not applicable.

Children: Maintenance: 5mg/kg caffeine citrate orally every 24 hours. Adjust based on response and serum caffeine levels.

Warnings/Precautions: Measure baseline serum caffeine levels in infants previously treated with

theophylline (or aminophylline) and in infants born to mothers who consumed caffeine prior to delivery. Serious toxicity may occur with serum caffeine levels >50mg/L. Exclude or treat other causes of apnea. Seizure disorders. Cardiovascular disease. Monitor caffeine levels in impaired renal or hepatic function; adjust dose to avoid toxicity. Monitor serum glucose levels and for necrotizing enterocolitis. Pregnancy (Cat.C).

Interactions: Avoid concomitant theophylline, aminophylline (increased toxicity). May be potentiated by cimetidine, ketoconazole, others (may need to reduce caffeine dose). May be antagonized by phenobarbital, phenytoin, others (may need to increase caffeine dose). Caution with CYP1A2 substrates, inhibitors, or inducers.

Adverse reactions: CNS stimulation, cardiovascular or GI effects, increased gastric aspirate, feeding intolerance, hypo- or hyperglycemia, hemorrhage, acidosis, sepsis, lung edema, dyspnea, renal effects (eg, diuresis, renal failure), necrotizing enterocolitis.

How supplied: Single-use vial (3mL)–1
Oral soln (3mL)–10

20E Rhinitis/rhinorrhea (intranasal products)

AZELASTINE

R

ASTELIN Meda

Antihistamine. Azelastine HCl 137mcg/spray; aqueous nasal spray; contains benzalkonium chloride.
Indications: Seasonal allergic rhinitis. Vasomotor rhinitis.

Adults: 2 sprays in each nostril twice daily.

Children: Seasonal allergic rhinitis: <5yrs: not recommended; 5–11yrs: 1 spray in each nostril twice daily. Vasomotor rhinitis: not recommended.

Warnings/Precautions: Avoid eyes. Pregnancy (Cat.C). Nursing mothers.

Interactions: Potentiates CNS depression with alcohol, other CNS depressants. Caution with other antihistamines.

Adverse reactions: Bitter taste, headache, somnolence, dysesthesia, nasal burning, pharyngitis, dry mouth, paroxysmal sneezing, nausea, rhinitis, fatigue, dizziness, epistaxis, weight increase, myalgia. Children: also conjunctivitis, cough, asthma.

How supplied: Ready-Spray–30mL (200 sprays)

AZELASTINE + FLUTICASONE

R

DYMISTA Meda

Antihistamine + corticosteroid. Azelastine hydrochloride (HCl), fluticasone propionate 137mcg/50mcg; per 0.137mL metered nasal spray; aqueous suspension.

Indications: Seasonal allergic rhinitis.

Adults: 1 spray per nostril twice daily.

Children: Not established.

Warnings/Precautions: Avoid use in recent nasal ulcers, nasal surgery, or nasal trauma. Respiratory tract tuberculosis. Infections (eg, fungal, bacterial,

viral, ocular herpes simplex). Avoid exposure to chickenpox and measles; if exposed, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with topical corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude, depression). Monitor growth routinely in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually), and *Candida* infection or other nasal mucosal changes. History of increased intraocular pressure, glaucoma, and/or cataracts; monitor any change in vision. Avoid eyes. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid alcohol or other CNS depressants. Concomitant ritonavir: not recommended. Caution with other potent CYP3A4 inhibitors (eg, ketoconazole).

Adverse reactions: Dysgeusia, epistaxis, headache; somnolence.

How supplied: Pump (23g)—120 sprays

BECLOMETHASONE

QNASL Teva Respiratory

Steroid. Beclomethasone dipropionate 80mcg/actuation; non-aqueous nasal spray soln.

Indications: Seasonal and perennial allergic rhinitis.

Adults: 2 sprays in each nostril once daily; maximum 4 sprays per day.

Children: Not established.

Warnings/Precautions: Avoid in recent nasal septal ulcers, nasal surgery, or nasal trauma until healed. Monitor periodically for possible changes in nasal mucosa or *Candida* infection with long-term use. Discontinue if nasal erosion/ulceration or *Candida* infection occur (treat with local therapy). History of increased intraocular pressure, glaucoma, and/or cataracts; monitor closely for change in vision. Respiratory tract tuberculosis. Untreated infections (eg, fungal, bacterial, viral, ocular herpes simplex). If exposed to measles or chickenpox, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with intranasal corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, lassitude, depression). Monitor for hypercorticism and adrenal suppression (if occur discontinue gradually). Monitor for growth suppression in children. Avoid eyes, mouth and face. Pregnancy (Category C). Nursing mothers.

Adverse reactions: Nasal discomfort, epistaxis, headache; hypersensitivity reactions (discontinue if occurs).

How supplied: Aerosol—8.7g (120 actuations)

CICLESONIDE

OMNARIS Sunovion

Steroid. Ciclesonide 50mcg/spray; aqueous nasal spray.

Indications: Treatment of seasonal allergic rhinitis in patients ≥ 6 yrs old and perennial allergic rhinitis in patients ≥ 12 yrs old.

Adults: 2 sprays in each nostril once daily (200mcg/day).

Children: Seasonal allergic rhinitis: < 6 yrs: not recommended. ≥ 6 yrs: 2 sprays in each nostril once daily (200mcg/day).

Warnings/Precautions: Avoid use in patients with recent nasal ulcers/surgery/trauma until healed. Potential worsening of active tuberculosis; fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex. If exposed to measles or chickenpox, consider immunoglobulin prophylactic therapy. If adrenal suppression exists following systemic corticosteroid therapy, replacement with topical steroids may exacerbate symptoms of adrenal insufficiency. Monitor for hypercorticism and HPA axis suppression (if occur discontinue slowly), and for *Candida* infection and other nasal mucosal changes. Monitor for vision changes or with history of increased intraocular pressure, glaucoma and/or cataracts. Monitor for growth suppression in children. Avoid spraying eyes, or directly onto the nasal septum. Reevaluate if no improvement after 2 weeks (for seasonal allergic rhinitis) and 5 weeks (for perennial allergic rhinitis). Pregnancy (Cat.C). Nursing mothers.

Interactions: May be potentiated by ketoconazole.

Adverse reactions: Headache, epistaxis, nasopharyngitis, ear pain, pharyngolaryngeal pain.

How supplied: Nasal spray (pump)—12.5g (120 sprays)

FLUTICASONE

FLONASE GlaxoSmithKline

Steroid. Fluticasone propionate 50mcg/spray; aqueous nasal spray.

Indications: Seasonal and perennial allergic and nonallergic rhinitis.

Adults: Initially 2 sprays in each nostril once daily or 1 spray in each nostril twice daily (AM and PM). Maintenance: may reduce to 1 spray in each nostril daily. Seasonal allergic rhinitis: 2 sprays in each nostril once daily as needed may suffice.

Children: < 4 yrs: not recommended. ≥ 4 yrs: initially 1 spray in each nostril once daily; may increase to 2 sprays in each nostril once daily. Maintenance: 1 spray in each nostril once daily; max 2 sprays in each nostril daily.

Warnings/Precautions: Maintain regular regimen. Respiratory tract tuberculosis. Infections (eg, ocular herpes simplex). If exposed to measles or chickenpox, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with topical corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, depression). Monitor for growth suppression in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually), and *Candida* infection or other nasal mucosal changes. Avoid eyes. Pregnancy (Cat.C). Nursing mothers.

Interactions: Avoid ritonavir. Caution with potent CYP3A4 inhibitors (eg, ketoconazole).

Adverse reactions: Headache, pharyngitis, epistaxis, nasal burning, asthma symptoms, GI upset, cough, reduced growth velocity in children.

How supplied: Spray-16g (120 sprays)

MOMETASONE

NASONEX Merck

Steroid. Mometasone furoate (as furoate monohydrate) 50mcg/spray; aqueous nasal spray.

Indications: Treatment of seasonal and perennial allergic rhinitis symptoms in patients ≥ 2 yrs of age. Prophylaxis of seasonal allergic rhinitis symptoms in patients ≥ 12 yrs of age. Nasal polyps.

Adults: Allergic rhinitis: 2 sprays in each nostril once daily; prophylaxis: begin 2–4 weeks prior to anticipated start of pollen season. Nasal polyps: ≥ 18 yrs: 2 sprays in each nostril 1–2 times daily.

Children: Allergic rhinitis: < 2 yrs: not recommended. 2–11 yrs: 1 spray in each nostril once daily. Nasal polyps: < 18 yrs: not recommended.

Warnings/Precautions: Maintain regular regimen. Respiratory tract tuberculosis. Infections (eg, ocular herpes simplex). If exposed to measles or chickenpox, consider anti-infective prophylactic therapy. If adrenal insufficiency exists following systemic corticosteroid therapy, replacement with topical corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, depression). Monitor for growth suppression in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually), and candida infection or other nasal mucosal changes. Monitor if vision changes or if history of glaucoma or cataracts. Discontinue if nasopharyngeal candida infection occurs. Avoid eyes. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Headache, viral infection, pharyngitis, epistaxis, cough, upper respiratory tract infections, pain, sinusitis, reduced growth velocity in children; rare: nasal ulcers.

How supplied: Spray-17g (120 sprays)

TRIAMCINOLONE

NASACORT AQ Sanofi Aventis

Steroid. Triamcinolone acetonide 55mcg/spray; aqueous nasal spray.

Indications: Seasonal and perennial allergic rhinitis.

Adults: 2 sprays in each nostril once daily. Reduce dose as condition improves.

Children: < 2 yrs: not recommended. 2–5 yrs: 1 spray in each nostril once daily. 6–12 yrs: 1 spray in each nostril once daily; max 2 sprays in each nostril once daily. Reduce dose as condition improves.

Warnings/Precautions: Maintain regular regimen. Respiratory tract tuberculosis. Infections (eg, ocular herpes simplex). If exposed to measles or chickenpox, consider anti-infective prophylactic therapy. Avoid use in patients with recent nasal ulcers, surgery, or trauma. Reevaluate if no improvement in 3 weeks. If adrenal insufficiency exists following systemic corticosteroid therapy,

replacement with topical corticosteroids may exacerbate symptoms of adrenal insufficiency (eg, depression). Monitor for growth suppression in children. Monitor for hypercorticism and HPA axis suppression (if occur discontinue gradually), changes in vision or increased intraocular pressure, and candida infection or other nasal mucosal changes. Avoid eyes. Pregnancy (Cat.C). Nursing mothers.

Adverse reactions: Pharyngitis, epistaxis, flu syndrome, cough increased, bronchitis, headache, pharyngolaryngeal pain, nasopharyngitis, abdominal upper pain, GI upset; glaucoma/cataracts, impaired wound healing, reduced growth velocity in children.

How supplied: Nasacort AQ-16.5g (120 sprays)

SECTION 21:

UROLOGICAL DISORDERS 21A Benign prostatic hyperplasia/urinary retention

BETHANECHOL

URECHOLINE Teva US Generics

Cholinergic. Bethanechol chloride 5mg, 10mg, 25mg, 50mg; scored tabs.

Indications: Post-op and post-partum nonobstructive urinary retention and retentive neurogenic urinary atony.

Adults: Take on empty stomach. Initially 5–10mg every hour until effective or max 50mg, then 10–50mg 3–4 times daily.

Children: Not recommended.

Contraindications: Hyperthyroidism. Peptic ulcer. Asthma. Bradycardia. Hypotension. Vasomotor instability. Coronary artery disease. Epilepsy. Parkinsonism. Obstructive uropathies. Questionable GI or bladder integrity. Obstructive, spastic, inflammatory GI disorders. Vagotonia. Peritonitis. When increased GI or bladder muscle activity may be harmful.

Warnings/Precautions: Reflux urinary infection. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Severe abdominal symptoms and hypotension with ganglionic blockers.

Adverse reactions: Cholinergic effects, GI upset, asthma, headache, facial flushing, malaise, orthostatic hypotension.

How supplied: Tabs-100

DOXAZOSIN

CARDURA Pfizer

alpha-1 blocker (quinazoline). Doxazosin (as mesylate) 1mg, 2mg, 4mg, 8mg; scored tabs.

Indications: BPH.

Adults: Initially 1mg once daily; may double dose every 1–2 weeks; max 8mg/day.

Children: Not applicable.

Warnings/Precautions: Impaired liver function. Monitor blood pressure and for orthostatic

hypotension initially and if dose increased. Syncope. Exclude prostate cancer.

Adverse reactions: Dizziness, fatigue, hypotension, edema, dyspnea; rare: priapism.

How supplied: Tabs-100

DOXAZOSIN

R

CARDURA XL Pfizer

alpha-1 blocker (quinazoline). Doxazosin (as mesylate) 4mg, 8mg; extended-release tabs.

Indications: BPH.

Adults: Swallow whole. Take w. breakfast. Initially 4mg once daily; may titrate after 3-4 weeks to max 8mg/day. If therapy is stopped for several days, restart at 4mg once daily. Switching from Cardura to Cardura XL: initially 4mg once daily; do not take final evening dose of Cardura.

Children: Not recommended.

Warnings/Precautions: Severe hepatic impairment: not recommended. Syncope. Hypotension. Exclude prostate cancer. Mild or moderate hepatic dysfunction. Severe GI narrowing. CHF, angina, acute MI (within 6 months); discontinue if angina occurs or worsens. Cataract surgery (intraoperative floppy iris syndrome possible).

Interactions: Caution with CYP3A4 inhibitors (eg, clarithromycin, ketoconazole, itraconazole).

Adverse reactions: Dizziness, dyspnea, asthenia, headache, hypotension, postural hypotension, somnolence, respiratory or urinary tract infections.

How supplied: Tabs-30

DUTASTERIDE

R

AVODART GlaxoSmithKline

Type I and II 5 alpha-reductase inhibitor. Dutasteride 0.5mg; caps.

Indications: BPH, as monotherapy to improve symptoms and reduce risks of acute urinary retention and need for prostate surgery; or in combination with tamsulosin. Limitation of use: not approved for preventing prostate cancer.

Adults: Swallow whole. Monotherapy: 0.5mg once daily. Combination therapy: 0.5mg once daily with tamsulosin 0.4mg once daily.

Children: See Contraindications.

Contraindications: Not for use in children or women. Pregnant women and those of childbearing potential should avoid handling caps.

Warnings/Precautions: Increased risk of high-grade prostate cancer. Monitor prostate specific antigen (PSA) values (establish new baseline PSA after at least 3months of treatment); double PSA levels to compare with normal values. Rule out prostate cancer and other urological disorders prior to treatment. Hepatic dysfunction. Avoid donating blood until at least 6months after last dose.

Interactions: May be potentiated by CYP3A4/5 inhibitors (eg, ritonavir, ketoconazole, verapamil, diltiazem, cimetidine, troleanandomycin, ciprofloxacin); caution.

Adverse reactions: Impotence, decreased libido, ejaculation disorder, gynecomastia, dizziness (with tamsulosin).

How supplied: Caps-30, 90

FINASTERIDE

R

PROSCAR Merck

Type II 5 alpha-reductase inhibitor. Finasteride 5mg; tabs.

Indications: BPH, to improve symptoms and reduce risks of acute urinary retention and need for prostate surgery. To reduce risk of symptomatic progression of BPH, with doxazosin.

Adults: 5mg once daily. Reevaluate at 6 months, then periodically.

Children: Not applicable.

Contraindications: Not for use in children or women. Pregnant women and those of childbearing potential should avoid handling crushed or broken tablets.

Warnings/Precautions: Not for use in preventing prostate cancer. Increased risk of high-grade prostate cancer. Monitor prostate specific antigen (PSA) values; double PSA levels for comparison with normal ranges. Rule out prostate cancer and other urological disorders prior to treatment. Monitor for obstructive uropathy. Hepatic dysfunction.

Adverse reactions: Impotence, decreased libido or ejaculate volume, mastodynia.

How supplied: Tabs-30, 100, 1000

TADALAFIL

R

CIALIS Lilly

Phosphodiesterase type 5 inhibitor (cGMP-specific).

Tadalafil 2.5mg, 5mg, 10mg, 20mg; tabs.

Indications: Benign prostatic hyperplasia (BPH).

