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Federal Employee Program.

OPIOID ANTAGONIST DRUG CLASS

Movantik (naloxegol) / Relistor (methylnaltrexone bromide) / Symproic (naldemedine)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Opioids are a class of drugs used in the management of pain. A common side effect of opiates is decreased gastrointestinal motility which leads to constipation. Movantik, Relistor and Symproic are opioid receptor antagonists used to treat the constipating side effects of opioids. When administered at the recommended dose levels, Movantik, Relistor and Symproic bind at the mu-opioid receptor in the peripheral tissues such as the gastrointestinal tract, thereby decreasing the constipating side effects of opioids without impacting the opioid effects on the central nervous system (1-3).

Regulatory Status

FDA-approved indications:

Movantik is an oral opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g. weekly) opioid dosage escalation (1).

Relistor the injectable and oral opioid antagonist are indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation (2).

Symproic is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation (3).

Relistor injectable is indicated for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care (2).

Movantik, Relistor and Symproic have not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, Movantik, Relistor and Symproic are not recommended for use in



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Rare cases of gastrointestinal (GI) perforation have been reported in advanced illness patients with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the GI tract. Relistor should be used with caution in patients with known or suspected lesions of the GI tract (2). Movantik, Relistor and Symproic are contraindicated in patients with known or suspected gastrointestinal obstruction (1-3).

Movantik is also contraindicated in patients using strong CYP3A4 inhibitors concomitantly because these drugs can significantly increase exposure to Movantik which may precipitate opioid withdrawal symptoms (1).

Cases of severe abdominal pain and/or diarrhea have been reported in patients taking over 25mg of Movantik. Monitor patients for the development and discontinue therapy if severe symptoms occur (1).

The safety and effectiveness of Movantik, Relistor and Symproic in patients below the age of 18 years have not been established (1-3).

Summary

Movantik, Relistor and Symproic are opioid receptor antagonists used to treat opioid-induced constipation in adult patients. Movantik, Relistor and Symproic is indicated for patients with chronic non-cancer pain. Injectable Relistor is also indicated for patients with advanced illness who are receiving palliative care. Movantik, Relistor and Symproic have not been studied in patients with severe hepatic impairment (Child-Pugh Class C). Therefore, these three medications are not recommended for use in patients with severe hepatic impairment. Movantik, Relistor and Symproic are contraindicated in patients with known or suspected gastrointestinal obstruction. The safety and effectiveness of Movantik, Relistor and Symproic in patients below the age of 18 years have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of



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Movantik, Relistor and Symproic while maintaining optimal therapeutic outcomes.

References

1. Movantik [package insert]. Chicago, IL: Valinor Pharma, LLC; March 2023.
2. Relistor [package insert]. Tarrytown, NY: Progenics Pharmaceuticals, Inc.; April 2020.
3. Symproic [package insert]. Raleigh, NC: BioDelivery Sciences International, Inc.; May 2020.