

## **Package leaflet: Information for the user**

### **Relistor 12 mg/0.6 mL solution for injection** Methylnaltrexone bromide

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Relistor is and what it is used for
2. What you need to know before you use Relistor
3. How to use Relistor
4. Possible side effects
5. How to store Relistor
6. Contents of the pack and other information

#### **1. What Relistor is and what it is used for**

Relistor contains an active substance called methylnaltrexone bromide which acts by blocking the side effects of opioid pain medicines that affect the bowel.

It treats constipation that is caused by medicines for moderate to severe pain called opioids (for example morphine or codeine). It is used for patients when other medicines for constipation, called laxatives, have not worked well enough. Opioids are prescribed by your doctor. Your doctor will tell you whether you should stop or continue taking your usual laxatives when you start using this medicine.

This medicine is for use in adults (aged 18 and over).

#### **2. What you need to know before you use Relistor**

##### **Do not use Relistor**

- If you are allergic to methylnaltrexone bromide or any of the other ingredients of this medicine (listed in section 6).
- If you or your doctor know that your bowels were or are obstructed or your bowels are in a state where there is an immediate need for surgical intervention (which has to be diagnosed by your doctor).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Relistor.

- If you have severe stomach symptoms which continue or get worse, contact your doctor immediately because these could be symptoms of a hole developing in the bowel wall (intestinal perforation). See section 4.
- If you have Crohn's disease or gastrointestinal ulcers
- If you feel sick, vomit, shiver, sweat, have belly pain and/or feel a fast heart beat shortly after taking Relistor talk to your doctor

- If you have severe liver or kidney disease.
- If you develop severe or persistent diarrhoea (passing of frequent watery stools), discontinue therapy and contact your doctor immediately.
- 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.
- Please talk to your doctor if you experience stomach ache which continues, nausea (feeling sick) or vomiting (being sick) that is new or becomes worse.
- Please also talk to your doctor if you have a colostomy, a tube in your abdomen (peritoneal catheter), or suffer from diverticular disease or faecal impaction as this medicine should be used carefully in these circumstances.
- If you are receiving supportive care for your advanced illness, this medicine will only be used for a limited period of time, which will usually be less than 4 months.
- This medicine should not be used for treatment of patients with constipation which is not related to opioid use. If you have suffered from constipation before you had to take opioids (for pain), please talk to your doctor.

### **Children and adolescents**

Do not give this medicine to children and adolescents under the age of 18 because the potential risks and benefits are not known.

### **Other medicines and Relistor**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may allow you to take other medicines, including those used for constipation.

### **Pregnancy and breast-feeding**

The effects of methylnaltrexone bromide in pregnant women are not known. Your doctor will decide if you can use Relistor if you are pregnant.

Women using this medicine should not breast-feed, since it is not known if methylnaltrexone bromide passes into human breast milk.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Dizziness is a common side effect of this medicine. This may have an effect on your ability to drive and use machines.

### **Important information about some of the ingredients of Relistor**

This medicine contains less than 1 mmol sodium (23 mg) per dose i.e., essentially “sodium free.”

## **3. How to use Relistor**

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for patients with long-term pain (except patients receiving supportive care for advanced illness) is 12 mg methylnalrexone bromide (0.6 mL of solution) given as an injection under the skin, as needed, but at least given 4-times a week and up to once a day (7 times a week).

The recommended dose for patients receiving supportive care for advanced illness is 8 mg methylnaltrexone bromide (0.4 mL of solution) for patients weighing 38-61 kg or 12 mg (0.6 mL of

solution) for patients weighing 62-114 kg. The dose is given every 48 hours (every two days) as an injection under the skin.

Your doctor will determine your dose.

This medicine 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). (See INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF RELISTOR at the end of this leaflet.)

You may 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.

#### **If you use more Relistor than you should**

If you have used more this medicine than you should (either by injecting too much on a single occasion or by using more than one injection in 24 hours), you may feel dizzy when standing up, so talk to a doctor or pharmacist immediately. Always have the outer carton of the medicine with you, even if it is empty.

