RELISTOR®

helps restore gut function[1]

Take a proactive approach to opioid-induced constipation (OIC)

to help increase the number of spontaneous bowel movements[1]

INDICATIONS

- RELISTOR® (methylnaltrexone bromide) is an opioid antagonist. RELISTOR tablets and RELISTOR injection are indicated for the treatment of opioid-induced constipation (OIC) in adults 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.
- RELISTOR injection is also 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.

IMPORTANT SAFETY INFORMATION

- RELISTOR tablets and injection are contraindicated in patients with known or suspected mechanical gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

RELISTOR®
methylnaltrexone bromide
Tablets & Subcutaneous Injection

RELISTOR: The only OIC treatment with 2 routes of administration for adults with chronic non-cancer pain (CNCP)[1-5]

Choose RELISTOR tablets for your adult patients with OIC experiencing CNCP[1]

Choose RELISTOR injection for your adult patients with OIC experiencing CNCP[1]

Dosing recommendations for adult patients with CNCP[1]

RELISTOR tablet dosing[1]		
Once daily in the morning	Three 150-mg tablets	450 mg total dose

RELISTOR tablets should be taken with water on an empty stomach at least 30 minutes before the first meal of the day

A dosage reduction of RELISTOR tablets to 150 mg, once daily in the morning, is recommended in patients with moderate or severe renal impairment or patients with moderate or severe hepatic impairment.[1]

RELISTOR injection dosing[1]		
Once-daily subcutaneous injection	12-mg syringe	12-mg dose

A dosage reduction of RELISTOR injection to 6 mg is recommended in patients with moderate or severe renal impairment and in patients with severe hepatic impairment. See full Prescribing Information for details.[1]

Additional dosing recommendations

RELISTOR therapy should be continued only during opioid use. Re-evaluate the need for RELISTOR if the opioid regimen is changed to avoid adverse reactions.[1]

For adults with OIC and CNCP: Discontinue all maintenance laxative therapy prior to initiation of RELISTOR. Laxative(s) can be used as needed if there is a suboptimal response to RELISTOR after 3 days.[1]

IMPORTANT SAFETY INFORMATION *(continued)*

- Cases of gastrointestinal perforation have been reported in adult patients with opioid-induced constipation and advanced illness with conditions that may be associated with localized or diffuse reduction of structural integrity in the wall of the gastrointestinal tract (e.g., peptic ulcer disease, Ogilvie's syndrome, diverticular disease, infiltrative gastrointestinal tract malignancies or peritoneal metastases). Take into account the overall risk-benefit profile when using RELISTOR in patients with these conditions or other conditions which might result in impaired integrity of the gastrointestinal tract wall (e.g., Crohn's disease). Monitor for the development of severe, persistent, or worsening abdominal pain; discontinue RELISTOR in patients who develop this symptom.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

RELISTOR subcutaneous injection: The first and only PAMORA indicated for the treatment of OIC in adults with advanced illness or active cancer pain who require opioid dosage escalation for palliative care[1-5]

Dosing recommendations for adult patients with advanced illness and active cancer pain[1]

RELISTOR injection weight-based dosing[1]

	Weight of adult patient	Subcutaneous dose, QOD	Injection volume
Every other day (QOD) as needed; maximum once daily	Less than 38 kg	0.15 mg/kg	See below*
	38 kg to <62 kg	8 mg	0.4 mL
	62 kg to 114 kg	12 mg	0.6 mL
	More than 114 kg	0.15 mg/kg	See below*
8-mg syringe, 12-mg syringe, and 12-mg vial available	For detailed administration instructions, please see the Instructions For Use in the accompanying full Prescribing Information		

The prefilled syringe is only for patients who require a RELISTOR injection dose of 8 mg or 12 mg. Use the vial for patients who require other doses of RELISTOR injection.[1]
Dose reduction is recommended in patients with moderate or severe renal impairment and patients with severe hepatic impairment.[1]
*Calculate the injection volume for these patients by multiplying the patient weight in kilograms by 0.0075 and then rounding up the volume to the nearest 0.1 mL.[1]
PAMORA, peripherally acting mu-opioid receptor antagonist.

