

# RELISTOR®

## Subcutaneous, Solution for Injection

Methylnaltrexone bromide

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about RELISTOR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RELISTOR against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

#### What RELISTOR is used for

The name of your medicine is RELISTOR. It contains the active ingredient called methylnaltrexone bromide.

RELISTOR is used to relieve constipation caused by strong pain relievers called opiates (for example, morphine, codeine) prescribed by your doctor. RELISTOR works by stimulating the muscle contractions of the digestive tract. This helps waste move more easily through the intestines. RELISTOR is used when other medicines to treat constipation, called laxatives, have not worked well enough.

Your doctor may have prescribed RELISTOR for another reason. Ask your doctor if you have any questions about why RELISTOR has been prescribed for you.

There is no evidence that RELISTOR is addictive.

This medicine is available only with a doctor's prescription.

3. The packaging is torn or shows signs of tampering.

4. The expiry date (EXP) printed on the pack has passed.

If you use RELISTOR after the expiry date has passed, it may have no effect at all, or worse, have an entirely unexpected effect.

**If you are not sure whether you should start using RELISTOR, contact your doctor.**

#### *Before you use RELISTOR*

#### *When you must not use it*

##### **Do not use RELISTOR if:**

1. You have an allergy to RELISTOR or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include wheezing, shortness of breath, difficulty breathing, or a tight feeling in your chest, swelling of the face, lips, tongue or other parts of the body, rash, itching, hives or flushed red skin, dizziness or light-headedness.

2. You think you have any acute abdominal condition other than constipation, or if you experience persistent stomach pain, nausea (feeling sick in the stomach) or vomiting that is new or has worsened.

Symptoms of an acute abdominal condition include tenderness of the abdomen, increasing abdominal pain, increased abdominal bloating.

#### *Before you use it*

##### **Tell your doctor if:**

1. You have any allergies to the following:

- Any other medicines
- Any other substances, such as foods, preservatives or dyes.

2. You have severe kidney or liver disease

3. You have a colostomy, a peritoneal catheter, or already known disease called diverticular disease or faecal impaction

4. You have suffered from constipation before you had to take opiates (for pain)

5. You are pregnant or intend to become pregnant

The effects of RELISTOR in pregnant women are not known, and so the use of RELISTOR during pregnancy is not recommended unless clearly necessary.

## **6. You are breast-feeding or plan to breast-feed**

Women using RELISTOR should not breast-feed, since it is not known if RELISTOR passes into human breast milk.

**If you have not told your doctor about any of the above, tell them before you start using RELISTOR.**

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when using RELISTOR with other medicines. RELISTOR may interact with other medicines such as:

- bevacizumab, used to treat some cancers
- non-steroidal anti inflammatory drugs (NSAIDs), used to treat inflammation, pain and fever
- steroids, used to treat inflammation.

## **How to use RELISTOR**

RELISTOR contains no additives that would prevent the growth of bacteria. For this reason, each vial of RELISTOR is for single use only, in one patient only. Discard any residue.

**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

### *How much to use*

Your doctor will determine what dose you should take. Never inject more than the dose recommended by your doctor.

### *How to use it*

RELISTOR is given by an injection under the skin (by subcutaneous injection) in either (1) your upper legs (thighs), (2) your abdomen (stomach), and (3) your upper arm (if not self-injecting). RELISTOR can be taken with or without food.

### **See INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF RELISTOR.**

It is recommended to move to a different site each time an injection is given. Do not inject into areas where the skin is tender, bruised, red, or hard, taking care to avoid areas with scars or stretch marks.

Most patients who respond to RELISTOR have a bowel movement within a few minutes to a few hours of the injection; therefore it is recommended to have a toilet facility or bedpan near you.

### *When to use it*

RELISTOR should be used as a single dose on alternate days. Doses may also be given with longer intervals, as needed. If there has been no bowel movement within 24 hours of the last dose, an additional dose may be given. No more than one dose of RELISTOR should be given in a 24-hour period.

