Movantik (naloxegol) - Drug Summary

AstraZeneca Pharmaceuticals LP

Related Drug Information

Movantik
(naloxegol)

THERAPEUTIC CLASS

Opioid antagonist

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Opioid-Induced Constipation

In Patients W/ Chronic Non-Cancer Pain:
Usual: 25mg qd in am; reduce dose to 12.5mg qd if not tolerated

D/C all maint laxative therapy prior to initiation of therapy
Laxative(s) can be used prn, if suboptimal response to therapy after 3 days

DOSING CONSIDERATIONS

Concomitant Medications
Moderate CYP3A4 Inhibitors: Avoid use; reduce dose to 12.5mg qd and monitor for adverse reactions if use is unavoidable

Renal Impairment
CrCl <60mL/min:
Initial: 12.5mg qd
Titrate: If dosage is well tolerated but opioid-induced constipation symptoms continue, may increase dose to 25mg qd taking into consideration potential for markedly increased exposures in some patients w/ renal impairment and increased risk of adverse reactions w/ higher exposures

Hepatic Impairment
Severe (Child-Pugh Class C): Avoid use

Discontinuation
D/C therapy if treatment w/ the opioid pain medication is also discontinued

Other Important Considerations
Shown to be efficacious in patients who have taken opioids for at least 4 weeks
Avoid consumption of grapefruit or grapefruit juice during treatment

ADMINISTRATION

Oral route

Take on an empty stomach at least 1 hr prior to or 2 hrs after the 1st meal of the day
Swallow tab whole, do not crush or chew

HOW SUPPLIED

Tab: 12.5mg, 25mg

CONTRAINDICATIONS

Known/suspected GI obstruction and patients at increased risk of recurrent obstruction, concomitant use of strong CYP3A4 inhibitors (eg, clarithromycin, ketoconazole), known serious or severe hypersensitivity reaction to naloxegol or any of its excipients.

WARNINGS/PRECAUTIONS

GI perforation may occur in patients w/ conditions that may be associated w/ localized or diffuse reduction of structural integrity in the wall of the GI tract (eg, peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative GI tract malignancies); caution in patients w/ these conditions and in patients w/ other conditions which might result in impaired integrity of the GI tract wall (eg, Crohn's disease). D/C in patients who develop severe, persistent, or worsening abdominal pain. Clusters of symptoms consistent w/ opioid withdrawal (eg, hyperhidrosis, chills, diarrhea) reported. Patients receiving methadone as therapy for pain were reported to have higher frequency of GI adverse reactions that may have been related to opioid withdrawal than patients receiving other opioids. May be at increased risk for opioid withdrawal or reduced analgesia in patients w/ disruptions to the blood-brain barrier; use w/ caution.

ADVERSE REACTIONS

Abdominal pain, diarrhea, N/V, flatulence, headache, hyperhidrosis.

DRUG INTERACTIONS

See Dosing Considerations and Contraindications. Potential for additive effect of opioid receptor antagonism and increased risk of opioid withdrawal w/ other opioid antagonists; avoid use w/ another opioid antagonist. Strong CYP3A4 inducers (eg, rifampin, carbamazepine, St. John's wort) may significantly decrease plasma levels and efficacy; not recommended for use w/ strong CYP3A4 inducers. Grapefruit or grapefruit juice may increase plasma levels.

PREGNANCY AND LACTATION

Category C, not for use in nursing.

MECHANISM OF ACTION

Opioid antagonist; antagonist of opioid binding at the mu-opioid receptor. Peripherally acts as mu-opioid receptor antagonist in tissues such as the GI tract, thereby decreasing the constipating effects of opioids.

PHARMACOKINETICS

Absorption: T_{max}<2 hrs. **Distribution:** V_d=968-2140L; plasma protein binding (4.2%). **Metabolism:** CYP3A; N-dealkylation, O-demethylation, oxidation, and partial loss of the PEG chain. **Elimination:** Feces (68%, approx 16% unchanged), urine (16%, <6% parent); $T_{1/2}$= 6-11 hrs.

ASSESSMENT

Assess for serious/severe hypersensitivity reaction to the drug or any of its excipients, GI obstruction, increased risk of recurrent GI obstruction, conditions associated w/ localized or diffuse reduction of structural integrity in the wall of the GI tract, conditions which might result in impaired integrity of GI tract wall, disruptions to the blood-brain barrier, renal/hepatic impairment, pregnancy/nursing status, and other possible drug interactions.

MONITORING

Monitor for signs/symptoms of GI perforation, severe/persistent/worsening abdominal pain, opioid withdrawal symptoms, and other adverse reactions.

PATIENT COUNSELING

Advise to take exactly ud. Counsel to inform physician when starting or stopping any concomitant medication. Advise to d/c therapy and to promptly seek medical attention if unusually severe, persistent, or worsening abdominal pain develops. Inform that clusters of symptoms consistent w/ opioid withdrawal may occur while taking therapy. Counsel that taking methadone as therapy for pain condition may increase likelihood of having GI adverse reactions that may be related to opioid withdrawal. Advise females of reproductive potential that the use of drug during pregnancy may precipitate opioid withdrawal in a fetus. Advise females who are nursing against breastfeeding during treatment due to potential for opioid withdrawal in nursing infants.

STORAGE

20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F).

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