IMPORTANT SAFETY INFORMATION *(continued)*

- If severe or persistent diarrhea occurs during treatment, advise patients to discontinue therapy with RELISTOR and consult their healthcare provider.
- Symptoms consistent with opioid withdrawal, including hyperhidrosis, chills, diarrhea, abdominal pain, anxiety, and yawning have occurred in patients treated with RELISTOR. Patients having disruptions to the blood-brain barrier may be at increased risk for opioid withdrawal and/or reduced analgesia and should be monitored for adequacy of analgesia and symptoms of opioid withdrawal.
- Avoid concomitant use of RELISTOR with other opioid antagonists because of the potential for additive effects of opioid receptor antagonism and increased risk of opioid withdrawal.
- The use of RELISTOR during pregnancy may precipitate opioid withdrawal in a fetus due to the immature fetal blood-brain barrier and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Because of the potential for serious adverse reactions, including opioid withdrawal, in breastfed infants, advise women that breastfeeding is not recommended during treatment with RELISTOR. In nursing mothers, a decision should be made to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.
- A dosage reduction of RELISTOR tablets and RELISTOR injection is recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute as estimated by Cockcroft-Gault). No dosage adjustment of RELISTOR tablets or RELISTOR injection is needed in patients with mild renal impairment.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

SEE LAST PAGE FOR APPLICABLE ICD-10-CM CODES

RELISTOR®
methylnaltrexone bromide
Tablets & Subcutaneous Injection

You have the power to intervene early. Choose RELISTOR for your adult chronic pain patients with OIC[1,6]

Applicable ICD-10-CM codes*

K59.03	Drug-induced constipation
K59.00	Constipation, unspecified
K59.09	Other constipation

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification

*The *ICD-10-CM* codes and all other patient access–related information are provided for informational purposes only. It is the treating physician's responsibility to determine the proper diagnosis, treatment, and applicable *ICD-10-CM* code. Salix does not guarantee coverage or reimbursement for the product.

LEARN MORE ABOUT RELISTOR DOSING AT **RELISTORHCP.COM**

IMPORTANT SAFETY INFORMATION *(continued)*

- A dosage reduction of RELISTOR tablets is recommended in patients with moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment. No dosage adjustment of RELISTOR tablets is needed in patients with mild hepatic impairment (Child-Pugh Class A). No dosage adjustment of RELISTOR injection is needed for patients with mild or moderate hepatic impairment. In patients with severe hepatic impairment, monitor for methylnaltrexone-related adverse reactions and dose adjust per Prescribing Information as may be indicated.
- In the clinical studies, the most common adverse reactions were:

OIC in adult patients with chronic non-cancer pain

- RELISTOR tablets (≥ 2% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (14%), diarrhea (5%), headache (4%), abdominal distention (4%), vomiting (3%), hyperhidrosis (3%), anxiety (2%), muscle spasms (2%), rhinorrhea (2%), and chills (2%).
- RELISTOR injection (≥ 1% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (21%), nausea (9%), diarrhea (6%), hyperhidrosis (6%), hot flush (3%), tremor (1%), and chills (1%).

OIC in adult patients with advanced illness

- RELISTOR injection (≥ 5% of RELISTOR patients and at a greater incidence than placebo): abdominal pain (29%), flatulence (13%), nausea (12%), dizziness (7%), and diarrhea (6%).

To report SUSPECTED ADVERSE REACTIONS, contact Salix Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

REFERENCES: 1. RELISTOR [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals. **2.** AMITIZA (lubiprostone) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc; 2020. **3.** MOVANTIK® (naloxegol) [prescribing information]. Raleigh, NC: RedHill Biopharma Inc; 2023. **4.** SYMPROIC® (naldemedine) [prescribing information]. Raleigh, NC: BioDelivery Sciences International, Inc; 2020. **5.** Pergolizzi JV Jr, Christo PJ, LeQuang JA, et al. The use of peripheral μ-opioid receptor antagonists (PAMORA) in the management of opioid-induced constipation: an update on their efficacy and safety. *Drug Des Devel Ther.* 2020;14:1009-1025. doi:10.2147/DDDT.S221278 **6.** Coyne KS, LoCasale RJ, Datto CJ, Sexton CC, Yeomans K, Tack J. Opioid-induced constipation in patients with chronic noncancer pain in the USA, Canada, Germany, and the UK: descriptive analysis of baseline patient-reported outcomes and retrospective chart review. *Clinicoecon Outcomes Res.* 2014;6:269-281.

Salix Pharmaceuticals

www.salix.com
400 Somerset Corporate Boulevard Bridgewater, NJ 08807
Tel 800-321-4576

REL.0136.USA.23

RELISTOR® methylnaltrexone bromide Tablets & Subcutaneous Injection