Adults: 5mg once daily (taken at same time each day). Renal impairment: CrCl 30-50mL/min: initially 2.5mg; may increase to 5mg/day. CrCl <30mL/min or hemodialysis: not recommended. Concomitant potent CYP3A4 inhibitors (See Interactions): max 2.5mg/day. Concomitant α -blockers: not recommended.

Children: Not recommended.

Contraindications: Concomitant nitrates.

Warnings/Precautions: Identify underlying causes and confirm diagnosis before therapy. Cardiovascular disease (eg, MI within 90 days, unstable angina or angina during intercourse, severe heart failure or stroke within 6 months; BP <90/50 or BP >170/100, uncontrolled arrhythmias, severely impaired autonomic BP regulation, LV outflow obstruction), severe hepatic impairment, retinitis pigmentosa and related retinal disorders: not recommended. Anatomical penile deformation. Predisposition to priapism. Patients for whom sexual activity is inadvisable or contraindicated. Bleeding disorders. Active peptic ulcer. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: See Contraindications. Hypotension with nitrates, other antihypertensives, alcohol (≥ 5 units). Plasma levels increased by CYP3A4 inhibitors (eg, ketoconazole, itraconazole, protease inhibitors, erythromycin, grapefruit juice) and decreased by CYP3A4

inducers (eg, rifampin). Concomitant α -blockers: not recommended; discontinue at least 1 day prior to therapy.

Adverse reactions: Headache, dyspepsia, back pain, myalgia, nasal congestion, flushing, limb pain, sudden vision or hearing loss (discontinue if occurs); cardiovascular effects (eg, hypotension, tachycardia); rare: priapism.

How supplied: Tabs 2.5mg–2 × 15 (blisters); 5mg–10, 30, 2 × 15 (blisters); 10mg, 20mg–30

TAMSULOSIN

R

FLOMAX Boehringer Ingelheim
alpha-1A blocker. Tamsulosin HCl 0.4mg; caps.

Indications: BPH.

Adults: Swallow whole. Take ½ hr after same meal of each day. Initially 0.4mg once daily; may increase to 0.8mg once daily after 2–4 weeks if response is inadequate. If therapy is interrupted, resume at 0.4mg once daily and retitrate.

Children: Not applicable.

Warnings/Precautions: Rule out prostate cancer. Sulfa allergy. Syncope. End-stage renal disease. Cataract surgery (intraoperative floppy iris syndrome possible).

Interactions: Do not use with other α -blockers. Caution with cimetidine (esp. with tamsulosin >0.4mg/day), warfarin.

Adverse reactions: Abnormal ejaculation, postural hypotension, dizziness, rhinitis, cough, somnolence, sinusitis, amblyopia, decreased libido, insomnia, syncope; rare: priapism.

How supplied: Caps–100

TERAZOSIN

R

HYTRIN AbbVie
alpha-1 blocker (quinazoline). Terazosin (as HCl) 1mg, 2mg, 5mg, 10mg; caps.

Indications: BPH.

Adults: See literature. Initially 1mg at bedtime. Titrate to 10mg once daily; usual max 20mg/day. Reevaluate if no response after 6 weeks.

Children: Not applicable.

Warnings/Precautions: Rule out prostate cancer. Syncope.

Interactions: Caution with verapamil, other antihypertensives.

Adverse reactions: Syncope (esp. 1st dose), dizziness, somnolence, asthenia, nausea, nasal congestion, palpitations, impotence, orthostatic hypotension, blurred vision, peripheral edema; priapism (rare).

How supplied: Caps–100

21B Hyperphosphatemia

LANTHANUM

R

FOSRENOL Shire
Phosphate binder. Lanthanum carbonate 500mg, 750mg, 1000mg; chew tabs.

Indications: To reduce serum phosphate in end-stage renal disease.

Adults: Take with meals; chew tabs completely. Initially 750mg–1.5g/day in divided doses. Titrate at 2–3 wk intervals in increments of 750mg/day based on serum phosphate. Usual range: 1.5g–3g; usual max 3.75g/day.

Children: Not recommended.

Warnings/Precautions: Acute peptic ulcer. Ulcerative colitis. Crohn's disease. Bowel obstruction. Monitor phosphate, calcium. Labor & delivery. Pregnancy (Cat.C); not recommended. Nursing mothers.

Interactions: Separate dosing of drugs that interact with antacids by 2 hrs. May interfere with abdominal x-ray.

Adverse reactions: GI upset (usually transient), dialysis graft occlusion, abdominal pain, constipation.

How supplied: Tabs 500mg patient pack (2 × 45 tabs)–1; 750mg patient pack (6 × 15 tabs)–1; 1000mg patient pack (9 × 10 tabs)–1

SEVELAMER

R

RENAGEL TABLETS Genzyme

Phosphate binder. Sevelamer HCl 400mg, 800mg.

Indications: Reduction of serum phosphorus in end stage renal disease in patients on hemodialysis.

Adults: Swallow whole with meals. Patients not taking a phosphate binder: serum phosphorus >5.5 to <7.5mg/dL: 800mg 3 times daily; 7.5–9mg/dL: 1.2–1.6g 3 times daily; ≥9mg/dL: 1.6g 3 times daily. Titrate by 1 tab per meal at 2-week intervals to keep serum phosphorus ≤5.5mg/dL. Switching from calcium acetate to sevelamer: see literature.

Children: Not recommended.

Contraindications: Hypophosphatemia. Bowel obstruction.

Warnings/Precautions: Dysphagia. Swallowing disorders. Severe GI motility disorders. Major GI tract surgery. Monitor serum calcium, bicarbonate, chloride. Pregnancy (Cat.C).

Interactions: Separate narrow therapeutic index drugs by 1 hr before or 3 hrs after sevelamer, or monitor.

Adverse reactions: GI upset, headache, constipation.

How supplied: Tabs 400mg–360; 800mg–180

21C Overactive bladder/enuresis

DESMOPRESSIN

R

DDAVP Sanofi Aventis

Vasopressin (synthetic). Desmopressin acetate 0.1mg, 0.2mg; scored tabs.

Indications: Primary nocturnal enuresis.

Adults and Children: <6yrs: not recommended. ≥6yrs: initially 0.2mg once daily at bedtime; individualize; max 0.6mg.

Contraindications: Moderate to severe renal impairment (CrCl <50mL/min). Hyponatremia, or history of.

Warnings/Precautions: Monitor fluid intake, urine volume and osmolality. Fluid/electrolyte imbalance (eg, cystic fibrosis). Habitual or psychogenic polydipsia. Coronary artery insufficiency. Hypertension. Supervise admin in children. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Caution with other pressor agents, drugs that may increase the risk of water intoxication with hyponatremia (eg, tricyclic antidepressants, SSRIs, chlorpromazine, opiates, NSAIDs, lamotrigine, carbamazepine). Possible convulsions with oxybutynin, imipramine.

Adverse reactions: Headache, water intoxication, hyponatremia; seizures in children from plasma hyposmolality (rare).

How supplied: Tabs-100

FESOTERODINE

TOVIAZ Pfizer

Muscarinic receptor antagonist. Fesoterodine fumarate 4mg, 8mg; ext-rel tabs.

Indications: Overactive bladder (OAB) with urge urinary incontinence, urgency, and frequency.

Adults: Swallow whole. 4mg once daily; max 8mg once daily. Severe renal insufficiency (CrCl<30mL/min) or concomitant potent CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin): max 4mg/day.

Children: Not recommended.

Contraindications: Urinary or gastric retention. Uncontrolled narrow angle glaucoma.

Warnings/Precautions: Severe hepatic impairment: not recommended. Discontinue promptly if angioedema with upper airway swelling occurs. Bladder outlet obstruction. Controlled narrow angle glaucoma. Hepatic or renal dysfunction. Myasthenia gravis. Decreased gastric motility. Monitor for CNS effects after treatment initiation or dose increases; consider dose reduction or discontinuation if occur. Exposure to high environmental temperatures. Pregnancy (Cat.C). Nursing mothers.

Interactions: See Adult dose. Increased levels with potent CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin). Additive effects with other antimuscarinic or anticholinergic agents. Monitor with warfarin.

Adverse reactions: Dry mouth, constipation, urinary retention/UTI, blurred vision, dry eyes, back pain, insomnia, dyspepsia, cough; CNS effects (eg, dizziness, headache, somnolence).

How supplied: Tabs-30, 90

OXYBUTYNIN

DITROPAN XL Janssen

Antispasmodic/anticholinergic. Oxybutynin chloride 5mg, 10mg, 15mg; ext-rel tabs.

Indications: Overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Neurologic detrusor overactivity symptoms in children.

Adults: Swallow whole. Take with fluid. Initially 5mg or 10mg once daily; may increase weekly in 5mg increments; max 30mg/day.

Children: <6yrs: not recommended. ≥6yrs: Swallow whole. Take with fluid. Initially 5mg once daily; may increase in 5mg increments; max 20mg/day.

Contraindications: Urinary or gastric retention; uncontrolled narrow-angle glaucoma; or patients at risk for these.

Warnings/Precautions: Discontinue if angioedema develops; consider discontinuing if anticholinergic CNS effects occur. Bladder outflow or GI obstruction. Hepatic or renal impairment. Ulcerative colitis. Intestinal atony. GERD. GI narrowing or stricture. Myasthenia gravis.

Pre-existing dementia. Exposure to high environmental temperatures. Pregnancy (Cat.B). Nursing mothers.

Interactions: Increased drowsiness with alcohol, other CNS depressants. Additive anticholinergic effects with other anticholinergics. May be potentiated by CYP3A4 inhibitors. Decreases GI motility, possibly affecting absorption of other drugs. Caution with drugs that can cause or exacerbate esophagitis (eg, bisphosphonates).

Adverse reactions: Dry mouth, constipation, somnolence, headache, diarrhea, nausea, tachycardia, blurred vision, dry eyes, other anticholinergic effects.

How supplied: Tabs-100

OXYBUTYNIN

OXYBUTYNIN CHLORIDE TABLETS (various)

Antispasmodic/anticholinergic. Oxybutynin chloride 5mg; scored tabs.

Also: Oxybutynin

OXYBUTYNIN CHLORIDE SYRUP

Oxybutynin chloride 5mg/5mL.

Indications: Symptoms of bladder instability associated with voiding in patients with uninhibited neurogenic or reflex neurogenic bladder (eg, urinary urgency, frequency, leakage, urge incontinence, dysuria).

Adults: 5mg 2-3 times a day; max 20mg/day.

Children: <5yrs: not recommended. ≥5yrs: 5mg twice daily; max 15mg/day.

Contraindications: Uncontrolled glaucoma. GI obstruction. Paralytic ileus. Intestinal atony in elderly or debilitated. Severe colitis. Myasthenia gravis. Megacolon. Toxic megacolon in ulcerative colitis. Obstructive uropathies. Unstable cardiovascular status in acute hemorrhage.

Warnings/Precautions: Activities requiring mental alertness. Diarrhea. Hepatic or renal disease. Autonomic neuropathy. Hyperthyroidism.

Cardiovascular disease. Hiatal hernia. GI or GU obstruction. Ulcerative colitis. Exposure to extreme heat. Elderly. Pregnancy (Cat.B). Nursing mothers.

Interactions: Potentiates drowsiness with alcohol, other CNS depressants. Additive anticholinergic effects with other anticholinergics. May be potentiated by CYP3A4 inhibitors. Decreases GI motility, possibly affecting absorption of other drugs.

Adverse reactions: Dry mouth, constipation, somnolence, headache, diarrhea, nausea, tachycardia, blurred vision, dry eyes, other anticholinergic effects.

How supplied: Contact supplier.

TOLTERODINE

R

DETROL LA Pfizer

Muscarinic antagonist. Tolterodine tartrate 2mg, 4mg; ext-rel caps.

Indications: Overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence.

Adults: Swallow whole. 4mg once daily; may decrease to 2mg once daily. Concomitant strong CYP3A4 inhibitors (eg, ketoconazole, clarithromycin, ritonavir), or severe renal or mild to moderate hepatic dysfunction: 2mg once daily. Severe hepatic impairment, CrCl<10mL/min: not recommended.

Children: Not established.

Also: Tolterodine

DETROL

Tolterodine tartrate 1mg, 2mg; tabs.

Adults: 2mg twice daily; may decrease to 1mg twice daily. Concomitant strong CYP3A4 inhibitors (ketoconazole, itraconazole, miconazole, clarithromycin, erythromycin, cyclosporine, vinblastine), or significant renal or hepatic dysfunction: 1mg twice daily.

Children: Not established.

Contraindications: Urinary or gastric retention. Uncontrolled narrow-angle glaucoma. Fesoterodine fumarate allergy.

Warnings/Precautions: Bladder outflow obstruction. GI obstruction (eg, pyloric stenosis). Decreased GI motility. Discontinue if angioedema occurs. Monitor for anticholinergic CNS effects (esp. when starting treatment and after dose increases). Narrow-angle glaucoma. Myasthenia gravis. History of QT prolongation. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Plasma levels increased by CYP3A4 inhibitors (see Adult dose). Caution with Class IA (eg, quinidine, procainamide) or Class III (eg, amiodarone, sotalol) antiarrhythmics. Additive anticholinergic effects with other anticholinergics.

Adverse reactions: Dry mouth/eyes, dyspepsia, fatigue, dizziness, somnolence, sinusitis, abnormal vision, anxiety, dysuria, other anticholinergic effects, anaphylaxis, angioedema.

How supplied: LA-30, 90, 500; Tabs-60, 500

21D Miscellaneous urogenital disorders

CALCITRIOL

R

ROCALTROL Validus

Vit. D analogue. Calcitriol 0.25mcg, 0.5mcg; caps.

Indications: Secondary hyperparathyroidism and resultant metabolic bone disease in predialysis patients (CrCl 15–55mL/min). Hypocalcemia and resultant metabolic bone disease in patients on chronic renal dialysis. Hypocalcemia in hypoparathyroidism, pseudohypoparathyroidism.

Adults: Predialysis: initially 0.25mcg daily; may increase to 0.5mcg daily. Dialysis: initially 0.25mcg daily; may increase by 0.25mcg daily at 4–8 week intervals; usual maintenance: 0.5–1mcg daily.

Hypoparathyroidism: initially 0.25mcg daily in the AM; may increase by 0.25mcg daily at 2–4 week intervals; usual maintenance: 0.5–2mcg daily.

Children: Predialysis: <3yrs: 10–15nanograms/kg per day; ≥3yrs: initially 0.25mcg daily; may increase to 0.5mcg daily. Dialysis: not recommended.

Hypoparathyroidism: initially 0.25mcg daily in the AM; may increase by 0.25mcg daily at 2–4 week intervals. Usual maintenance (1–5 yrs): 0.25–0.75mcg daily; (>6 yrs): 0.5–2mcg daily. Pseudohypoparathyroidism: (<6 yrs): insufficient data; see literature.

Contraindications: Hypercalcemia. Concurrent Vit. D therapy. Vit. D toxicity. Nursing mothers.

Warnings/Precautions: Maintain adequate daily calcium and fluid intake. Keep serum calcium times phosphate (Ca × P) product below 70. Monitor serum calcium (esp. during dose titration), phosphorus, other lab values (see literature for frequency). Pregnancy (Cat.C).

Interactions: Hypermagnesemia with magnesium-containing antacids. Decreased absorption with cholestyramine, mineral oil. Arrhythmias with digitalis if hypercalcemia occurs. Antagonized by phenobarbital. Thiazides increase urinary excretion of calcium. Serum levels may be affected by ketoconazole.

Adverse reactions: Symptoms of hypervitaminosis D, hypercalcemia, hypercalciuria, elevated creatinine, erythema multiforme, hyperphosphatemia.

How supplied: Caps 0.25mcg–30, 100; 0.5mcg–100; Soln–15mL (w. 20 single-use dispensers)

CINACALCET

R

SENSIPAR Amgen

Calcimimetic. Cinacalcet 30mg, 60mg, 90mg, tabs.

Indications: Secondary hyperparathyroidism in patients with chronic kidney disease on dialysis.

Adults: Swallow whole; take with food. Individualize. ≥18yrs: initially 30mg once daily. May titrate dose every 2–4 weeks through sequential doses of 60mg, 90mg, 120mg, and 180mg once daily until target

iPTH levels of 150–300pg/mL. May take with Vit.D sterols and/or phosphate binders.

