

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using RELISTOR?

RELISTOR contains the active ingredient methylnaltrexone bromide. RELISTOR is used to relieve constipation caused by strong pain relievers called opiates (for example, morphine, codeine).

For more information, see Section [1. Why am I using RELISTOR?](#) in the full CMI.

### 2. What should I know before I use RELISTOR?

Do not use if you have ever had an allergic reaction to RELISTOR or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use RELISTOR?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with RELISTOR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use RELISTOR?

- RELISTOR is given by subcutaneous injection in the upper arm, abdomen or thigh as a single dose, on alternate days.
- RELISTOR is for single use in one patient only.

More instructions can be found in Section [4. How do I use RELISTOR?](#) in the full CMI.

### 5. What should I know while using RELISTOR?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Be near a toilet. A bowel movement may occur quickly, within 30mins after being given RELISTOR.</li><li>• Remind any doctor, dentist or pharmacist you visit that you are using RELISTOR.</li><li>• Tell your doctor if you experience severe or persistent diarrhoea whilst using RELISTOR.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use RELISTOR if you know or suspect there is a blockage of the intestines (mechanical bowel obstruction).</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating dangerous machinery until you know how it affects you, as RELISTOR may cause dizziness.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• RELISTOR should be stored below 30°C, protected from light.</li><li>• Once RELISTOR is drawn into a syringe, use immediately or discard after 6 hours.</li></ul>

For more information, see Section [5. What should I know while using Relistor?](#) in the full CMI.

### 6. Are there any side effects?

Abdominal cramping or abdominal pain are common, after receiving RELISTOR. However if this pain is not relieved by having a bowel motion, speak to your doctor. If you have severe, persistent and/or worsening abdominal pain, nausea, or vomiting, stop using RELISTOR and tell your doctor.

Side effects that require urgent medical attention include: Signs of an allergic reaction, such as chest tightness, difficulty breathing, swelling of face lips and tongue.

Other possible side effects include: flatulence, nausea, dizziness, diarrhoea, excessive sweating.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# RELISTOR®

Active ingredient(s): *methylnaltrexone bromide*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using RELISTOR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RELISTOR.**

Where to find information in this leaflet:

- [1. Why am I using RELISTOR?](#)
- [2. What should I know before I use RELISTOR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RELISTOR?](#)
- [5. What should I know while using RELISTOR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

### 1. Why am I using RELISTOR?

RELISTOR contains the active ingredient **methylnaltrexone bromide**. RELISTOR is a type of opioid receptor antagonist, that blocks the effects of opioids in the gastrointestinal tract, without affecting pain relief.

**RELISTOR is used to relieve constipation caused by opioid pain relievers.**

RELISTOR is used when other medicines used to treat constipation (laxatives) have not worked effectively.

### 2. What should I know before I use RELISTOR?

#### Warnings

**Do not use RELISTOR if:**

- You are allergic to methylnaltrexone bromide, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have or suspect a blockage in the bowel (mechanical bowel obstruction).
- You have severe, persistent or worsening abdominal pain, nausea or vomiting.

**Check with your doctor if you:**

- Take any medicines for any other condition
- Have any existing bowel related conditions, such as a colostomy, a peritoneal catheter, diverticular disease, or any faecal impaction.
- Have suffered from constipation before you had to take opioid pain killers

- Have severe kidney disease. Your doctor may reduce your dose of RELISTOR.
- You have severe liver disease.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. The effect of RELISTOR on pregnancy is unknown. The use of RELISTOR during pregnancy is therefore not recommended.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is unknown whether RELISTOR passes into human breast milk. The use of RELISTOR whilst breastfeeding is therefore not recommended.

### 3. What if I am taking other medicines?

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

**The following medicines, when used in conjunction with RELISTOR may increase the risk of gastric side effects:**

- Bevacizumab (used to treat some cancers)
- Non-steroidal anti inflammatory drugs (NSAIDs), used to treat inflammation, pain and fever
- Steroids (used to treat inflammation)

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RELISTOR.**

### 4. How do I use RELISTOR?

#### How much to use

- Your doctor will determine what dose, and for how long you should be given RELISTOR.
- RELISTOR is usually given as a single dose on alternate days. The interval between doses may be longer. 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 to use RELISTOR

- RELISTOR is given by subcutaneous (under the skin) injection in either the upper arm, abdomen or thigh.

- It is recommended to change the site of injection every time the injection is given
- Do not inject into areas where the skin is tender, bruised, red or hard. Take care to avoid areas with scars or stretch marks.
- RELISTOR may be injected without regard to food.
- RELISTOR is for single use, in one patient only. Discard any residue.
- Only use RELISTOR if the solution is clear, colourless to pale yellow, and does not contain lumps or flakes or particles.

### If you forget to use RELISTOR

If you miss a dose of RELISTOR, you should contact your doctor or pharmacist as soon as possible.

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

### If you use too much RELISTOR

If you think that you have used too much RELISTOR, you may need urgent medical attention.

Be careful when standing up, as your blood pressure may be affected. If sitting or lying down, stand up slowly.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), or (by calling 0800 764 766 in New Zealand)
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using RELISTOR?

### Things you should do

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

**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 very quickly, within 30 minutes after injection of the medicine.

Remind any doctor, dentist or pharmacist you visit that you are using RELISTOR.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how RELISTOR affects you.**

RELISTOR may cause dizziness in some people

### Looking after your medicine

- Store below 30°C.
- Protect from light.

- Use as soon as possible after opening and withdrawal into the syringe. If immediate use is not possible, store at room temperature, and discard after 6 hours.

**Keep it where young children cannot reach it.**

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal side effects:</b> <ul style="list-style-type: none"> <li>Abdominal pain</li> <li>Flatulence</li> <li>Nausea</li> <li>Diarrhoea</li> </ul> <b>Other:</b> <ul style="list-style-type: none"> <li>Dizziness</li> <li>Excessive sweating</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>New, persistent or worsening abdominal pain, nausea, or vomiting</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at

[www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What RELISTOR contains

<b>Active ingredient (main ingredient)</b>	Methylnaltrexone bromide
<b>Other ingredients (inactive ingredients)</b>	Glycine hydrochloride Hydrochloride acid Sodium calcium edetate Sodium chloride Sodium hydroxide Water for injections

**Do not take this medicine if you are allergic to any of these ingredients.**

### What RELISTOR looks like

RELISTOR is a sterile, clear and colourless to pale yellow aqueous solution for injection.

(Aust R 144062).

### Who distributes RELISTOR

Link Medical Products Pty Ltd  
5 Apollo Street  
Warriewood, NSW 2102  
Australia  
Ph: 1800 181 060  
linkhealthcare.com.au

Link Pharmaceuticals Ltd  
Suite 38, Level 8,  
139 Quay Street  
Auckland 1010  
New Zealand  
Ph: +64(9) 358 7146

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