Yosprala

(aspirin delayed-release, omeprazole immediate-release)

New Product Slideshow

MPR

Introduction

- **Brand name:** Yosprala
- **Generic name:** Aspirin delayed-rel, omeprazole immediate-rel
- **Pharmacological class:** Antiplatelet + proton pump inhibitor
- **Strengths and Formulations:** 81mg/40mg, 325mg/40mg; delayed-rel tabs
- **Manufacturer:** Aralez
- **How supplied:** Bottle—30, 90
- **Legal Classification:** Rx

Indications

- Patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers

- For separate components: see full labeling

Limitations of Use

- **Not** for use as initial dose of aspirin therapy during onset of acute coronary syndrome, acute myocardial infarction, or before PCI
- **Not** shown to reduce risk of GI bleeding due to aspirin
- **Not** interchangeable with individual aspirin and omeprazole

Dosage & Administration

- Swallow whole
- Take 1 tab daily at least 1hr before a meal
- Use lowest effective dose for shortest duration
- Usually aspirin 81mg is acceptable; can consider the need for 325mg and refer to current guidelines

Considerations for Special Populations

- **Pregnancy:** ≥30 weeks gestation: avoid
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Geriatric:** No overall differences in safety or efficacy
- **Renal impairment:** Severe (GFR <10mL/min): not recommended
- **Hepatic impairment:** Not recommended
- **Asians with unknown CYP2C19 genotype or poor metabolizers:** Not recommended

Contraindications

- NSAID allergy and syndrome of asthma, rhinitis, nasal polyps
- Viral infections in pediatric patients
- Concomitant rilpivirine-containing drugs (due to omeprazole component)

Warnings/Precautions

- Coagulation abnormalities; monitor for increased bleeding
- Increased risk of serious GI adverse events (including inflammation, bleeding, ulceration, perforation)
- Discontinue if significant bleeding from any source, acute interstitial nephritis, or cutaneous/systemic lupus erythematosus develops
- Gastric malignancy

Warnings/Precautions

- Increased risk of osteoporosis-related fractures (hip, wrist or spine) with long-term and multiple daily dose PPI therapy
- Long-term therapy may lead to malabsorption/deficiency of Vit. B12
- Monitor magnesium levels with long-term therapy
- Avoid abrupt cessation
- Pre-existing renal disease

Interactions

- See Contraindications
- Concomitant St. John's wort, rifampin, atazanavir, nelfinavir, voriconazole: not recommended
- Concomitant heparin, warfarin: monitor and adjust dose as needed
- Avoid concomitant clopidogrel; consider alternative antiplatelet therapy

Interactions

- **Potentiates** saquinavir, hypoglycemics, acetazolamide, valproic acid, citalopram (limit to max 20mg daily), cilostazol (reduce to 50mg twice daily)
- **May potentiate** phenytoin, diazepam, tacrolimus, digoxin, methotrexate (consider temporary withdrawal if on high-doses); monitor and adjust dose as needed
- **May antagonize** ACE inhibitors, β-blockers, diuretics, uricosurics; monitor

Interactions

- Increased bleeding risk with NSAIDs or chronic, heavy alcohol use
- NSAIDs increase risk of renal dysfunction
- Caution with drugs that may cause hypomagnesemia (eg, digoxin, diuretics); monitor
- May alter absorption of pH-dependent drugs (eg, iron salts, erlotinib, dasatinib, nilotinib, ketoconazole, itraconazole, mycophenolate mofetil)

Interactions

- Monitor drugs metabolized by CYP450 (eg, cyclosporine, disulfiram)
- May interfere with lab tests; discontinue ≥14 days prior to CgA level assessment and secretin stimulation test
- May cause false (+) THC urine test; use alternative confirmatory method
- For the **325mg/40mg** tab strength: avoid concomitant ticagrelor

Adverse Reactions

- Gastritis
- Nausea
- Diarrhea
- Gastric polyps
- Non-cardiac chest pain
- Ulcers (monitor)
- Infertility
- Abnormal labs (eg, increased liver enzymes, BUN, creatinine, proteinuria, hyperkalemia, prolonged bleeding time)
- *C. diff*-associated diarrhea
- Cutaneous/systemic lupus erythematosus

Mechanism of Action

- Aspirin (acetylsalicylic acid) is an inhibitor of both prostaglandin synthesis and platelet aggregation
  - The acetyl group is is responsible for the inactivation of cyclo-oxygenase via acetylation
- Omeprazole suppresses gastric acid secretion by specific inhibition of the [H+/K+]-ATPase enzyme system at the secretory surface of the gastric parietal cell

Clinical Studies

- Study 1 and 2 were randomized, multi-center, double-blind trials that evaluated the omeprazole component by comparing the incidence of gastric formation
- 524 patients were randomized to Yosprala 325mg/40mg tablets and 525 patients were randomized to aspirin 325mg
- Approximately 11% of patients were on chronic NSAID therapy

Mechanism of Action

- Patients were included with a cerebro- or cardiovascular diagnosis if they:
  - Had been taking daily aspirin 325mg for at least 3 months
  - Were expected to require daily aspirin 325mg therapy for at least 6 months
  - Were over 55 years old

Mechanism of Action

- Studies 1 and 2 showed Yosprala 325mg/40mg tablets once daily statistically significantly reduced the 6-month cumulative incidence of gastric ulcers vs. EC-aspirin 325mg once daily
- From 0-6 months:
  - **Study 1:** 3.8% of Yosprala patients experienced gastric ulcers vs. 8.7% of EC-aspirin patients
  - **Study 2:** 2.7% of Yosprala patients experienced gastric ulcers vs. 8.5% of EC-aspirin patients

Mechanism of Action

- For both trials, Yosprala 325mg/40mg patients had a statistically significantly lower 6-month cumulative incidence of gastric and/or duodenal ulcers (3%) vs. EC-aspirin 325mg (12%)

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the complete product monograph available at:

  http://www.empr.com/yosprala/drug/34618/