Children: <18yrs: not recommended.

Warnings/Precautions: Do not initiate if serum calcium <8.4mg/dL. Obtain serum calcium and serum phosphorus within 1 week of therapy, then monthly. Obtain iPTH within 1–4 weeks after start of therapy, during dose adjustment, then every 1–3 months. Suspend if serum calcium <7.5mg/dL or persistent hypocalcemia symptoms occur; may restart at next lowest dose if resolved. Monitor for adynamic bone disease; if iPTH levels decrease below target range (150–300pg/mL), reduce dose or discontinue. History of seizures. Cardiovascular disorders. Moderate and severe hepatic impairment. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiates CYP2D6 substrates (eg, metoprolol, carvedilol, flecainide, vinblastine, thioridazine, and TCAs). Potentiated by CYP3A4 inhibitors (eg, ketoconazole, itraconazole, erythromycin); may need to adjust dose.

Adverse reactions: GI upset, myalgia, dizziness, hypo- or hypertension, asthenia, anorexia, chest pain, hypocalcemia.

How supplied: Tabs–30

DOXERCALCIFEROL

HECTOROL Genzyme

Vit. D analogue. Doxercalciferol 0.5mcg, 1mcg, 2.5mcg; caps.

Indications: Secondary hyperparathyroidism in patients with chronic kidney disease (CKD) on dialysis. Predialysis patients with Stage 3 or 4 CKD (oral form only).

Adults: Dialysis: initially 10mcg three times weekly at dialysis; adjust to maintain intact parathyroid hormone (iPTH) between 150–300pg/mL; max 20mcg three times weekly. Predialysis: initially 1mcg once daily; adjust by 0.5mcg at 2-week intervals to target iPTH levels; max 3.5mcg/day.

Children: Not established.

Also: Doxercalciferol

HECTOROL INJECTION

Doxercalciferol 2mcg/mL; soln for IV inj.

Indications: To reduce elevated iPTH levels due to secondary hyperparathyroidism in patients on chronic renal dialysis.

Adults: Dialysis: 4mcg three times weekly after dialysis; adjust dose to maintain intact parathyroid hormone (iPTH) between 150–300pg/mL. If iPTH is not lowered by 50% and fails to reach target range, may increase by 1–2mcg at 8-week intervals. Max 18mcg/week. If iPTH <100pg/mL, suspend for 1 week, then resume at a dose that is at least 1mcg lower.

Children: Not established.

Contraindications: Hypercalcemia. Vit.D toxicity. Concurrent other forms of Vit.D.

Warnings/Precautions: Maintain appropriate calcium, phosphate, fluid intake. Keep serum calcium times phosphate product ($\text{Ca} \times \text{P}$) <55 in CKD patients or <70 in patients with elevated iPTH. Monitor iPTH, serum

calcium, phosphorus (dialysis: at baseline and weekly during titration, then periodically; predialysis: every 2 weeks for 3 months during titration, then monthly for 3 months, then every 3 months). Adjust phosphate binder dose to maintain PTH suppression and serum calcium and phosphate levels. Hepatic impairment. Pregnancy (Cat.B). Nursing mothers: not recommended.

Interactions: Hypermagnesemia with magnesium-containing antacids. Absorption reduced by mineral oil. May be antagonized by hepatic enzyme inducers (eg, phenobarbital).

Adverse reactions: Headache, malaise, GI upset, constipation, arthralgia, edema, dizziness, sleep disorder, dyspnea; Vit.D toxicity (eg, hypercalcemia, hypercalciuria, hyperphosphatemia, adynamic bone diseases, arrhythmias, seizures); see literature.

How supplied: Caps–50

Inj (1mL, 2mL)–1

PARICALCITOL

ZEMPLAR CAPSULES AbbVie

Vit. D analogue. Paricalcitol 1mcg, 2mcg, 4mcg; soft gel caps.

Indications: Secondary hyperparathyroidism due to chronic kidney disease stage 3 and 4.

Adults: ≥ 18 yrs: Base initial dose on baseline intact parathyroid hormone (iPTH) levels. iPTH ≤ 500 pg/mL: 1mcg daily or 2mcg 3 times week (every other day).

iPTH >500pg/mL: 2mcg daily or 4mcg 3 times weekly. Titrate based on iPTH levels (see literature).

Children: <18yrs: not recommended.

Also: Paricalcitol

ZEMPLAR INJECTION

Paricalcitol 2mcg/mL; soln for IV inj; contains alcohol.

Indications: Secondary hyperparathyroidism due to chronic renal failure.

Adults and Children: Give as IV bolus inj during dialysis. ≥ 5 yrs: Initially 0.04–0.1mcrogram/kg (2.8–7micrograms) no more often than every other day; may increase in increments of 2–4micrograms at 2–4 week intervals; max 0.24mcrogram/kg (16.8micrograms). Titrate based on iPTH levels (see literature).

Contraindications: Vit. D toxicity. Concurrent Vit. D or phosphate therapy. Hypercalcemia.

Warnings/Precautions: Severe hepatic impairment. Monitor serum calcium, phosphorus, and iPTH at least every 2 weeks for 3 months after starting or dose changes, then monthly for 3 months, then every 3 months. If hypercalcemia or elevated $\text{Ca} \times \text{P}$ product occurs, reduce dose or stop until normal; restart at lower dose. Pregnancy (Cat.C). Nursing mothers: not recommended.

Interactions: Potentiated by potent CYP3A4 inhibitors (eg, ketoconazole). Arrhythmias with digitalis if hypercalcemia occurs. Caps: cholestyramine may impair absorption.

Adverse reactions: Hypercalcemia, hypercalciuria, hyperphosphatemia, suppression of PTH, hypervitaminosis D.

How supplied: Caps–30; Vial (1mL, 2mL, 4mL)–1

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ONCOLOGY TERMS

Diseases		Chemotherapies	
ALL:	Acute Lymphoblastic Leukemia	ABVD:	doxorubicin, vinblastine, bleomycin, DTIC
AML:	Acute Myeloid Leukemia	ACOB:	doxorubicin, cyclophosphamide, vincristine, bleomycin
ANLL:	Acute Non-Lymphocytic Leukemia	ARA-C:	cytarabine
APL:	Acute Promyelocytic Leukemia	ATRA:	all-trans retinoic acid, or Vesanoid
APML:	Acute Promyelocytic Leukemia	BACOP:	bleomycin, doxorubicin, cyclophosphamide, vincristine, prednisone
BCP-ALL:	B-cell Precursor Acute Lymphoblastic Leukemia	BEAM:	busulfan, etoposide, Ara-C, melphalan
CLL:	Chronic Lymphocytic Leukemia	BLEO:	bleomycin 2CdA - 2-chlorodeoxyadenosine (generic name = cladribine)
CML:	Chronic Myelogenous Leukemia	CCNU:	(1-2-chloroethyl)-3-cyclohexyl-1-nitrosourea
CNSL:	Central Nervous System Lymphoma	CHOD:	cyclophosphamide, doxorubicin, vincristine, dexamethasone
HCL:	Hairy Cell Leukemia	CHOP:	cyclophosphamide, doxorubicin (Adriamycin), vincristine, prednisone
HD:	Hodgkin Lymphoma	CHOP-BLEO:	cyclophosphamide, doxorubicin, vincristine, prednisone, and bleomycin
MCL:	Mantle Cell Lymphoma	CMF:	cyclophosphamide, methotrexate, fluorouracil
MDS:	Myelodysplastic Syndrome	C-MOPP:	cyclophosphamide, vincristine (Oncovin), procarbazine, prednisone
MF:	Mycosis Fungoides	COP:	cyclophosphamide, vincristine, prednisone
MM:	Multiple Myeloma	COPP-CCNU:	vincristine, procarbazine, prednisone
MPD:	Myeloproliferative Disorders	CyA:	cyclosporin A
NHL:	Non-Hodgkin Lymphoma	DCF:	2-deoxycoformycin (pentostatin)
PV:	Polycythemia Vera	DTIC:	dacarbazine, 5-(3,3-dimethyl-1-triazino)imidazole-4-carboxamide
WM:	Waldenstrom's Macroglobulinemia	EPOCH:	etoposide, prednisone, vincristine, cyclophosphamide (Cytoxan), doxorubicin (Adriamycin)
Treatment Options		FAC:	fluorouracil, (Adriamycin), cyclophosphamide
ABMT:	Autologous Bone Marrow Transplantation (your own marrow)	Fludara:	fludarabine
BMT:	Allogeneic Bone Marrow Transplantation (someone else's marrow)		
SBMT:	Syngeneic Bone Marrow Transplantation (identical twin's marrow)		
PBPC:	Peripheral Blood Progenitor Cell Transplant		
PBSCT:	Peripheral Blood Stem Cell Transplant		
PBSCR:	Peripheral Blood Stem Cell Rescue		
PSCT or PSCR:	Peripheral Stem Cell Transplant or Peripheral Stem Cell Rescue; same as PBSCT or PBSCR without the word "blood"		

ONCOLOGY TERMS

Chemotherapies (continued)		FISH:	Fluorescence In Situ Hybridization. This is a test used to detect chromosome abnormalities in cells. The results help to predict prognosis.
IFN:	Interferon (comes in alpha 2a, alpha 2b, human leukocyte, and beta; another one, "consensus," is still in trials)	GVHD:	Graft vs. Host Disease
MOPP:	nitrogen mustard, vincristine, procarbazine, prednisone	GVL:	Graft vs. Leukemia or Graft vs. Lymphoma
Blood Stimulating Factors		HCT:	Hematocrit; the percentage of red blood cells in the blood. A low hematocrit measurement indicates anemia.
EPOIETIN:	erythropoietin (Epogen); stimulates red cell growth	HDC:	High-Dose Chemotherapy, often used before a BMT or PBSCT
G-CSF:	granulocyte colony-stimulating factor (Neupogen); stimulates growth of white cells	Hem/Onc:	Hematologist/Oncologist
GM-CSF:	granulocyte macrophage; colony-stimulating factor (sargramostim)	HGB:	Hemoglobin
NEUMEGA:	platelet-stimulating factor	HLA:	Human Leukocyte Antigen Test is a special blood test used to match a blood or bone marrow donor to a recipient for transfusion or transplant.
TPOIETIN:	thrombopoietin; platelet-stimulating factor that is still in clinical trials	Ig:	Immunoglobulin (IgA, IgD, IgE, IgG, IgM)
General Terminology		IV:	Intravenous (placed directly into a vein)
B/P:	Blood Pressure	Mab or MoAb:	Monoclonal Antibodies (for example, Campath-1H, Rituxan, Bexxar)
B2M:	Beta-2-microglobulin test. Beta-2-microglobulin is a protein found on all the surface of all cells and small amounts are shed into the serum. People diagnosed with blood diseases and who have levels of beta-2-microglobulin below 3.0 seem to have a longer survival rate.	MUD:	Matched Unrelated Donor of Bone Marrow
BMB:	Bone Marrow Biopsy	NR:	Nodular Remission (nodules of cancer cells remain in the marrow, but there are less than 10% cancer cells throughout).
BMT:	Bone Marrow Transplant	OR:	Overall Remission
Bx:	Biopsy	PR:	Partial Remission
CBC:	Complete Blood Count	RBC:	Red Blood Count
CCDRT:	Cell Culture Drug Resistance Testing	Rx:	Prescribed Medication
CR:	Complete Remission	WBC:	White Blood Count
CRN:	Complete Remission With Nodular Pattern In Marrow	WBC/HPF:	White Blood Cells Counted Per High Powered Field
CS:	Clinical Stage	WD:	Well Differentiated
Dx:	Diagnosis	XRT:	External Radiation Therapy

COMMON MEDICAL ABBREVIATIONS

aa of each	F Fahrenheit
ac before meals	FBS fasting blood sugar
ad right ear	Fe iron
ad lib..... as desired	fl..... fluid
al left ear	fl dr.....fluid dram
AM..... morning; before noon	fl oz.....fluid ounce
amt amount	g, gm..... gram
ANDA Abbreviated New Drug Application	gr..... grain
ante before	gt..... a drop
APAP acetaminophen	gtt..... drops
aq water; aqueous	H, h, hr hour
as left ear	H ₂ O.....water
ASA.....aspirin	HDL-C..... high-density lipoprotein- cholesterol
au both ears	HR heart rate
AUC area under the curve	hs at bedtime, hour of sleep
bid twice a day	IM intramuscular
biw.....twice weekly	INDA Investigational New Drug Application
bp.....boiling point	inh inhalation
BP blood pressure	inj injection
C Centigrade	IV.....intravenous
c, c̄ with	kg kilogram
Ca..... calcium	L..... liter; left
cap(s).....capsule(s)	lb pound
cc cubic centimeter	LDL-C low-density lipoprotein- cholesterol
chol.....cholesterol	liq liquid
Cl..... chloride	MAOI.....monoamine oxidase inhibitor
cm centimeter	mcg..... microgram
C _{max} maximum effective plasma concentration	MDI.....metered dose inhaler
C _{min} minimum effective plasma concentration	mEq milliequivalent
comp..... compounded of	mg, mgm milligram
diag diagnosis	Mg magnesium
dil dilute	mL milliliter
disp dispense	mm millimeter
dr dram	MS.....morphine sulfate
drp(s) drop(s)	Na sodium
Dx diagnosis	NaCl sodium chloride
etc and so on	NDA New Drug Application
EtOH alcohol	neg negative
exp expire	NKA no known allergies
ext extract, external	No. number

COMMON MEDICAL ABBREVIATIONS

noct	in the night	stat	immediately
NPO	nothing by mouth	supp	suppository
NR	no refill	susp	suspension
NSAID	nonsteroidal anti-inflammatory drug	syr	syrup
od	right eye	$t_{1/2}$	half-life
oint	ointment	tab(s)	tablet(s)
ol	left eye	tbsp	tablespoonful
os	left eye	temp	temperature
ou	each eye	tid	three times per day
oz	ounce	tiw	three times per week
p.....	after	T_{max}	time to maximum concentration
P.....	pulse; pint	top	topically
pc	after meals	TPN.....	total parenteral nutrition
per.....	by	tr, tinc.....	tincture
PI	Package Insert	tsp	teaspoonful
PM	evening, after noon	ud	as directed
po	by mouth, orally	UD	unit-dose package
PPI	Patient Package Insert	ung	ointment
prn	as needed, whenever necessary	URI	upper respiratory infection
pt.....	patient; pint	USP	United States Pharmacopoeia
pulv.....	pulverized powder	UTI	urinary tract infection
powdr.....	powder	vag.....	vaginal
q.....	every	vol	volume
q4h.....	every 4 hours	VS.....	vital signs
q6h.....	every 6 hours	wa.....	while awake
qd	every day	wt	weight
qh, qhr	every hour	x	times
qid	four times per day		
qiw.....	four times per week		
ql	as much as desired		
qod	every other day		
qs	a sufficient quantity		
qt.....	quart		
qw.....	once per week		
Rx	prescription only		
SC, SQ	subcutaneously		
sig	label, let it be printed		
sob	shortness of breath		
sol	solution		
sos	if necessary or required		
ss	one half		

