

**MEDICATION GUIDE**  
**RELISTOR® (rel - i - store)**  
**(methylnaltrexone bromide)**  
**Subcutaneous Injection**

Read this Medication Guide before you start using RELISTOR and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**What is the most important information I should know about RELISTOR?**

**RELISTOR can cause serious side effects, including:**

- **Tear in your stomach or intestinal wall (perforation).** Stomach pain that is severe can be a sign of a serious medical condition. If you get stomach pain that does not go away, stop taking RELISTOR and get emergency medical help right away.
- **Diarrhea that is severe or that will not go away.** Stop using RELISTOR and call your healthcare provider if you get diarrhea that is severe or that does not go away during treatment with RELISTOR.
- **Opioid withdrawal.** You may have symptoms of opioid withdrawal during treatment with RELISTOR including sweating, chills, diarrhea, stomach pain, anxiety, and yawning. Tell your healthcare provider if you have any of these symptoms.

**What is RELISTOR?**

RELISTOR is a prescription medicine used to treat constipation that is caused by prescription pain medicines called opioids, in adults:

- with long-lasting (chronic) pain that is not caused by cancer
- receiving treatment for advanced illness, when other medicines for constipation have not worked well enough

It is not known if RELISTOR is safe and effective if used for longer than 4 months in people with advanced illness.

It is not known if RELISTOR is safe and effective in children.

**Who should not use RELISTOR?**

**Do not use RELISTOR if you** have a bowel blockage (intestinal obstruction) or have a history of bowel blockage.

**What should I tell my healthcare provider before using RELISTOR?**

**Before you start using RELISTOR, tell your healthcare provider about all of your medical conditions, including if you:**

- have kidney problems
- have any stomach or bowel (intestines) problems, including stomach ulcer, Crohn's disease, diverticulitis, cancer of the stomach or bowel, or Ogilvie's syndrome
- are pregnant or plan to become pregnant. Taking RELISTOR during pregnancy may cause opioid withdrawal symptoms in your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with RELISTOR.
- are breastfeeding or plan to breastfeed. It is not known if RELISTOR passes into your breast milk. Taking RELISTOR while you are breastfeeding may cause opioid withdrawal in your baby. You and your healthcare provider should decide if you will take RELISTOR or breastfeed. You should not do both.

**Tell your healthcare provider about all of the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

## How should I use RELISTOR?

See the detailed Instructions for Use that comes with RELISTOR for information about how to prepare and inject RELISTOR, and properly throw away (dispose of) used needles and syringes the right way.

- RELISTOR is injected under the skin (subcutaneous injection) of the upper arm, stomach-area (abdomen), or thigh.
- Inject RELISTOR exactly as your healthcare provider tells you.
- Stay close to a toilet after using RELISTOR.
- Stop using RELISTOR if you stop taking your prescription opioid pain medicine. Tell your healthcare provider if your pain medication changes.
- If you take too much RELISTOR, call your healthcare provider or go to the nearest emergency room right away.
- **If you use RELISTOR for long-lasting (chronic) pain that is not caused by cancer:**
  - RELISTOR has been shown to be effective in people who have taken opioid pain medicines for at least 4 weeks to treat long-lasting (chronic) pain not caused by cancer.
  - Stop taking other laxatives before you start treatment with RELISTOR. You may use other laxatives if RELISTOR does not work after 3 days of treatment.
  - Inject 1 dose of RELISTOR each day.
- **If you use RELISTOR and are receiving treatment for advanced illness:**
  - Inject 1 dose of RELISTOR every other day, as needed. You should not inject more than 1 dose of RELISTOR in a 24-hour period.

## What are the possible side effects of RELISTOR?

See “What is the most important information I should know about RELISTOR?”

- **The most common side effects of RELISTOR in people with long-lasting (chronic) pain that is not caused by cancer include:** stomach-area (abdomen) pain, nausea, diarrhea, sweating, hot flush, tremor, and chills.
- **The most common side effects of RELISTOR in people receiving treatment for their advanced illness include:** stomach-area (abdomen) pain, gas, nausea, dizziness, and diarrhea.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of RELISTOR.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Salix Pharmaceuticals at 1-800-508-0024.

## How should I store RELISTOR?

- Store RELISTOR vials and pre-filled syringes at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze RELISTOR.
- Keep RELISTOR away from light until you are ready to use it.

If RELISTOR has been drawn into a syringe and you are unable to use the medicine right away, keep the syringe at room temperature for up to 24 hours.

**Keep RELISTOR and all medicines, needles and syringes out of the reach of children.**

## General information about RELISTOR

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use RELISTOR for a condition for which it was not prescribed. Do not give RELISTOR to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RELISTOR that is written for health professionals.

**What are the ingredients in RELISTOR?****Active ingredient:** methylnaltrexone bromide**Inactive ingredients:** sodium chloride, edetate calcium disodium USP, glycine hydrochloride. During manufacture, the pH may have been adjusted with hydrochloric acid and/or sodium hydroxide.

Manufactured for: Salix Pharmaceuticals, Inc., Raleigh, NC 27615

Under license from: Progenics Pharmaceuticals, Inc., Tarrytown, NY 10591

Product protected by U.S. Patent Nos. 6,559,158, 8,247,425, and 8,420,663.

Please see [www.salix.com](http://www.salix.com) for patent information. For more information, go to [www.RELISTOR.com](http://www.RELISTOR.com) or call 1-800-508-0024.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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