#### **If you forget to use Relistor**

If you forget a dose, talk to your doctor or pharmacist as soon as possible. Do not take a double dose to make up for a forgotten dose.

#### **If you stop using Relistor**

You should talk to a doctor or pharmacist if you want to stop using this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Cases of a hole developing in the bowel wall (gastrointestinal perforation) have been reported in patients using Relistor. How often this happens is not known from the data that is available. If you get a stomach ache that is either severe or will not go away, stop taking this medicine and call your doctor straight away.

The following side effects are very common and may affect more than 1 in 10 people. If you experience any of these side effects, which are either severe or will not go away, you should talk to your doctor:

- Abdominal pain (stomach ache)
- Nausea (feeling sick)
- Diarrhoea (passing of frequent watery stools)
- Flatulence (passing wind)

Other common side effects that may affect up to 1 in 10 people are:

- Dizziness (light-headed)

- Opioid-withdrawal-like symptoms (any of the following: feeling cold, shivering, runny nose, sweating, hair standing on end, blushing, fast heart beat)
- Reaction at the site of injection (e.g., stinging, burning, pain, redness, oedema)
- Vomiting

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Relistor**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Keep the vial in the outer carton in order to protect from light.

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Relistor contains**

- The active substance is methylnaltrexone bromide. Each vial of 0.6 mL contains 12 mg methylnaltrexone bromide. One mL of solution contains 20 mg methylnaltrexone bromide.
- The other ingredients are sodium chloride, sodium calcium edetate, glycine hydrochloride, water for injections, hydrochloric acid (to adjust pH) and sodium hydroxide (to adjust pH).

### **What Relistor looks like and contents of the pack**

Relistor is a solution for injection. It is clear, colourless to pale yellow, and does not contain flakes or particles.

Each vial contains 0.6 mL of solution.

Packs of more than one vial contain inner cartons consisting of: one vial, one 1 mL injection syringe with retractable injection needle, and two alcohol swabs.

The following packs are available:

Single vial

Pack containing 2 vials, 2 injection syringes with retractable injection needle, and 4 alcohol swabs (i.e. 2 inner cartons).

Pack containing 7 vials, 7 injection syringes with retractable injection needle, and 14 alcohol swabs (i.e. 7 inner cartons).

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

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**Manufacturer**

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**PATIENT CHECKLIST**

This section contains important questions that you will need to answer before you take Relistor, and during treatment with Relistor.

If you answer No to any of the following questions during the course of treatment with your medicine, please contact your doctor, nurse or pharmacist.

1. Are you receiving opioid therapy (for example morphine or codeine) for your illness?
2. Has it been 48 hours or longer since your last bowel movement?
3. Are you familiar with the technique of self injection or have you discussed this with your doctor (or nurse or pharmacist)?
4. Are you mobile enough to reach the toilet, or do you have a caregiver looking after you who can help?
5. Do you have a contact number for your community nurse or the health centre?

**INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF RELISTOR**

This section is divided into the following subsections:

Introduction

Step 1: Setting up for an injection

Step 2: Preparing the injection syringe

Step 3: Choosing and preparing an injection site

Step 4a: Injecting Relistor using a pack containing injection syringe with retractable injection needle

Step 4b: Injecting Relistor using a standard injection syringe and injection needle

Step 5 Disposing of supplies

## Introduction

The following instructions explain how to inject Relistor. Please read the instructions carefully and follow them step by step. You will be instructed by your doctor, nurse or pharmacist on the techniques of self-administration. Do not attempt to administer an injection until you are sure that you understand how to give the injection. This injection should not be mixed in the same syringe with any other medicine.

You may receive either a pack containing an inner carton with everything needed for the injection, or a single vial only. If you receive only the vial, you will need to obtain alcohol swabs and an injection syringe.