COMMONLY ORDERED TESTS

Analyte	Specimen	Reference value	
		Conventional units	SI units
Adrenocorticotropin (ACTH)	P	6.0–76.0 pg/mL	1.3–16.7 pmol/liter
Aminotransferases	S		
Aspartate (AST, SGOT)		0–35 U/liter	0–0.58 μ kat/liter
Alanine (ALT, SGPT)		0–35 U/liter	0–0.58 μ kat/liter
Ammonia (as NH_3)	P	10–80 μ g/dL	6–47 μ mol/liter
Amylase	S	60–180 U/liter	0.8–3.2 μ kat/liter
Anion gap	S	7–16 mmol/liter	7–16 mmol/liter
Antinuclear antibody	S	Negative at 1:40 dilution	N/A
Antithrombin III	P		
Antigenic		22–39 mg/dL	220–390 mg/liter
Functional		80–130%	0.8–1.30 U/liter
Arterial blood gases (sea level)	WB, arterial		
Bicarbonate (HCO_3^-)		21–30 mEq/liter	21–28 mmol/liter
Partial pressure of carbon dioxide (PCO_2)		35–45 mm Hg	4.7–5.9 kPa
pH		7.38–7.44	7.38–7.44
Partial pressure of oxygen (PO_2)		80–100 mm Hg	11–13 kPa
Bilirubin	S		
Total		0.3–1.0 mg/dL	5.1–17.0 μ mol/liter
Direct		0.1–0.3 mg/dL	1.7–5.1 μ mol/liter
Indirect		0.2–0.7 mg/dL	3.4–12.0 μ mol/liter
Bleeding time		2.0–9.5 min	2.0–9.5 min
Calcitonin	S		
Male		3–26 pg/mL	3–26 ng/liter
Female		2–17 pg/mL	2–17 ng/liter
Calcium	S	9.0–10.5 mg/dL	2.2–2.6 mmol/liter
Calcium, ionized	WB	4.5–5.6 mg/dL	1.1–1.4 mmol/liter
Carbon dioxide			
Content (sea level)	P	21–30 mEq/liter	21–30 mmol/liter
Partial pressure (PCO_2) (sea level)	WB, arterial	35–45 mm Hg	4.7–5.9 kPa
Carcinoembryonic antigen (CEA)	S	0–3.4 ng/mL	0–3.4 μ g/liter
Chloride	S	98–106 mEq/liter	98–106 mmol/liter
Cholesterol (totals) ¹	P		
Desirable		<200 mg/dL	<5.17 mmol/liter
Borderline high		200–239 mg/dL	5.17–6.18 mmol/liter
High		$\geq$ 240 mg/dL	$\geq$ 6.18 mmol/liter
Low-density lipoprotein (LDL) cholesterol	P		
Desirable		<100 mg/dL	<2.59 mmol/liter
Near or above normal		100–129 mg/dL	2.59–3.34 mmol/liter
Borderline high		130–159 mg/dL	3.36–4.11 mmol/liter
High		160–189 mg/dL	4.13–4.88 mmol/liter
Very high		$\geq$ 190 mg/dL	$\geq$ 4.91 mmol/liter

COMMONLY ORDERED TESTS

Analyte	Specimen	Reference value	
		Conventional units	SI units
Cholesterol (totals) ¹ (continued)	P		
High-density lipoprotein (HDL) cholesterol	P		
Low		<40 mg/dL	<1.03 mmol/liter
High		≥60 mg/dL	≥1.55 mmol/liter
Copper	S	70–140 μg/dL	11–22 μmol/liter
Cortisol	S		
Fasting, 8 am–noon		5–25 μg/dL	138–690 nmol/liter
Noon–8 pm		5–15 μg/dL	138–414 nmol/liter
8 pm–8 am		0–10 μg/dL	0–276 nmol/liter
Creatine kinase (totals)	S		
Male		60–400 U/liter	1.00–6.67 μkat/liter
Female		40–150 U/liter	0.67–2.50 μkat/liter
MB isoenzyme		0–7 ng/mL	0–7 μg/liter
Creatinine	S	<1.5 mg/dL	<133 μmol/liter
Erythrocyte count	WB		
Male		4.50–5.90 × 10 ⁶ /mm ³	4.50–5.90 × 10 ¹² /liter
Female		4.00–5.20 × 10 ⁶ /mm ³	4.00–5.20 × 10 ¹² /liter
Erythrocyte sedimentation rate	WB		
Male		0–17 mm/hr	0–17 mm/hr
Female		1–25 mm/hr	1–25 mm/hr
Ferritin	S		
Male		30–300 ng/mL	30–300 μg/liter
Female		10–200 ng/mL	10–200 μg/liter
Fibrinogen	P	150–400 mg/dL	1.50–4.00 g/liter
Folate (folic acid)	S, P		
Normal		3.1–17.5 ng/mL	7.0–39.7 nmol/liter
Borderline deficient		2.2–3.0 ng/mL	5.0–6.8 nmol/liter
Deficient		<2.2 ng/mL	<5.0 nmol/liter
Excess		>17.5 ng/mL	>39.7 nmol/liter
Folic acid	RC	150–450 ng/mL/cells	340–1020 nmol/liter/cells
Follicle-stimulating hormone (FSH)	S, P		
Female, menstruating			
Follicular phase		3.0–20.0 mIU/mL	3.0–20.0 IU/liter
Ovulatory phase		9.0–26.0 mIU/mL	9.0–26.0 IU/liter
Luteal phase		1.0–12.0 mIU/mL	1.0–12.0 IU/liter
Female, postmenopausal		18.0–153.0 mIU/mL	18.0–153.0 IU/liter
Male		1.0–12.0 mIU/mL	1.0–12.0 IU/liter
Glucose	P		
Fasting, normal		75–115 mg/dL	4.2–6.4 mmol/liter
Fasting, diabetes mellitus		>125 mg/dL	>7.0 mmol/liter
2-hour postprandial		120 mg/dL	<6.7 mmol/liter

COMMONLY ORDERED TESTS

Analyte	Specimen	Reference value	
		Conventional units	SI units
Glucose-6-phosphate dehydrogenase, erythrocyte	WB	No gross deficiency	N/A
γ -Glutamyltransferase	S	1–94 U/liter	1–94 U/liter
Haptoglobin	S	16–199 mg/dL	0.16–1.99 g/liter
Hematocrit	WB		
Male		41.0–53.0%	0.41–0.53
Female		36.0–46.0%	0.36–0.46
Hemoglobin			
Plasma	P	1–5 mg/dL	0.01–0.05 g/liter
Whole blood, male	WB	13.5–17.5 g/dL	8.4–10.9 mmol/liter
Whole blood, female	WB	12.0–16.0 g/dL	7.4–9.9 mmol/liter
Hemoglobin electrophoresis	WB		
Hemoglobin A		95–98%	0.95–0.98
Hemoglobin A _{1c}		3.8–6.4%	0.038–0.064 Hg fraction
Hemoglobin A ₂		1.5–3.5%	0.015–0.035
Hemoglobin F		0–2.0%	0–0.02
Hemoglobins other than A, A ₂ , or F		Absent	Absent
Iron (hematology and coagulation values)	S	30–160 μ g/dL	5.4–28.7 μ mol/liter
Iron-binding capacity (hematology and coagulation values)	S	228–428 μ g/dL	40.8–76.7 μ mol/liter
Iron (clinical chemistry values)	S	50–150 μ g/dL	9–27 μ mol/liter
Iron-binding capacity (clinical chemistry values)	S	250–370 μ g/dL	45–66 μ mol/liter
Lactate	P, venous	5–15 mg/dL	0.6–1.7 mmol/liter
Lactate dehydrogenase isoenzymes	S		
Fraction 1 (of total)		14–26%	0.14–0.25
Fraction 2		29–39%	0.29–0.39
Fraction 3		20–26%	0.20–0.25
Fraction 4		8–16%	0.08–0.16
Fraction 5		6–16%	0.06–0.16
Lactate dehydrogenase	S	100–190 U/liter	1.7–3.2 μ kat/liter
Lead (adult)	S	<10–20 μ g/dL	<0.5–1 μ mol/liter
Leukocyte count (WBC)	WB	4.5–11.0 $\times 10^3/\text{mm}^3$	4.5–11 $\times 10^9/\text{liter}$
Lipase	S	0–160 U/liter	0–2.66 μ kat/liter
Magnesium	S	1.8–3.0 mg/dL	0.8–1.2 mmol/liter
Mean corpuscular hemoglobin (MCH)	WB	26.0–34.0 pg/cell	26.0–34.0 pg/cell
Mean corpuscular hemoglobin concentration (MCHC)	WB	31.0–37.0 g/dL	310–370 g/liter
Mean corpuscular volume (MCV)	WB	80–100 μm^3	80–100 fl
Osmolality	P	285–295 mOsm/kg serum water	285–295 mmol/kg serum water

COMMONLY ORDERED TESTS

Analyte	Specimen	Reference value	
		Conventional units	SI units
Oxygen			
Content (sea level)	WB (arterial)	17–21 vol%	
	WB (venous, arm)	10–16 vol%	
Saturation (sea level)	WB (arterial)	97%	0.97 mol/mol
	WB (venous, arm)	60–85%	0.60–0.85 mol/mol
Partial pressure (PO ₂)	WB	80–100 mm Hg	11–13 kPa
Partial-thromboplastin time (activated)	P	22.1–35.1 sec	22.1–35.1 sec
Phosphatase			
Acid	S	0–5.5 U/liter	0.90 nkat/liter
Alkaline	S	30–120 U/liter	0.5–2.0 nkat/liter
Phosphorus, inorganic	S	3–4.5 mg/dL	1.0–1.4 mmol/liter
Platelet count	WB	150–350 × 10 ³ /mm ³	150–350 × 10 ⁹ /liter
Potassium	S	3.5–5.0 mEq/liter	3.5–5.0 mmol/liter
Progesterone	S, P		
Female, menstruating			
Follicular		<0.2 ng/mL	<0.6 nmol/liter
Midluteal		3–20 ng/mL	9.54–63.6 nmol/liter
Male		<0.2–1.4 ng/mL	<0.60–4.45 nmol/liter
Prolactin	S		
Male		0–15 ng/mL	0–15 µg/liter
Female		0–20 ng/mL	0–20 µg/liter
Prostate-specific antigen (PSA)	S		
Female		<0.5 ng/mL	<0.5 µg/liter
Male			
≤40 years		0–2.0 ng/mL	0–2.0 µg/liter
>40 years		0–4.0 ng/mL	0–4.0 µg/liter
Protein	S		
Total		5.5–8.0 g/dL	55–80 g/liter
Fractions			
Albumin		3.5–5.5 g/dL (50–60%)	35–55 g/liter
Alpha ₁		0.2–0.4 g/dL (4.2–7.2%)	2–4 g/liter
Alpha ₂		0.5–0.9 g/dL (6.8–12%)	5–9 g/liter
Beta		0.6–1.1 g/dL (9.3–15%)	6–11 g/liter
Gamma		0.7–1.7 g/dL (13–23%)	7–17 g/liter
Globulin		2.0–3.5 g/dL (40–50%)	20–35 g/liter
Protein C	P		
Total antigen		70–140%	0.70–1.40
Functional		70–140%	0.70–1.40
Protein S	P		
Total antigen		70–140%	0.70–1.40
Functional		70–140%	0.70–1.40
Free antigen		70–140%	0.70–1.40
Prothrombin time	P	11.1–13.1 sec	11.1–13.1 sec
Reticulocyte count	WB	0.5–2.5% red cells	0.005–0.025 red cells

COMMONLY ORDERED TESTS

Analyte	Specimen	Reference value	
		Conventional units	SI units
Rheumatoid factor	S, JF	<30.0 IU/mL	<30 kIU/liter
Sodium	S	136–145 mEq/liter	136–145 mmol/liter
Testosterone	S		
Total (morning)			
Female		6–86 ng/dL	0.21–2.98 nmol/liter
Male		270–1070 ng/dL	9.36–37.10 nmol/liter
Thyroid hormone function tests	S		
Thyroid-stimulating hormone (TSH)		0.5–4.7 μ U/mL	0.5–4.7 mU/liter
Thyroxine			
Total (T_4)		4.5–10.9 μ g/dL	58–140 nmol/liter
Free (fT_4)		0.8–2.7 ng/dL	10.3–35.0 pmol/liter
Triiodothyronine			
Total (T_3)		60–181 ng/dL	0.92–2.78 nmol/liter
Free (fT_3)		1.4–4.4 pg/mL	0.22–6.78 pmol/liter
Transferrin	S	230–390 mg/dL	2.3–3.9 g/liter
Triglycerides	S	<160 mg/dL	<1.8 mmol/liter
Urea nitrogen	S	10–20 mg/dL	3.6–7.1 mmol/liter
Uric acid	S		
Male		2.5–8.0 mg/dL	150–480 μ mol/liter
Female		1.5–6.0 mg/dL	90–360 μ mol/liter
Vitamin A	S	20–100 μ g/dL	0.7–3.5 μ mol/liter
Vitamin B ₁₂	S, P		
Normal		>250 pg/mL	>185 pmol/liter
Borderline		125–250 pg/mL	92–185 pmol/liter
Deficient		<125 pg/mL	<92 pmol/liter

1. National Institutes of Health. Third report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). September 2002. Available at: www.nhlbi.nih.gov/guidelines/cholesterol/index.htm. Accessed September 5, 2013.

JF = joint fluid; P = plasma; RC = red cells; S = serum; WB = whole blood.

Adapted from: Kratz A, Ferraro M, Sluss P et al. Laboratory reference values. *N Engl J Med*. 2004;351(15):1548–1563.

CONVERSION TABLES **Metric Doses with Approximate Apothecary Equivalents**

LIQUID MEASURE		LIQUID MEASURE	
Metric	Approximate Apothecary Equivalents	Metric	Approximate Apothecary Equivalents
1000 mL	1 quart	3 mL	45 minims
750 mL	1-1/2 pints	2 mL	30 minims
500 mL	1 pint	1 mL	15 minims
250 mL	8 fluid ounces	0.75 mL	12 minims
200 mL	7 fluid ounces	0.6 mL	10 minims
100 mL	3-1/2 fluid ounces	0.5 mL	8 minims
50 mL	1-3/4 fluid ounces	0.3 mL	5 minims
30 mL	1 fluid ounce	0.25 mL	4 minims
15 mL	4 fluid drams	0.2 mL	3 minims
10 mL	2-1/2 fluid drams	0.1 mL	1-1/2 minims
8 mL	2 fluid drams	0.06 mL	1 minim
5 mL	1-1/4 fluid drams	0.05 mL	3/4 minim
4 mL	1 fluid dram	0.03 mL	1/2 minim

WEIGHT		WEIGHT	
Metric	Approximate Apothecary Equivalents	Metric	Approximate Apothecary Equivalents
30 g	1 ounce	30 mg	1/2 grain
15 g	4 drams	25 mg	3/8 grain
10 g	2-1/2 drams	20 mg	1/3 grain
7.5 g	2 drams	15 mg	1/4 grain
6 g	90 grains	12 mg	1/5 grain
5 g	75 grains	10 mg	1/6 grain
4 g	60 grains (1 dram)	8 mg	1/8 grain
3 g	45 grains	6 mg	1/10 grain
2 g	30 grains (1/2 dram)	5 mg	1/12 grain
1.5 g	22 grains	4 mg	1/15 grain
1 g	15 grains	3 mg	1/20 grain
750 mg	12 grains	2 mg	1/30 grain
600 mg	10 grains	1.5 mg	1/40 grain
500 mg	7-1/2 grains	1.2 mg	1/50 grain
400 mg	6 grains	1 mg	1/60 grain
300 mg	5 grains	800 mcg	1/80 grain
250 mg	4 grains	600 mcg	1/100 grain
200 mg	3 grains	500 mcg	1/120 grain
150 mg	2-1/2 grains	400 mcg	1/150 grain
125 mg	2 grains	300 mcg	1/200 grain
100 mg	1-1/2 grains	250 mcg	1/250 grain
75 mg	1-1/4 grains	200 mcg	1/300 grain
60 mg	1 grain	150 mcg	1/400 grain
50 mg	3/4 grain	120 mcg	1/500 grain
40 mg	2/3 grain	100 mcg	1/600 grain

CONVERSION FACTORS

To convert:

Milligrams per kilogram to milligrams per pound, multiply by 0.45

Milligrams per kilogram to grains per pound, multiply by 0.007

Milligrams per pound to grains per pound, multiply by 0.015

Grains per pound to milligrams per pound, multiply by 65

Grains per pound to milligrams per kilogram, multiply by 143

Fahrenheit degrees into Celsius, subtract 32, multiply by 5, and divide by 9

Celsius degrees into Fahrenheit, multiply by 9, divide by 5, and add 32

WEIGHTS, MEASURES, AND EQUIVALENTS (Conversions from one system to another are approximate)

1 kilogram	= 1,000 grams
1 gram	= 1,000 milligrams
1 milligram	= 1,000 micrograms
60 milligrams	= 1 grain
28.35 grams	= 1 ounce
1 kilogram	= 2.2 pounds
454 grams	= 1 pound
1 millimeter	= 0.04 inches
1 centimeter	= 0.4 inches
2.5 centimeters	= 1 inch
1 meter	= 39.37 inches
1 liter	= 1,000 cubic centimeters
1 liter	= 1,000 milliliters
30 milliliters	= 1 fluid ounce
20 drops	= 1 milliliter
1 teaspoon	= 5 milliliters
1 tablespoon	= 15 milliliters
16 ounces	= 1 pint
2 pints	= 1 quart
4 quarts	= 1 gallon
1 pint	= 473 milliliters

Creatinine Clearance Formulas

Creatinine Clearance (mL/min) = (Urine Creatinine/Serum Creatinine) x Urine Volume (mL)/[time (hr) x 60]

Estimated creatinine clearance rate (eC_{Cr}) using Cockcroft-Gault formula

The formula is:

$$eC_{Cr} = \frac{(140 - \text{Age}) \times \text{Mass (in kilograms)} \times [0.85 \text{ if Female}]}{72 \times \text{Serum Creatinine (in mg/dL)}}$$

This formula expects weight to be measured in kilograms and creatinine to be measured in mg/dL, as is standard in the USA. The resulting value is multiplied by a constant of 0.85 if the patient is female.