### *How long to take it*

**You should continue to use RELISTOR for as long as your doctor recommends.**

### *If you forget to take it*

**If you forget to give yourself an injection, you should contact your doctor or pharmacist as soon as possible.**

**Do not use a double dose to make up for the dose that you missed.**

### *If you take too much (overdose)*

**If you have used more RELISTOR than you should (either by injecting too much on a single occasion or by using more than one injection in 24 hours), immediately telephone your doctor or the Poisons Information Centre (in Australia Tel 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much RELISTOR. Do this even if there are no signs of discomfort or poisoning. Always take the labelled medicine carton with you, even if it is empty.**

You may need urgent medical attention. There is very limited data on overdose with RELISTOR. Ask your doctor if you have any concerns.

## **While you are using RELISTOR**

### *Things you must do*

**Tell any other doctors, dentists, and pharmacists who are treating you that you are using RELISTOR.**

**Tell your doctor if RELISTOR is not making your condition better.**

**Be careful driving or operating dangerous machinery until you know how it affects you.**

RELISTOR may cause dizziness, and this may have an effect on driving and use of machines.

**Tell your doctor if you experience severe or persistent diarrhoea whilst using RELISTOR.**

It is important to be near a toilet with assistance available if necessary, since bowel movement may happen within 30 minutes after injection of the medicine.

**Stop using RELISTOR and tell your doctor if you get abdominal pain that will not go away or nausea or vomiting that is new or worse.**

RELISTOR may increase the risk of stomach or intestinal perforation, especially in the presence of conditions that weaken the stomach or intestinal wall, such as cancer and ulcers of the stomach or intestine.

#### *Things you must not do*

**Do not give RELISTOR to anyone else even if they have the same condition as you.**

**Do not use RELISTOR to treat any other complaints unless your doctor tells you to.**

## **Side Effects**

**Check with your doctor as soon as possible if you have any problems while taking RELISTOR, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.**

Like all medicines, RELISTOR can cause side effects, although not everyone gets them.

As with other injected medicines, common injection site reactions (e.g. stinging, burning, pain, redness, oedema) may occur.

The most common side effects likely to occur in more than one in ten patients receiving RELISTOR are:

- Abdominal pain (belly ache)
- Nausea (feeling sick in the stomach)
- Flatulence (passing wind)
- Diarrhoea (passing of frequent watery stools)
- Excessive sweating

Common side effects likely to occur in more than one in 100 patients, but in less than one in ten patients receiving RELISTOR are:

- Dizziness (light-headed)

Other side effects may occur when using RELISTOR.

**Tell your healthcare professional if you have any side effect that bothers you or that does not go away or that gets serious.**

## **How to store RELISTOR**

**Keep out of the reach and sight of children.**

RELISTOR should be stored below 30°C and should be protected from light.

**Do not use RELISTOR after the expiry date, which is stated on the carton and vial.**

Only use RELISTOR if the solution is clear, colourless to pale yellow and does not contain lumps or flakes or particles.

## **Disposal**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

The syringe and needle should NEVER be reused. NEVER recap the needle. Needles should be disposed of properly in a "puncture-resistant container" or as per instructions from your doctor, nurse or pharmacist.

## **Product Description**

### *What it looks like*

The following packs are available:

- A single vial.
- A convenience pack containing 7 cartons. Each carton contains:

One 12 mg/0.6 ml single-use vial (20 mg/ml), one 1 ml syringe, two alcohol swabs.

## *Ingredients*

The active substance is methylnaltrexone bromide.

The other ingredients are sodium chloride, sodium calcium edetate, glycine hydrochloride and water for injections.

RELISTOR does not contain lactose, gluten, tartrazine or any other azo dyes.

## *Supplier*

**Link Medical Products Pty Ltd**  
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Warriewood  
NSW 2102

**Australian Registration Number**  
12 mg solution; AUST R 144062

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