Syndros (dronabinol)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Syndros
- **Generic name:** Dronabinol
- **Pharmacological class:** Cannabinoid
- **Strength and Formulation:** 5mg/mL; oral soln; contains 50% w/w dehydrated alcohol, 5.5% w/w propylene glycol
- **Manufacturer:** Insys Therapeutics
- **How supplied:** Oral soln—30mL (with syringe and adapter)
- **Legal Classification:** CII

SYNDROS


NDC 20482-335-30
SYNDROS™
(dronabinol)
oral solution
5 mg/mL
Dispense in original container with oral syringe for administration
30 mL
Rx Only
For Oral Administration Only
insys

Indications

- **Anorexia** associated with weight loss in patients with AIDS
- Refractory **nausea and vomiting** associated with cancer chemotherapy

Dosage & Administration

- Individualize
- Take each dose with 6–8oz water

Dosage & Administration

- **Anorexia**:
  - Initially 2.1mg twice daily 1hr before lunch and dinner
  - If **elderly** or severe or persistent CNS effects occur, reduce to 2.1mg once daily 1hr before dinner or bedtime
  - If **tolerated**, may gradually increase to 2.1mg 1hr before lunch and 4.2mg before dinner; may further titrate up to 4.2mg twice daily as tolerated; max 8.4mg twice daily

Dosage & Administration

- **Nausea and vomiting:**
  - Give 1st dose ≥30mins before eating
  - Initially 4.2mg/m^2 1–3hrs before chemotherapy then every 2–4hrs after chemotherapy; total 4–6 doses daily
  - **Elderly**: 2.1mg/m^2 once daily 1–3hrs before chemotherapy
  - May increase in increments of 2.1mg/m^2; max 12.6mg/m^2 per dose for 4–6 doses per day
  - May reduce to 2.1mg once daily 1–3hrs before chemotherapy if needed

Considerations for Special Populations

- **Pregnancy:** Not recommended
- **Nursing mothers:** Not recommended
- **Pediatric:** Not established
- **Elderly:** May be more sensitive to neurological, psychoactive, and postural hypotensive effects; caution with dose selection

Contraindications

- Concomitant disulfiram- or metronidazole-containing products within the past 14 days
- Alcohol hypersensitivity

Warnings/Precautions

- **Seizure disorders**; monitor and discontinue if seizure occurs
- **Cardiac disorders**; monitor changes in BP, HR, syncope after initiation or dose increase
- Screen for **psychiatric disorders** prior to starting; avoid in those with a psychiatric history (eg, mania, depression, schizophrenia); if unavoidable, monitor for new or worsening symptoms

Warnings/Precautions

- Substance abuse or dependence; monitor
- **Monitor** for neurological and psychoactive effects (esp. children, elderly); reduce or discontinue dose if cognitive impairment or nausea/vomiting/abdominal pain worsens
- Diminished **CYP2C9 function**; monitor for increased adverse effects
- **Avoid** in preterm neonates in immediate postnatal period

Interactions

- See **Contraindications**
- Do not give disulfiram- or metronidazole-containing products within 7 days of completing treatment
- Highly protein bound drugs (eg, warfarin, cyclosporine, amphotericin B); monitor

Interactions

- **CYP2C9** and **CYP3A4 inducers** may decrease systemic exposure; effects may be potentiated by **inhibitors** of CYP2C9 (eg, amiodarone, fluconazole) and CYP3A4 (eg. ketoconazole, itraconazole, clarithromycin, ritonavir, erythromycin, grapefruit juice); monitor

Interactions

- **Additive CNS effects** with other CNS depressants (eg, barbiturates, benzodiazepines, lithium, opioids, buspirone, scopolamine, antihistamine, TCAs, other anticholinergics, muscle relaxants)
- **Caution** with antiepileptics or factors that can lower seizure threshold

Interactions

- **Avoid** concomitant psychoactive drugs or drugs with cardiac effects (eg, amphetamines, other sympathomimetics, atropine, amoxapine, scopolamine, antihistamines, other anticholinergics, amitriptyline, desipramine, other TCAs)
- May potentiate propylene glycol

Adverse Reactions

- Dizziness
- Euphoria
- Paranoid reactions
- Somnolence
- Abnormal thinking
- Amnesia
- Feeling high
- Abdominal pain
- Nausea
- Vomiting
- Hemodynamic instability
- Preterm neonatal toxicity

Mechanism of Action

- Dronabinol is an orally active cannabinoid which has complex effects on the CNS, including central sympathomimetic activity
- Cannabinoid receptors, found in neural tissues, may play a role mediating the effects of dronabinol

Clinical Studies

- The effectiveness of Syndros has been established based on studies of dronabinol capsules for the treatment of anorexia associated with weight loss in patients with AIDS, and nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional antiemetic treatments

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/syndros/drug/34619/