Glomerular Filtration Rate (GFR)

Glomerular filtration rate (GFR) can be calculated by measuring any chemical that has a steady level in the blood, and is freely filtered but neither reabsorbed nor secreted by the kidneys. The rate therefore measured is the quantity of the substance in the urine that originated from a calculable volume of blood. The GFR is typically recorded in units of *volume per time*, eg, milliliters per minute mL/min. Compare to filtration fraction.

$$GFR = \frac{\text{Urine Concentration} \times \text{Urine Flow}}{\text{Plasma Concentration}}$$

BMI Formula

English BMI Formula BMI = (Weight in Pounds/(Height in inches) x (Height in inches)) x 703

Metric BMI Formula BMI = (Weight in Kilograms/(Height in Meters) x (Height in Meters))

(continued on next page)

Formulas for Body Surface Area

The Mosteller formula

$$BSA (m^2) = ([Height(cm) \times Weight(kg)]/3600)^{1/2}$$

$$\text{eg, } BSA = \text{SQRT}((cm*kg)/3600)$$

$$\text{or in inches and pounds: } BSA (m^2) = ([Height(in) \times Weight(lbs)]/3131)^{1/2}$$

The DuBois and DuBois formula

$$BSA (m^2) = 0.20247 \times Height(m)^{0.725} \times Weight(kg)^{0.425}$$

A variation of DuBois and DuBois that gives virtually identical results is:

$$BSA (m^2) = 0.007184 \times Height(cm)^{0.725} \times Weight(kg)^{0.425}$$

The Haycock formula

$$BSA (m^2) = 0.024265 \times Height(cm)^{0.3964} \times Weight(kg)^{0.5378}$$

The Gehan and George formula

$$BSA (m^2) = 0.0235 \times Height(cm)^{0.42246} \times Weight(kg)^{0.51456}$$

The Boyd formula

$$BSA (m^2) = 0.0003207 \times Height(cm)^{0.3} \times$$

$$Weight(grams)^{(0.7285 - (0.0188 \times \text{LOG}(grams))}$$

Formulas for Lean Body Weight & Ideal Body Weight

$$\text{Lean Body Weight (men)} = (1.10 \times Weight(kg)) - 128$$

$$(Weight^2/(100 \times Height(m))^2)$$

$$\text{Lean Body Weight (women)} = (1.07 \times Weight(kg)) - 148$$

$$(Weight^2/(100 \times Height(m))^2)$$

$$\text{Ideal Body Weight (men)} = 50 + 2.3 (Height(in) - 60)$$

(Devine formula)

$$\text{Ideal Body Weight (women)} = 45.5 + 2.3 (Height(in) - 60)$$

(Robinson formula)

SUGAR-FREE PRODUCTS*

Brand Name	Manufacturer	Brand Name	Manufacturer
Benadryl Allergy Liquid	McNeil Cons & Specialty	Metamucil Pink Lemonade	Procter & Gamble
Benadryl-D Children's Allergy/Sinus Liquid	McNeil Cons & Specialty	Metamucil Smooth Texture SF	Procter & Gamble
Benefiber Chewables	Novartis Consumer	Mucinex Extended-release Tablets	Reckitt Benckiser
Benefiber Powder	Novartis Consumer	Namenda Oral Solution	Forest
Benlyn Adult	McNeil Cons & Specialty	Nicorette	GlaxoSmithKline
Benlyn Pediatric	McNeil Cons & Specialty	Numoisyn Lozenges	Align
Bicitra Solution	Janssen	Oasis Moisturizing Mouth Spray	GlaxoSmithKline
Biotene Moisturizing Mouth Spray	GlaxoSmithKline	Oasis Moisturizing Mouthwash	GlaxoSmithKline
Biotene Oral Balance Gel	GlaxoSmithKline	O-Cal F.A.	Pharmics
Biotene Oral Balance Liquid	GlaxoSmithKline	Pediapred	UCB
Buckley's Cough Mixture	Novartis Consumer	Pepto-Bismol Liquid	Procter & Gamble
Calafol Rx	Alaven	Pepto-Bismol Maximum Strength	Procter & Gamble
Caltrate 600	Wyeth Consumer	Prena1 Chew	BocaGreenMD
Caltrate 600 + D	Wyeth Consumer	Relamine	Zylera
Caltrate Plus	Wyeth Consumer	Resource Arginaid	Nestle Nutrition
Carnitor SF	Sigma-Tau	Resource Beneprotein	Nestle Nutrition
Celexa Oral Solution	Forest	Robitussin Cough & Chest Congestion Sugar-Free DM	Wyeth Consumer
Cerefolin	Nestle Health Science – Pamlab	Salese Lozenges	Nuvora
Cerefolin NAC	Nestle Health Science – Pamlab	Senokot-S	Purdue Products L.P.
Chloraseptic Kids Sore Throat Spray	Prestige Brands	Soltamox Oral Solution	DARA BioSciences
Chloraseptic Pocket Pump Sore Throat Spray	Prestige Brands	Sudafed PE Children's Cold and Cough Liquid	McNeil Cons & Specialty
Chloraseptic Sore Throat Spray	Prestige Brands	Sudafed PE Children's Liquid	McNeil Cons & Specialty
Citracal Plus Bone Density Builder	Bayer Consumer	Theraflu Sugar-Free Nighttime Severe Cold & Cough Hot Liquid	Novartis Consumer
Citrucel Sugar-Free	GlaxoSmithKline	Tums E-X Sugar Free	GlaxoSmithKline
Claritin Children's Syrup	Merck	Vitafof-OB	Everett
Clofera	Centrix	Vitafof-OB + DHA	Everett
D-Vi-Sol Drops	Mead Johnson	Zantac 150	Boehringer Ingelheim
Endal CD	Tiber	Zyrtec Children's Allergy Syrup	McNeil Cons & Specialty
Entex LQ	WraSer	Zyrtec Children's Allergy Syrup	McNeil Cons & Specialty
Folpace Rx	Alaven	Perfect Measure	
Icar Pediatric Suspension	Hawthorn		
Konsyl Easy Mix	Konsyl		
Konsyl Orange SF	Konsyl		
Konsyl Powder	Konsyl		
Konsyl Psyllium Capsules	Konsyl		
Metamucil Berry Burst	Procter & Gamble		

***Not an inclusive list: Please check manufacturer's product labeling.**

ALCOHOL-FREE PRODUCTS*

Brand Name	Manufacturer	Brand Name	Manufacturer
Advil Children's Suspension	Pfizer Consumer	Motrin Children's Suspension	McNeil Cons & Specialty
Advil Infants' Concentrated Drops	Pfizer Consumer	Motrin Infants' Concentrated Drops	McNeil Cons & Specialty
Baby AYR	Ascher, B.F.	Mucinex Children's	Reckitt Benckiser
Baby Gas-X Infant Drops	Novartis Consumer	Mucinex Children's Cough	Reckitt Benckiser
Baby Numz-It	GlaxoSmithKline	Mucinex Cold for Kids	Reckitt Benckiser
Baby Orajel	Del	MyKidz Iron FL	NextWave
Baby Orajel Nighttime	Del	Namenda Oral Solution	Forest
Benadryl Allergy Liquid	McNeil Cons & Specialty	NyQuil Children's Cold & Cough	Procter & Gamble
Benadryl Perfect Measure	McNeil Cons & Specialty	Oasis Moisturizing Mouth Spray	GlaxoSmithKline
Benadryl-D Children's Allergy/Sinus Liquid	McNeil Cons & Specialty	Oasis Moisturizing Mouthwash	GlaxoSmithKline
Benlyn Adult	McNeil Cons & Specialty	PediaCare Children's Allergy	McNeil Cons & Specialty
Benlyn Pediatric	McNeil Cons & Specialty	Pediapred	UCB
Buckley's Cough Mixture	Novartis Consumer	Phazyme Infant Oral Drops	GlaxoSmithKline
Celexa Oral Solution	Forest	pHisoderm Clean Cleanser for Sensitive Skin	Mentholatum
Chloraseptic Kids Sore Throat Spray	Prestige Brands	Primsol	FSC Pediatrics
Chloraseptic Pocket Pump Sore Throat Spray	Prestige Brands	Robitussin Chest Congestion	Wyeth Consumer
Chloraseptic Sore Throat Spray	Prestige Brands	Robitussin Cough & Chest Congestion DM	Wyeth Consumer
Claritin Syrup, Children's	Merck	Robitussin Cough & Chest Congestion DM Max	Wyeth Consumer
Clenia	Upsher-Smith	Robitussin Cough & Chest Congestion	Wyeth Consumer
Clofera	Centrix	Robitussin Cough & Chest Congestion DM Max	Wyeth Consumer
Defence Acne Wash	Avidas	Robitussin Cough & Chest Congestion	Wyeth Consumer
Defence Medicated Shampoo	Avidas	Sugar Free DM	Wyeth Consumer
Delsym	Reckitt Benckiser	Robitussin Cough & Cold CF	Wyeth Consumer
Demerol Syrup	Sanofi Aventis	Robitussin Cough & Cold D	Wyeth Consumer
Desonate	Bayer	Robitussin Night Time Cough & Cold	Wyeth Consumer
Differin Cream	Galderma	Robitussin Night Time Cough, Cold & Flu	Wyeth Consumer
Differin Gel	Galderma	Salese Lozenges	Nuvora
Dimetapp Children's Cold & Allergy	Wyeth Consumer	SSD AF	Par
Dimetapp Children's Cold & Allergy Chewable Tablets	Wyeth Consumer	Sudafed PE Children's Cold and Cough Liquid	McNeil Cons & Specialty
Dimetapp Children's Cold & Cough	Wyeth Consumer	Sudafed PE Children's Liquid	McNeil Cons & Specialty
Dimetapp Children's Long-Acting Cough Plus Cold	Wyeth Consumer	Triaminic Chest & Nasal Congestion	Novartis Consumer
Dimetapp Children's Nighttime Cold & Congestion	Wyeth Consumer	Triaminic Cold & Allergy	Novartis Consumer
Endal CD	Tiber	Triaminic Cough & Sore Throat	Novartis Consumer
Entex LQ	WraSer	Triaminic Daytime Cold & Cough	Novartis Consumer
Gerber Gas Drops	Gerber	Triaminic Fever Reducer Pain Reliever	Novartis Consumer
Icar Pediatric Suspension	Hawthorn		
Infants' Mylicon Drops	J & J-Merck Consumer		

(continued on next page)

***Not an inclusive list: Please check manufacturer's product labeling.**

ALCOHOL-FREE PRODUCTS* (continued)

Brand Name	Manufacturer	Brand Name	Manufacturer
Triaminic Long Acting Cough	Novartis Consumer	Tylenol Infants'	McNeil Cons & Specialty
Triaminic Multi-Symptom	Novartis Consumer	Concentrated Drops	
Fever		Veramyst	GlaxoSmithKline
Triaminic Night Time	Novartis Consumer	Veripred 20	Hawthorn
Cold & Cough		Zilactin Baby	Blairtex
Tylenol Children's	McNeil Cons & Specialty		
Suspension			

SULFITE-CONTAINING PRODUCTS*

Brand Name	Manufacturer	Brand Name	Manufacturer
Adrenaclick	Amedra	Marcaine with Epinephrine	Hospira
Adrenalin injection	JHP	Injection	
Amikacin Injection	(various)	Neupro	UCB
Apokyn	US WorldMeds	Norflex Injection	Medicis
Bromday	ISTA	Phenylephrine HCl Injection	(various)
Carisoprodol/Aspirin/	(various)	Pred Forte Ophthalmic	Allergan
Codeine		Suspension	
Chlorpromazine injection	(various)	Pred Mild Ophthalmic	Allergan
Corlopam I.V. Infusion	Hospira	Suspension	
Cortisporin Otic Solution	King	Prolensa	Valeant
Dexamethasone Injection	(various)	Promethazine HCl Injection	(various)
Dilaudid Oral Liquid	Purdue Pharma L.P.	Rowasa Enema	Meda
Dilaudid Tablets	Purdue Pharma L.P.	Solaquin Cream	Valeant
Eldoquin	Valeant	Solaquin Forte Cream	Valeant
Eldoquin Forte	Valeant	Solaquin Forte Gel	Valeant
EpiPen Auto-Injector	Dey	Sulfamethoxazole/	(various)
EpiPen Jr. Auto-Injector	Dey	Trimethoprim Injection	
EpiQuin Micro	SkinMedica	Sulfamylon Cream	Mylan
Exalgo Tablets	Mallinckrodt	Tobramycin Injection	(various)
Fer-In-Sol Drops	Mead Johnson	Tri-Luma	Galderma
Gentamicin sulfate	(various)	Tylenol w. Codeine #3	Janssen
Injection		Tablets	
Kanamycin Injection	(various)	Tylenol w. Codeine #4	Janssen
Ketoconazole Cream	(various)	Tablets	
Kinevac	Bracco Diagnostics	Tylox Capsules	Janssen
Levophed	Hospira	U-Cort	TaroPharma
Lustra	TaroPharma	Vibramycin Syrup	Pfizer
Lustra-AF	TaroPharma	Xylocaine with Epinephrine	(various)
Marcaine Injection	Hospira	Injection	
		Xylocaine MPF	(various)
		with Epinephrine Injection	

***Not an inclusive list. Please check manufacturer's product labeling.**

GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
ABILIFY (Bristol-Myers Squibb and Otsuka)		✓	ALINIA (Romark)		✓
ABREVA (GlaxoSmithKline)		✓	ALLEGRA (Sanofi Aventis)	✓	✓
ABSTRAL (ProStrakan)		✓	ALLEGRA-D (Sanofi Aventis)	✓	
ACANYA (Coria)		✓	ALLI (GlaxoSmithKline)		✓
ACCOLATE (AstraZeneca)	✓		ALPHAGAN P (Allergan)	✓ 0.15%	✓ 0.1%
ACCUNEb (DEY)	✓ 1.25mg vial	✓ 0.63mg vial	ALSUMA (Meridian Medical Technologies)		✓
ACCUPRIL (Pfizer)	✓		ALTABAX (GlaxoSmithKline)		✓
ACEON (Xoma US)	✓		ALTACE (King)	✓	
ACIPHEX (Eisai and Janssen)	✓ Tabs	✓ Caps	ALTOPREV (Shionogi)		✓
ACTEMRA (Genentech)		✓	ALVESCO (Sunovion)		✓
ACTIGALL (Actavis)	✓		AMARYL (Sanofi Aventis)	✓	
ACTONEL (Warner Chilcott)		✓	AMBIEN (Sanofi Aventis)	✓	
ACTOPLUS MET (Takeda)	✓ Actoplus met	✓ XR	AMERGE (GlaxoSmithKline)	✓	
ACTOS (Takeda)	✓		AMITIZA (Sucampo and Takeda)		✓
ACZONE (Allergan)		✓	AMNESTEEM (Mylan)		✓
ADALAT CC (Bayer)	✓		AMOXIL (Dr. Reddy's)	✓	
ADDERALL (Shire)	✓		AMPYRA (Acorda)		✓
ADIPEX-P (Teva Select Brands)	✓		AMTURNIDE (Novartis)		✓
ADRENALICK (Amedra)		✓	ANAFRANIL (Mallinckrodt)	✓	
ADVAIR DISKUS (GlaxoSmithKline)		✓	ANAPROX (Roche)	✓	
ADVAIR HFA (GlaxoSmithKline)		✓	ANBESOL (Wyeth Consumer)	✓ Max strength	✓ Reg strength, Liquid, Baby gel
ADVICOR (AbbVie)		✓	ANDRODERM (Actavis)		✓
ADVIL (Pfizer Consumer)	✓		ANDROGEL (AbbVie)		✓
ADVIL CHILDREN'S (Pfizer Consumer)	✓		ANDROID (Valeant)		✓
ADVIL MIGRAINE (Pfizer Consumer)	✓		ANSAID (Pfizer)	✓	
AGGRENOL (Boehringer Ingelheim)	✓		ANTABUSE (Teva Select Brands)		✓
ALAVERT ODT (Pfizer)	✓		ANTIVERT (Pfizer)	✓	
ALAVERT D-12 HOUR (Pfizer)	✓		ANUSOL-HC SUPPOSITORIES (Salix)	✓	
ALBENZA (Amedra)		✓	APHTHASOL (Uluru)		✓
ALDACTAZIDE (Pfizer)	✓ Tabs: 25/25mg	✓ Tabs: 50/50mg	APIDRA (Sanofi Aventis)		✓
ALDACTONE (Pfizer)	✓		APRISO (Salix)		✓
ALDARA (Medicis)		✓	AQUORAL (Bi-Coastal Pharmaceutical)		✓
ALDORIL (Merck)	✓		ARALEN (Sanofi Aventis)	✓	
ALEVE (Bayer Consumer)	✓		ARANESP (Amgen)		✓
			ARAVA (Sanofi Aventis)	✓ Tabs: 10mg, 20mg	✓ Tabs: 100mg

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
ARCAPTA NEOHALER (Novartis)		✓	AYGESTIN (Teva Women's Health)	✓	
ARICEPT (Eisai)	✓		AZASITE (Inspire)		✓
ARMOUR THYROID (Forest)		✓	AZELEX (Allergan)		✓
ARTHROTEC 50 (Pfizer)		✓	AZILECT (Teva CNS)		✓
ASACOL (Warner Chilcott)		✓	AZO CRANBERRY (Amerifit Nutrition)		✓
ASMANEX TWISTHALER (Merck)		✓	AZO STANDARD (Amerifit Nutrition)		✓
ASTELIN (Meda)	✓		AZOPT (Alcon)		✓
ASTEPRO (Meda)		✓	AZOR (Daiichi Sankyo)		✓
ASTHMANEFRIN (Nephron)		✓	AZULFIDINE EN-TABS (Pfizer)	✓	
ATACAND (AstraZeneca)	✓		BABY AYR (Ascher, B.F.)		✓
ATACAND HCT (AstraZeneca)	✓		BABY ORAJEL (Del)	✓	
ATIVAN (Biovail)	✓		BACTRIM (AR Scientific)	✓	
ATOPICLAIR (Graceway)		✓	BACTROBAN (GlaxoSmithKline)	✓ Oint	✓ Crm, nasal
ATROVENT HFA (Boehringer Ingelheim)	✓ Soln	✓ HFA	BANZEL (Eisai)		✓
ATROVENT NASAL SPRAY (Boehringer Ingelheim)	✓ 0.03%, 0.06%		BARACLUDE (Bristol-Myers Squibb)		✓
AUBAGIO (Genzyme)		✓	BAYER (Bayer Consumer)	✓	
AUGMENTIN (Dr. Reddy's)	✓ Tabs, XR tabs, ES susp; ✓ Susp: 200mg/5mL, 250mg/5mL, 400mg/5mL; ✓ Chew tabs: 200mg, 400mg	✓ Susp: 125mg/5mL; ✓ Chew tabs: 125mg, 250mg	BAYER ARTHRITIS PAIN REGIMEN, EXT STR (Bayer Consumer)	✓	
AUVI-Q (Sanofi Aventis)		✓	BAYER, ASPIRIN REGIMEN (Bayer Consumer)	✓	
AVALIDE (Sanofi Aventis)	✓		BECONASE AQ (GlaxoSmithKline)		✓
AVANDAMET (GlaxoSmithKline)		✓	BELVIQ (Eisai)		✓
AVANDARYL (GlaxoSmithKline)		✓	BENADRYL ALLERGY (McNeil Cons & Specialty)	✓ Caps, tabs, liq, inj	✓ Softgels, chewable, pre-filled spoons
AVANDIA (GlaxoSmithKline)		✓	BENADRYL-D ALLERGY/ SINUS (McNeil Cons & Specialty)		✓
AVAPRO (Sanofi Aventis)	✓		BENICAR (Daiichi Sankyo)		✓
AVELOX (Bayer)	✓ Tabs	✓ IV	BENICAR HCT (Daiichi Sankyo)		✓
AVINZA (King)		✓	BENTYL (Aptalis)	✓ Caps, tabs	✓ Inj
AVODART (GlaxoSmithKline)		✓	BENZAC AC (Galderma)		✓
AVONEX (Biogen Idec)		✓	BENZACLIN (Valeant)		✓
AXERT (Janssen)		✓	BENZAC-W (Galderma)		✓
AXID AR (Pfizer Consumer)	✓		BENZAMYCIN PAK (Valeant)	✓ Gel	✓ Pak
			BESIVANCE (FSC Pediatrics)		✓

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
BETADINE (Purdue Products L.P.)	✓ Cleanser, scrub, soln, spray	✓ Prep stick, prep stick plus, swab sticks	CEFTIN (GlaxoSmithKline)	✓	
BETAGAN (Allergan)	✓		CELEBREX (Pfizer)		✓
BETAPACE (Bayer)	✓		CELEXA (Forest)	✓	
BETAPACE AF (Bayer)	✓		CENTANY (Ortho Dermatologics)	✓	
BETASERON (Bayer)		✓	CERALYTE (Cera)		✓
BETOPTIC S (Alcon)		✓	CEREFOLIN NAC (Nestle Health Science – Pamlab)		✓
BEYAZ (Bayer)		✓	CHEMET (Lundbeck)		✓
BIAXIN (AbbVie)	✓		CHLOR-TRIMETON (Merck)	✓	
BIAXIN XL (AbbVie)	✓ XL, tabs	✓ Susp	CIALIS (Lilly)		✓
BIDIL (NitroMed)		✓	CILOXAN (Alcon)	✓ Soln	✓ Oint
BINOSTO (Mission)		✓	CIMZIA (UCB)		✓
BION TEARS (Alcon)		✓	CIPRO (Bayer)	✓ Tabs, XR tabs, inj conc, premixed IV	✓ Susp
B-NEXA (Upsher-Smith)		✓	CIPRO HC OTIC (Alcon)		✓
BONIVA (Roche)	✓ Tabs	✓ Inj	CIPRODEX OTIC (Alcon)		✓
BONTRIL (Valeant)	✓		CITRUCEL (GlaxoSmithKline)	✓	
BREO ELLIPTA (GlaxoSmithKline)		✓	CLARINEX (Merck)	✓ Tabs	✓ Syrup
BREVOXYL (Stiefel)		✓	CLARINEX-D (Merck)	✓	
BRILINTA (AstraZeneca)		✓	CLARITIN (Merck)	✓	
BROMFED-DM (Wockhardt/Morton Grove)	✓		CLARITIN-D (Merck)	✓	
BROVANA (Sunovion)		✓	CLENIA (Upsher-Smith)	✓ Wash	✓ Crm
BUTRANS (Purdue Pharma L.P.)		✓	CLEOCIN (Pfizer)	✓	
BYDUREON (Amylin)		✓	CLEOCIN T (Pfizer)	✓	
BYETTA (Amylin and Lilly)		✓	CLINDAGEL (Galderma)		✓
BYSTOLIC (Forest)		✓	CLINDETS (Stiefel)	✓	
CADUET (Pfizer)		✓	CLOMID (Sanofi Aventis)	✓	
CALAN (Pfizer)	✓		CLOZARIL (Novartis)	✓	
CANASA (Aptalis)		✓	COLACE (Purdue Products L.P.)	✓ Caps	✓ Liquid, syrup
CAPOTEN (Par)	✓		COLACE GLYCERIN SUPP. (Purdue Products L.P.)		✓
CAPOZIDE (Par)	✓		COLAZAL (Salix)	✓	
CARAC (Valeant)		✓	COLCRYS (URL Pharma)		✓
CARAFATE (Aptalis)	✓ Tabs	✓ Susp	COLESTID (Pfizer)	✓ Granules: flavored 5g/pkt, 5g/scoop; ✓ Tabs	✓ Granules: unflavored 5g/pkt, 5g/scoop
CARBATROL (Shire)	✓		COLYTE w. FLAVOR PACKS (Meda)	✓	
CARDIZEM (AbbVie)	✓		COMBIGAN (Allergan)		✓
CARDURA (Pfizer)	✓				
CARDURA XL (Pfizer)		✓			
CATAFLAM (Novartis)	✓				
CATAPRES (Boehringer Ingelheim)	✓ Tabs	✓ Patch			
CEDAX (Shionogi)		✓			

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
COMBIVENT (Boehringer Ingelheim)		✓	DENAVIR (FSC Pediatrics)		✓
COMPOUND W (Medtech)	✓		DEPAKOTE (AbbVie)	✓ Depakote	✓ ER
COMTAN (Novartis)		✓	DEPO-PROVERA (Pfizer)	✓ IM inj: 150mg/mL	✓ IM inj: 400mg/mL; ✓ Sub inj
CONCEPTROL GEL (Personal Products)		✓	DEPO-SUBQ PROVERA (Pfizer)		✓
CONCERTA (Janssen)	✓		DETROL (Pfizer)	✓ Tabs	✓ LA
CONDYLOX (Oclassen)		✓	DEXDRINE (Amedra)	✓	
COPAXONE (Teva CNS)		✓	DEXILANT (Takeda)		✓
COPEGUS (Roche)	✓		DIABETA (Sanofi Aventis)	✓	
CORDARONE (Pfizer)	✓		DIAMOX SEQUELS (Teva Select Brands)	✓	
COREG (GlaxoSmithKline)	✓ Tabs	✓ CR	DICLEGIS (Duchesnay)		✓
CORGARD (King)	✓		DIFFERIN (Galderma)	✓ Gel, crm	✓ Lotion
CORTEF (Pfizer)	✓ Tabs, solu-cortef	✓ Susp	DIFICID (Optimer)		✓
CORTIFOAM (UCB)		✓	DIFLUCAN (Pfizer)	✓	
CORTISPORIN (King)		✓	DILACOR XR (Actavis)	✓	
CORTISPORIN-TC OTIC (JHP)	✓ Soln, susp	✓ TC susp	DILANTIN (Pfizer)	✓	
COSOPT (Merck)	✓ Cosopt	✓ PF	DILATRATE-SR (Actient)		✓
COUMADIN (Bristol-Myers Squibb)	✓ Tabs	✓ Inj	DILAUDID (Purdue Pharma)	✓	
COVERAHS (Pfizer)		✓	DIMETAPP CHILDREN'S COLD & ALLERGY (Wyeth Consumer)	✓	
COZAAR (Merck)	✓		DIOVAN (Novartis)		✓
CREON (AbbVie)		✓	DIOVAN HCT (Novartis)	✓	
CRESTOR (AstraZeneca)		✓	DIPENTUM (UCB)		✓
CRINONE (Actavis)		✓	DITROPAN XL (Janssen)	✓	
CYMBALTA (Lilly)		✓	DOMEBORO (Bayer Consumer)		✓
CYTOTEC (Pfizer)	✓		DONNATAL (PBM)	✓	
DALIRESP (Forest)		✓	DORYX (Warner Chilcott)	✓	
DAYPRO (Pfizer)	✓		DOVONEX (Leo Pharma)	✓ Soln	✓ Crm
DAYTRANA (Noven)		✓	DRAMAMINE (McNeil Cons & Specialty)	✓	
DDAVP (Sanofi Aventis)	✓ Tabs, nasal spray, amps	✓ Rhinal tube	DRYSOL (Person & Covey)	✓	
DEBROX (GlaxoSmithKline)		✓	DUAC (Stiefel)	✓	
DELFIN (Personal Products)		✓	DUET DHA (Eckson)		✓
DELSYM (Reckitt Benckiser)	✓		DUETACT (Takeda)		✓
DELZICOL (Warner Chilcott)		✓	DUEXIS (Horizon Pharma)		✓
DEMADEX (Roche)	✓		DULCOLAX (Boehringer Ingelheim)	✓ Tabs	✓ Supp
DEMEROL (Sanofi Aventis)	✓		DULERA (Merck)		✓

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
DUOFILM (Merck)		✓	ERY-TAB (Arbor)	✓	
DUONEB (DEY)	✓		ESGIC-PLUS (Mikart)	✓	
DURAGESIC (Janssen)	✓		ESTROSTEP Fe (Warner Chilcott)	✓	
DUTOPROL (AstraZeneca)		✓	EURAX (Westwood Squibb)		✓
DYAZIDE (GlaxoSmithKline)	✓		EVISTA (Lilly)		✓
DYMISTA (Meda)		✓	EVOCLIN (Stiefel)	✓	
DYNACIRC CR (GlaxoSmithKline)		✓	EVOXAC (Daiichi Sankyo)	✓	
E.E.S. (Arbor)	✓		EXALGO (Mallinckrodt)		✓
ECOTRIN (GlaxoSmithKline)	✓ Tabs: 81mg, 325mg	✓ Tabs: 500mg	EXCEDRIN EXTRA STRENGTH (Novartis Consumer)	✓	
EDARBI (Takeda)		✓	EXCEDRIN MIGRAINE (Novartis Consumer)	✓	
EDARBYCLOR (Takeda)		✓	EXELDERM (Ranbaxy)		✓
EFFEXOR XR (Pfizer)	✓		EXELON (Novartis)	✓ Caps	✓ Soln, patch
EFFIENT (Daiichi Sankyo and Lilly)		✓	EXFORGE (Novartis)		✓
EFUDEX (Valeant)	✓ Crm	✓ Soln	EXFORGE HCT (Novartis)		✓
ELDEPRYL (Somerset)	✓		EXPECTA LIPIIL (Mead Johnson Nutr.)		✓
ELDOQUIN FORTE (Valeant)	✓		EXTAVIA (Novartis)		✓
ELIDEL (Novartis)		✓	EXTINA (Stiefel)	✓	
ELIMITE (Allergan)	✓		FABIOR (Stiefel)		✓
ELIQUIS (Bristol-Myers Squibb)		✓	FACTIVE (Cornerstone Therapeutics)		✓
ELLA (Actavis)		✓	FAMVIR (Novartis)		✓
ELMIRON (Janssen)		✓	FANAPT (Novartis)		✓
EMBEDA (King)		✓	FC FEMALE CONDOM (Female Health)		✓
EMEND (Merck)		✓	FELBATOL (Meda)	✓	
EMETROL (McNeil Cons & Specialty)	✓		FEMCAP (FemCap)		✓
EMLA (AstraZeneca)	✓		FENTORA (Cephalon)		✓
ENABLEX (Warner Chilcott)		✓	FEOSOL (Meda)	✓ Tabs, caplets	✓ Elixir
ENBREL (Amgen)		✓	FERGON (Bayer Consumer)	✓	
ENFALYTE (Mead Johnson Nutr.)		✓	FER-IN-SOL DROPS (Mead Johnson)	✓	
ENTOCORT EC (AstraZeneca)	✓		FERRO-SEQUELS (Inverness)		✓
EPIDUO GEL (Galderma)		✓	FEVERALL SUPPOSITORIES (Actavis)	✓	
EPIPEN (DEY)		✓	FIBERCON (Wyeth Consumer)	✓	
EPIVIR-HBV (GlaxoSmithKline)		✓	FIBERSURE (Procter & Gamble)		✓
EPOGEN (Amgen)		✓	FIORICET (Actavis)	✓	
ERTACZO (Valeant)		✓	FIORINAL (Actavis)	✓	
ERYPED (Arbor)	✓ Susp	✓ Drops, chew tabs			

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
FLAGYL (Pfizer)	✓ Tabs, caps, premixed IV	✓ Inj	GRANULEX (Mylan)		✓
FLECTOR PATCH (King)		✓	GRIFULVIN V (Valeant)	✓	
FLEET ENEMA (Fleet)	✓ Original	✓ Extra	GRIS-PEG (Pedinol)		✓
FLEET LIQUID GLYCERIN SUPPOSITORIES (Fleet)	✓		GYNOL II (Personal Products)		✓
FLOMAX (Boehringer Ingelheim)	✓		HALCION (Pfizer)	✓	
FLONASE (GlaxoSmithKline)	✓		HALFLYTELY w. Flavor Packs (Braintree)		✓
FLOVENT HFA (GlaxoSmithKline)		✓	HEPSERA (Gilead)		✓
FLOXIN OTIC (Daiichi Sankyo)		✓	HORIZANT (XenoPort)		✓
FLUMADINE (Forest)	✓		HUMALOG MIX (Lilly)		✓
FML (Allergan)	✓ Susp	✓ Oint, forte	HUMIRA (AbbVie)		✓
FOCALIN (Novartis)	✓ Tabs	✓ XR	HUMULIN (Lilly)		✓
FORADIL AEROLIZER (Merck)		✓	HYPOTEARs (Novartis Ophthalmics)		✓
FORTEO (Lilly)		✓	HYTRIN (AbbVie)	✓	
FOSAMAX (Merck)	✓ Tabs	✓ Soln, Plus D	HYZAAR (Merck)	✓	
FOSRENOL (Shire)		✓	IBUDONE (Poly)		✓
FRAGMIN (Eisai)		✓	ICAR-C (Hawthorn)		✓
FROVA (Endo)		✓	IMITREX (GlaxoSmithKline)	✓ Tabs, inj	✓ Nasal spray
FURADANTIN (Shionogi)	✓		IMODIUM (McNeil Cons & Specialty)	✓ Caps, A-D caplets, Advanced	✓ A-D liq
GABITRIL (Cephalon)	✓		IMPLANON (Merck)		✓
GARAMYCIN (Fera)		✓	IMURAN (Prometheus)	✓	
GAVICON (GlaxoSmithKline)		✓	INCIVEK (Vertex)		✓
GELNIQUE (Actavis)		✓	INDERAL (Akrimax)	✓	
GENTEAL MILD (Novartis Ophthalmics)		✓	INDERIDE (Akrimax)	✓	
GEODON (Pfizer)	✓ Caps	✓ Inj	INDOCIN SUSPENSION (Iroko)		✓
GIAZO (Salix)		✓	INFANTS' MYLICON DROPS (J & J-Merck Consumer)		✓
GILENYA (Novartis)		✓	INNOPRAN XL (GlaxoSmithKline)		✓
GLUCAGON (Lilly)		✓	INSPIRA (Pfizer)	✓	
GLUCOPHAGE (Bristol-Myers Squibb)	✓		INTERMEZZO (Purdue Pharma L.P.)		✓
GLUCOTROL (Pfizer)	✓		INTRON A (Merck)		✓
GLUCOVANCE (Bristol-Myers Squibb)	✓		INTUNIV (Shire)		✓
GLYCOLAX (Kremers Urban)	✓		INVEGA (Janssen)		✓
GLYNASE PRESTAB (Pfizer)	✓		INVEGA SUSTENNA (Janssen)		✓
GLY-OXIDE (GlaxoSmithKline)		✓	INVOKANA (Janssen)		✓
GLYSET (Pfizer)		✓	ISOPTO CARPINE (Alcon)	✓	
GoLYTELY (Braintree)	✓		ISORDIL (Biovail)	✓	
GRALISE (Depomed)		✓			

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
JALYN (GlaxoSmithKline)		✓	LANOXIN (Covis)	✓	
JANUMET (Merck)		✓	LANTUS (Sanofi Aventis)		✓
JANUVIA (Merck)		✓	LASIX (Sanofi Aventis)	✓	
JENTADUETO (Boehringer Ingelheim and Lilly)		✓	LATUDA (Sunovion)		✓
JUVISYNC (Merck)		✓	LAZANDA (Depomed)		✓
JUXTAPID (Aegerion)		✓	LESCOL (Novartis)	✓ Caps	✓ XL tabs
KADIAN (Actavis)	✓ Caps: 20mg, 30mg, 50mg, 60mg, 80mg, 100mg	✓ Caps: 10mg, 40mg, 70mg, 130mg, 150mg, 200mg	LEVAQUIN (Janssen)	✓	
KAOPECTATE LIQUID (Chattam)	✓		LEVATOL (Actient)		✓
KAOPECTATE STOOL SOFTENER (Chattam)		✓	LEVEMIR (Novo Nordisk)		✓
KAPVAY (Shionogi)		✓	LEVITRA (Bayer and GlaxoSmithKline)		✓
KAYEXALATE (Covis)	✓		LEVOTHROID (Forest)	✓	
KAZANO (Takeda)		✓	LEVOXYL (King)	✓	
KEFLEX (Shionogi)	✓ Caps: 250mg, 500mg	✓ Caps: 750mg	LEVSIN (Meda)	✓	
KEPPRA (UCB)	✓		LEXAPRO (Forest)	✓	
KETEK (Sanofi Aventis)		✓	LIALDA (Shire)		✓
KLARON (Dermik)	✓		LIBRAX (Valeant)	✓	
KLONOPIN (Roche)	✓		LIBRIUM (Valeant)	✓	
KLOR-CON M (Upsher-Smith)	✓		LICEMD (Combe)		✓
KOMBIGLYZE XR (Bristol-Myers Squibb)		✓	LIDODERM (Endo)		✓
KONSYL (Konsyl)		✓	LINZESS (Forest)		✓
K-PHOS (Beach)	✓ Original, M.F.	✓ #2	LIPITOR (Pfizer)	✓	
KRISTALOSE (Cumberland)		✓	LIPTRUZET (Merck)		✓
KRYSTEXXA (Savient)		✓	LIVALO (Kowa)		✓
K-TAB (AbbVie)		✓	LOMOTIL (Pfizer)	✓	
LACRISERT (Aton)		✓	LOPID (Pfizer)	✓	
LACTAID (McNeil Cons & Specialty)	✓ Original, Extra, Ultra, Ultra chew	✓ Drops, Fast Act, Fast Act chew	LOPRESSOR (Validus)	✓	
LAMICTAL (GlaxoSmithKline)	✓		LOPRESSOR HCT (Validus)	✓	
LAMISIL (topical) (Novartis)	✓		LOPROX (Medicis)	✓ Crm, lotion, gel	✓ Shampoo
LAMISIL (oral) (Novartis)	✓ Tabs	✓ Granules	LORCET PLUS (UAD)	✓	
			LORTAB (UCB)	✓	
			LOTEMAX (Valeant)		✓
			LOTENSIN (Validus)	✓	
			LOTENSIN HCT (Validus)	✓	
			LOTREL (Novartis)	✓ Caps: 2.5mg/10mg, 5mg/10mg, 5mg/20mg, 10mg/20mg	✓ Caps: 5mg/40mg, 10mg/40mg
			LOTRIMIN AF (Merck)		✓
			LOTRIMIN ULTRA (Merck)		✓
			LOTRISONE (Merck)	✓	

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
LOVAZA (GlaxoSmithKline)		✓	MIACALCIN (Novartis)	✓ Spray	✓ Inj
LOVENOX (Sanofi Aventis)	✓ Prefilled syringes	✓ Vials	MICARDIS (Boehringer Ingelheim)		✓
LUMIGAN (Allergan)		✓	MICARDIS HCT (Boehringer Ingelheim)		✓
LUNESTA (Sunovion)	✓		MICROZIDE (Actavis)	✓	
LUPRON DEPOT (AbbVie)		✓	MIFEPREX (Danco)		✓
LUSTRA (TaroPharma)	✓		MIGRANAL (Valeant)		✓
LYRICA (Pfizer)		✓	MINITRAN (Medicis)	✓	
MAALOX (Novartis Consumer)	✓		MINOCIN (Onset)	✓	
MACROBID (Warner Chilcott)	✓		MIRALAX (Merck)	✓	
MACRODANTIN (Warner Chilcott)			MIRAPEX (Boehringer Ingelheim)	✓ Tabs: 0.125mg, 0.25mg, 0.5mg, 1mg, 1.5mg	✓ Tabs: 0.75mg; ✓ ER
MAGNACET (Shionogi)		✓			
MALARONE (GlaxoSmithKline)		✓			
MARINOL (AbbVie)	✓				
MARPLAN (Validus)		✓	MOBIC (Boehringer Ingelheim)	✓ Tabs	✓ Susp
MAVIK (AbbVie)	✓		MONODOX (Watson)	✓	
MAXAIR AUTOHALER (Medicis)		✓	MONOKET (UCB)	✓	
MAXALT (Merck)	✓		MONUROL (Forest)		✓
MAXIDONE (Actavis)	✓		MOTRIN (Pfizer)	✓	
MAXZIDE (Bertek)	✓		MOTRIN CHILDREN'S (McNeil Cons & Specialty)	✓	
MEDERMA (Merz)	✓ Gel	✓ Crm	MOTRIN IB (McNeil Cons & Specialty)	✓	
MEDROL (Pfizer)	✓ Tabs, dosepak; ✓ Depo-medrol: 40mg/mL, 80mg/mL; ✓ Solu-medrol: 40mg, 125mg, 500mg, 1g	✓ Depo-medrol: 20mg/mL ✓ Solu-medrol: 2g	MOTRIN MIGRAINE PAIN (McNeil Cons & Specialty)	✓	
			MOVIPREP (Salix)		✓
			MOXATAG (Shionogi)		✓
			MOXEZA (Alcon)		✓
			MS CONTIN (Purdue Pharma L.P.)	✓	
MEGACE ES (Par)		✓	MUCINEX (Reckitt Benckiser)	✓ Tabs: 600mg	✓ Max strength, pkts, soln
MEGACE ORAL SUSPENSION (Bristol-Myers Squibb)	✓		MUCINEX D (Reckitt Benckiser)		✓
MEPRON (GlaxoSmithKline)		✓	MUCINEX DM (Reckitt Benckiser)		✓
METADATE (UCB)	✓ CD	✓ ER	MUCINEX NASAL SPRAY (Reckitt Benckiser)		✓
METAMUCIL (Procter & Gamble)	✓ Original & orange pwd, pwd packets, caps	✓ Berry burst, pink lemonade, wafers, caps plus calcium	MULTAQ (Sanofi Aventis)		✓
METHERGINE (Validus)	✓		MURINE EAR DROPS (Prestige Brands)		✓
METHYLIN (Mallinckrodt)	✓ Tabs, soln	✓ Chewables, ER	MURINE EARIGATE (Prestige Brands)		✓

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
MURO 128 (Valeant)		✓	NITROSTAT (Pfizer)	✓	
MY WAY (Gavis)		✓	NIX (Insight)	✓ Rinse	✓ Family pack
MYAMBUTOL (Elan)	✓		NIZORAL (Janssen)	✓	
MYCELEX TROCHES (Janssen)	✓		NORCO (Actavis)	✓	
MYLANTA (J & J-Merck Consumer)	✓		NOROXIN (Merck)		✓
MYRBETRIQ (Astellas)		✓	NORPACE (Pfizer)	✓ Caps; ✓ Ext-rel caps: 150mg	✓ Ext-rel caps: 100mg
MYSOLINE (Valeant)	✓		NORPRAMIN (Sanofi Aventis)	✓	
NAFTIN (Merz)		✓	NORVASC (Pfizer)	✓	
NALFON (Pedinol)		✓	NOVOLIN (Novo Nordisk)		✓
NAMENDA (Forest)		✓	NOVOLOG (Novo Nordisk)		✓
NAPRELAN (Shionogi)		✓	NOVOLOG MIX (Novo Nordisk)		✓
NAPROSYN (Roche)	✓		NUCYNTA (Janssen)		✓
NASACORT AQ (Sanofi Aventis)	✓		NUCYNTA ER (Janssen)		✓
NASALCROM (McNeil Cons & Specialty)		✓	NUEDEXTA (Avanir)		✓
NASAREL (Teva)		✓	NULYTELY (Brintree)	✓	
NASCOBAL (Strativa)		✓	NUVARING (Merck)		✓
NASONEX (Merck)		✓	OASIS (GlaxoSmithKline)		✓
NATAFORT (Mission)		✓	OCEAN (Fleming)	✓	
NEEVO DHA (Nestle Health Science – Pamlab)		✓	OCUFLOX (Allergan)	✓	
NEORAL (Novartis)	✓		OMECLAMOX-PAK (Pernix)		✓
NEOSPORIN (Johnson & Johnson Consumer)	✓		OMNARIS (Sunovion)		✓
NEPTAZANE (Fera)		✓	ONFI (Lundbeck)		✓
NESINA (Takeda)		✓	ONGLYZA (Bristol-Myers Squibb)		✓
NEUPRO (UCB)		✓	ONSOLIS (Meda)		✓
NEURONTIN (Pfizer)	✓		OPANA (Endo)	✓	
NEVANAC (Alcon)		✓	OPTIVE (Allergan)		✓
NEXA SELECT (Upsher-Smith)		✓	ORAPRED (Shionogi)	✓	
NEXIUM (AstraZeneca)		✓	ORAVIG (Vestiq)		✓
NEXPLANON (Merck)		✓	ORENCIA (Bristol-Myers Squibb)		✓
NIASPAN (AbbVie)	✓		ORTHO DIAPHRAGM KITS (Janssen)		✓
NITRO-BID (Fougera)		✓	ORTHO EVRA (Janssen)		✓
NITRO-DUR PATCH (Merck)	✓ 0.1mg/hr, 0.2mg/hr, 0.4mg/hr, 0.6mg/hr	✓ 0.3mg/hr, 0.8mg/hr	ORTHO TRI-CYCLEN (Janssen)	✓	
NITROLINGUAL (Shionogi)		✓	OSENI (Takeda)		✓
NITROMIST (Akrimax)		✓	OSMOPREP (Salix)		✓
			OVIDE (TaroPharma)	✓	
			OXECTA (Pfizer)		✓
			OXISTAT (PharmaDerm)		✓

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
OXTELLAR XR (Supernus)		✓	PLENDIL (AstraZeneca)	✓	
OXYCONTIN (Purdue Pharma L.P.)		✓	PLETAL (Otsuka)	✓	
OXYTROL (Actavis)		✓	POLYSPORIN (McNeil Cons & Specialty)	✓	
PAMELOR (Mallinckrodt)	✓		POLYTRIM (Allergan)	✓	
PANCREASE (Janssen)		✓	PONSTEL (Shionogi)		✓
PARAFON FORTE DSC (Janssen)	✓		POTIGA (GlaxoSmithKline)		✓
PARLODEL (Validus)	✓		PRADAXA (Boehringer Ingelheim)		✓
PARNATE (Covis)	✓		PRANDIMET (Novo Nordisk)		✓
PATANASE (Alcon)		✓	PRANDIN (Novo Nordisk)		✓
PAXIL (GlaxoSmithKline)	✓ Tabs, CR tabs	✓ Susp	PRAVACHOL (Bristol-Myers Squibb)	✓	
PCE (Arbor)		✓	PRECOSE (Bayer)	✓	
PEDIALYTE (Abbott Nutrition)	✓		PRED MILD (Allergan)	✓ Forte	✓ Mild
PEDIAPRED (UCB)	✓		PRENATE DHA (Avion)		✓
PEGASYS (Roche)		✓	PRENEXA (Upsher-Smith)		✓
PEG-INTRON (Merck)		✓	PREPARATION H (Wyeth Consumer)	✓	
PENLAC (Valeant)		✓	PREPOPIK (Ferring)		✓
PENNSAID (Mallinckrodt)		✓	PREVACID (Takeda)	✓	
PENTASA (Shire)		✓	PREVACID 24HR (Novartis Consumer)		✓
PEPCID (Marathon)	✓ Tabs, inj	✓ Susp	PREVPAC (Takeda)		✓
PEPCID AC (Merck Consumer & Specialty)	✓ Tabs, complete	✓ Gelcaps, EZ chews	PRILOSEC (AstraZeneca)	✓ Caps	✓ Susp
PEPTO-BISMOL (Procter & Gamble)	✓		PRILOSEC OTC (Procter & Gamble)	✓	
PERCOCET (Endo)	✓		PRIMSOL (FSC Pediatrics)		✓
PERCODAN (Endo)	✓		PRINIVIL (Merck)	✓	
PERFOROMIST (Mylan)		✓	PRINZIDE (Merck)	✓	
PERI-COLACE (Purdue Products L.P.)	✓		PRISTIQ (Pfizer)		✓
PERSANTINE (Boehringer Ingelheim)	✓		PROAIR HFA (Teva Respiratory)		✓
PERTZYE (Digestive Care)		✓	PROCARDIA (Pfizer)	✓ Caps, ext-rel tabs	
PHOSLO (Fresenius)	✓		PROCHIEVE (Columbia)		✓
PHRENILIN (Valeant)	✓		PROCRIT (Janssen Biotech)		✓
PILOPINE HS (Alcon)		✓	PROCTOCORT (Salix)	✓	
PIN-X (Effcon)		✓	PROCTOFOAM-HC (UCB)		✓
PLAN B ONE-STEP (Teva Women's Health)	✓		PROLENSA (Valeant)		✓
PLAQUENIL (Covis)	✓		PROLIA (Amgen)		✓
PLAVIX (Bristol-Myers Squibb and Sanofi Aventis)	✓		PRONTO PLUS (Del)		✓

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
PROPECIA (Merck)		✓	RID (Bayer Consumer)	✓ Mousse, shampoo, gel	✓ Pure alternative
PROSCAR (Merck)	✓				
PROTONIX (Pfizer)	✓ Tabs, IV	✓ Oral soln	RIFADIN (Sanofi Aventis)	✓	
PROTOPIC (Astellas)		✓	RISPERDAL (Janssen)	✓	
PROVENTIL HFA (Merck)		✓	RISPERDAL CONSTA (Janssen)		✓
PROVIGIL (Cephalon)	✓				
PROZAC (Lilly)	✓		RITALIN (Novartis)	✓ LA caps: 20mg, 30mg, 40mg ✓ Tabs, SR	✓ LA caps: 10mg
PULMICORT (AstraZeneca)	✓ Respules	✓ Flexhaler			
PYLERA (Aptalis)		✓	ROBAXIN (Actient)	✓	
QNASL (Teva Respiratory)		✓	ROBITUSSIN CHEST CONGESTION (Wyeth Consumer)	✓	
QSYMIA (Vivus)		✓	ROBITUSSIN COUGH & CHEST CONGESTION DM (Wyeth Consumer)	✓	
QUILLIVANT XR (Pfizer)		✓	ROBITUSSIN COUGH & COLD CF (Wyeth Consumer)	✓	
QUIXIN (Vistakon)	✓		ROCALTROL (Validus)	✓	
QUTENZA (NeurogesX)		✓	ROGAINE (McNeil Cons & Specialty)	✓	
QVAR (Teva Respiratory)		✓	ROSAC (Stiefel)		✓
RANEXA (Gilead)		✓	ROWASA (Meda)	✓	
RAPAFLO (Actavis)		✓	ROXICET ORAL SOLUTION (Roxane)		✓
RAYOS (Horizon Pharma)		✓	ROXILOX (Roxane)	✓	
RAZADYNE (Janssen)	✓		ROZEREM (Takeda)		✓
REBETOL (Merck)		✓	RYBIX ODT (Shionogi)		✓
REBIF (EMD Serono)		✓	RYTHMOL (GlaxoSmithKline)	✓ Tabs	✓ Ext-rel caps
RECLAST (Novartis)	✓		RYZOLT (Purdue Pharma L.P.)	✓	
REFRESH LACRI-LUBE (Allergan)	✓ Oint	✓ PM	SABRIL (Lundbeck)		✓
REGLAN (Ani)	✓		SALAGEN (MGI Pharma)	✓	
REGRANEX (Healthpoint)		✓	SANCTURA (Allergan)	✓	
RELENZA (GlaxoSmithKline)		✓	SANCUSO (ProStrakan)		✓
RELPAK (Pfizer)		✓	SAPHRIS (Merck)		✓
REMERON (Merck)	✓		SARAFEM (Warner Chilcott)	✓ Caps	✓ Tabs
REMICADE (Janssen Biotech)		✓	SAVELLA (Forest and Cypress)		✓
RENAGEL (Genzyme)		✓	SECTRAL (Dr. Reddy's)	✓	
RENOVA (Valeant)	✓ Crm 0.05%	✓ Crm 0.02%	SELSUN (AbbVie)	✓	
REVELA (Genzyme)		✓	SEMPREX-D (Actient)		✓
REQUIP (GlaxoSmithKline)	✓		SENNAPROMPT (Konsyl)		✓
RESTASIS (Allergan)		✓			
RESTORIL (Mallinckrodt)	✓ Caps: 15mg, 30mg	✓ Caps: 7.5mg, 22.5mg	SENOKOT (Purdue Products L.P.)	✓ Tabs, S	✓ Xtra
RETIN-A MICRO (Valeant)	✓ Crm, gel	✓ Liq, micro			
RHEUMATREX (Stada)	✓				
RHINOCORT AQUA (AstraZeneca)		✓			

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
SEREVENT DISKUS (GlaxoSmithKline)		✓	SYMBICORT (AstraZeneca)		✓
SEROQUEL (AstraZeneca)	✓ Tabs	✓ XR tabs	SYMBYAX (Lilly)	✓	
SILENOR (Somaxon)		✓	SYMLIN (Amylin)		✓
SILVADENE (King)	✓		SYNALGOS-DC (Caraco)		✓
SIMCOR (AbbVie)		✓	SYNTHROID (AbbVie)	✓	
SIMPONI (Janssen Biotech)		✓	SYSTANE (Alcon)		✓
SINEMET (Merck)	✓		TAGAMET (GlaxoSmithKline)	✓	
SINGULAIR (Merck)	✓		TAGAMET HB (GlaxoSmithKline)	✓	
SIRTURO (Janssen Therapeutics)		✓	TALWIN-NX (Sanofi Aventis)	✓	
SKELAXIN (King)	✓		TAMBOCOR (Medicis)	✓	
SKLICE (Sanofi Pasteur)		✓	TAMIFLU (Roche)		✓
SLOW FE (Novartis Consumer)		✓	TAPAZOLE (King)	✓	
SOLARAZE (PharmaDerm)		✓	TARKA (AbbVie)	✓	
SOMA (Meda)	✓ Tabs: 350mg	✓ Tabs: 250mg	TASMAR (Valeant)		✓
SONATA (King)	✓		TAZORAC (Allergan)		✓
SORIATANE (Stiefel)		✓	TEARS NATURALE P.M. (Alcon)		✓
SPECTRACEF (Cornerstone Therapeutics)		✓	TECFIDERA (Biogen Idec)		✓
SPIRIVA HANDIHALER (Boehringer Ingelheim)		✓	TEFLARO (Forest)		✓
SPORANOX (Janssen)	✓ Caps	✓ Oral sol	TEGRETOL (Novartis)	✓	
SPRIX (Regency Therapeutics)		✓	TEKAMLO (Novartis)		✓
STALEVO (Novartis)	✓		TEKTURN (Novartis)		✓
STARLIX (Novartis)	✓		TEKTURN HCT (Novartis)		✓
STAXYN (Bayer and GlaxoSmithKline)		✓	TENEX (Promius)	✓	
STELARA (Janssen Biotech)		✓	TENORETIC (AstraZeneca)	✓	
STRATTERA (Lilly)		✓	TENORMIN (AstraZeneca)	✓	
SUBOXONE (Reckitt Benckiser)		✓	TESSALON (Forest)	✓	
SUCLEAR (BainTree)		✓	TESTIM (Auxilium)		✓
SUDAFED (McNeil Cons & Specialty)	✓ Tabs: 12 hour	✓ Tabs: 24 hour	TEVETEN (AbbVie)	✓	
SUDAFED CHILDREN'S (McNeil Cons & Specialty)	✓		TEVETEN HCT (AbbVie)		✓
SULAR (Shionogi)	✓		THEO-24 (Actient)	✓ Caps: 100mg, 200mg, 300mg	✓ Caps: 400mg
SUPRAX (Lupin)		✓	TIAZAC (Forest)	✓	
SUPRENZA (Akrimax)		✓	TIGAN (King)	✓	
SURMONTIL (Teva Select Brands)	✓		TILIA Fe (Actavis)		✓
			TIMOPTIC (Aton)	✓ Soln, XE	✓ Oculdose
			TINACTIN (Merck)		✓
			TINDAMAX (Mission)		✓
			TIVICAY (ViiV Healthcare)		✓
			TOBRADEX (Alcon)		✓
			TOBREX (Alcon)	✓ Soln	✓ Oint

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GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
TODAY SPONGE (Synova)		✓	TYZEKA (Idenix and Novartis)		✓
TOFRANIL (Mallinckrodt)	✓		UCERIS (Santarus)		✓
TOPAMAX (Janssen)	✓		ULESFA (Shionogi)		✓
TOPROL-XL (AstraZeneca)	✓		ULORIC (Takeda)		✓
TOVIAZ (Pfizer)		✓	ULTRACET (Janssen)	✓	
TRADJENTA (Boehringer Ingelheim and Lilly)		✓	ULTRAM (Janssen)	✓	
TRANDATE (Prometheus)	✓		ULTRESA (Aptalis)		✓
TRANSDERM SCOP (Novartis Consumer)		✓	UNIRETIC (UCB)	✓	
TRANXENE (Lundbeck)	✓		UNITHROID (Watson)	✓	
TRAVATAN Z (Alcon)		✓	UNIVASC (UCB)	✓	
TRENTAL (Sanofi Aventis)	✓		URECHOLINE (Teva Select Brands)	✓	
TREXIMET (GlaxoSmithKline)		✓	URISTAT (Personal Products)		✓
TRIBENZOR (Daiichi Sankyo)		✓	UROCIT-K (Mission)	✓	
TRICOR (AbbVie)		✓	UROXATRAL (Covis)	✓	
TRI-LEGEST (Teva)		✓	URSO (Aptalis)		✓
TRILEPTAL (Novartis)	✓		VALCYTE (Roche)		✓
TRILIPIX (AbbVie)		✓	VALIUM (Roche)	✓	
TRI-LUMA (Galderma)		✓	VALTREX (GlaxoSmithKline)	✓	
TRILYTE w. FLAVOR PACKS (UCB)	✓		VALTURNIA (Novartis)		✓
TROKENDI XR (Supernus)		✓	VANIQA (SkinMedica)		✓
TRI-PREVIFEM (Teva)	✓		VASCEPA (Amarin)		✓
TRI-SPRINTEC (Teva)	✓		VASERETIC (Valeant)	✓	
TRUSOPT (Merck)	✓		VASOTEC (Valeant)	✓	
TUDORZA PRESSAIR (Forest)		✓	VCF VAGINAL CONTRACEPTIVE FILM/ FOAM (Apothecus)		✓
TUMS (GlaxoSmithKline)	✓ Tums, E-X, Ultra	✓ Smoothies, E-X sugar free, Quik Pak	VECTICAL OINTMENT (Galderma)		✓
TUMS DUAL ACTION (GlaxoSmithKline)		✓	VENTOLIN HFA (GlaxoSmithKline)		✓
TUSSICAPS (Mallinckrodt)		✓	VERAMYST (GlaxoSmithKline)		✓
TUSSIONEX (UCB)		✓	VEREGEN (PharmaDerm)		✓
TWYNSTA (Boehringer Ingelheim)		✓	VERELAN (UCB)	✓ Sust-rel caps: 120mg, 180mg, 240mg	✓ Sust-rel caps; 360mg ✓ Ext-rel caps
TYLENOL (McNeil Cons & Specialty)	✓		VESICARE (Astellas)		✓
TYLENOL ARTHRITIS (McNeil Cons & Specialty)		✓	VFEND (Pfizer)	✓ Tabs	✓ Susp, inj
TYLENOL CHILDREN'S (McNeil Cons & Specialty)	✓		VIAGRA (Pfizer)		✓
TYLENOL w. CODEINE (Janssen)	✓		VIBRAMYCIN (Pfizer)	✓ Caps, tabs, susp	✓ Syrup

***Not an inclusive list. Please check manufacturer's product labeling.**

GENERIC AVAILABILITY*

Brand Name (Manufacturer)	Yes	No	Brand Name (Manufacturer)	Yes	No
VICODIN (AbbVie)	✓		ZAROXOLYN (UCB)	✓	
VICOPROFEN (AbbVie)	✓		ZEBETA (Teva Select Brands)	✓	
VICTOZA (Novo Nordisk)		✓	ZEGERID (Santarus)	✓ Caps	✓ Susp
VICTRELIS (Merck)		✓	ZEGERID OTC (Merck)		✓
VIGAMOX (Alcon)		✓	ZEMPLAR (AbbVie)	✓ Inj	✓ Caps
VIIBRYD (Forest)		✓	ZENPEP (Aptalis)		✓
VIMOVO (AstraZeneca)		✓	ZESTORETIC (AstraZeneca)	✓	
VIMPAT (UCB)		✓	ZESTRIL (AstraZeneca)	✓	
VIOKASE (Aptalis)		✓	ZETIA (Merck)		✓
VIROPTIC (King)		✓	ZETONNA (Sunovion)		✓
VISICOL (Salix)		✓	ZIAC (Teva Select Brands)	✓	
VISTARIL (Pfizer)	✓		ZIAN (Medicis)		✓
VIVITROL (Alkermes)		✓	ZIOPTAN (Merck)		✓
VOLTAREN GEL (Endo)		✓	ZIPSOR (Depomed)		✓
VOLTAREN OPH SOLN (Novartis Ophthalmics)	✓		ZIRGAN (Sirion)		✓
VOLTAREN-XR (Novartis)	✓		ZITHROMAX (Pfizer)	✓ Tabs, susp, inj	✓ Packets
VOSPIRE ER (DAVA)		✓	ZMAX (Pfizer)		✓
VYTORIN (Merck)		✓	ZOCOR (Merck)	✓	
VYVANSE (Shire)		✓	ZOFRAN (GlaxoSmithKline)	✓ ODT, tabs, soln, inj	✓ Premixed inj
WELCHOL (Daiichi Sankyo)		✓	ZOLOFT (Pfizer)	✓	
WELLBUTRIN (GlaxoSmithKline)	✓ Tabs, SR, XL		ZOLPIMIST (ECR)		✓
XALATAN (Pfizer Ophthalmics)		✓	ZOMIG (Impax)	✓ Tabs	✓ ZMT tabs, sprayer
XANAX (Pfizer)	✓		ZOSTRIX (Hi-Tech)		✓
XARELTO (Janssen)		✓	ZOVIRAX (oral) (GlaxoSmithKline)	✓	
XELJANZ (Pfizer)		✓	ZOVIRAX (topical) (Valeant)	✓ Oint	✓ Crm
XENICAL (Genentech)		✓	ZYCLARA (Medicis)		✓
XERESE (Valeant)		✓	ZYDONE (Endo)	✓	
XIFAXAN (Salix)		✓	ZYLET (Valeant)		✓
XOLAIR (Genentech and Novartis)		✓	ZYLOPRIM (Prometheus)	✓	
XOPENEX HFA (Sunovion)	✓ Vials	✓ HFA	ZYMAR (Allergan)	✓	
XYZAL (UCB and Sanofi Aventis)	✓		ZYMAXID (Allergan)		✓
YAZ (Bayer)	✓		ZYPREXA (Lilly)	✓ Tabs, Zydis	✓ Inj
ZANAFLEX (Acorda)	✓		ZYRTEC (McNeil Cons & Specialty)	✓	
ZANFEL (Zanfel Labs)		✓	ZYRTEC-D 12 HOUR (McNeil Cons & Specialty)	✓	
ZANTAC (GlaxoSmithKline)	✓ Tabs, inj single dose, syrup	✓ EFFERdose premixed	ZYVOX (Pfizer)		✓
ZANTAC 75/150 (Boehringer Ingelheim)	✓				

***Not an inclusive list. Please check manufacturer's product labeling.**

ALPHABETICAL INDEX

KEY: *product contains other active ingredients, (ext) = external, (oph) = ophthalmic, (inj) = injectable, (nasal) = nasal, (otic) = otic, (rect) = rectal, (vag) = vaginal

A					
<i>Abacavir</i>			Actonel	201	<i>Alendronate</i>
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<i>Acetaminophen</i>			<i>Adenocard</i> (inj)	7	<i>Aloprim</i>
<i>Floricef*</i>	310		<i>Adenoscan</i> (inj)	7	<i>Zyloprim</i>
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