### Step 1: Setting up for an injection

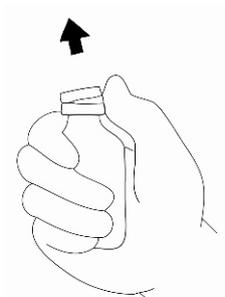
1. Select a flat, clean, well-lit working surface where you can lay out the contents of your Relistor carton. Make sure you have set aside a proper amount of time to complete the injection.
2. Wash your hands thoroughly with soap and warm water.



3. Assemble the supplies you will need for your injection. These include the Relistor vial, a 1 mL injection syringe (with or without retractable needle), 2 alcohol swabs, and a cotton ball or gauze.
4. Make sure the solution in the vial is clear and colourless to pale yellow, and does not contain flakes or particles. If it is not, do not use the solution. Contact your pharmacist, nurse or doctor for assistance.

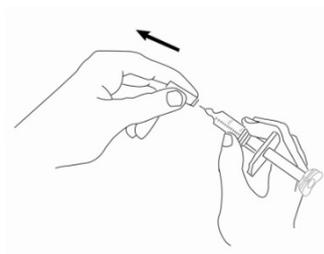
### Step 2: Preparing the injection syringe

1. Remove the protective plastic cap from the vial.



2. Wipe the vial's rubber stopper with an alcohol swab and place it on your flat work surface. Make sure not to touch the rubber stopper again.

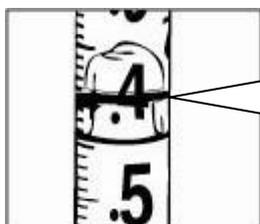
- Pick up the syringe from your work surface. Hold the barrel of the syringe with one hand and pull the needle cover straight off. Place the needle cover back on the work surface. **DO NOT** touch the needle or allow it to come into contact with any other surface.



Carefully pull back the plunger on the syringe to either the 0.4 mL mark for 8 mg of Relistor or the 0.6 mL mark for 12 mg Relistor. Your doctor, nurse or pharmacist will have advised you which dose they have prescribed for you and how often you need to take it. For patients receiving supportive care for advanced illness, the usual doses are given in the table below. The dose is normally given every 48 hours (every two days) as an injection under the skin.

<u>Patient weight in kg</u>	<u>Fill syringe to mL level (dose)</u>
Less than 38 kg	0.15 mg/kg
38-61 kg	0.4 mL (8 mg)
62-114 kg	0.6 mL (12 mg)
More than 114 kg	0.15 mg/kg

For patients with long-term pain (except patients receiving supportive care for advanced illness), fill the syringe to the 0.6 mL mark for 12 mg of Relistor.



Carefully pull back the plunger to correct level on syringe (e.g. 0.4 mL if you have been prescribed 8 mg)

- Insert the needle straight down into the centre of the vial stopper. Do not insert it at an angle as the needle may bend or break. Hold the vial on the work surface with the other hand so that it can not slip off. You will feel a slight resistance as the needle passes through the stopper. Look for the needle tip inside the vial.

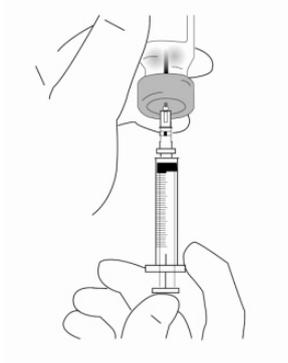


- In order to get the air out of the syringe, gently push the plunger down to inject the air into the vial.

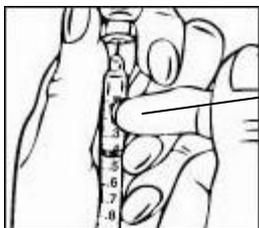


6. If you are using the supplied injection syringe with retractable injection needle, **DO NOT PUSH THE PLUNGER DOWN COMPLETELY**. Make sure you stop pushing the plunger when you feel resistance. If you push the plunger completely, you will hear a 'click' sound. This will mean that the safety mechanism has been activated, and the needle will disappear into the syringe. If this happens, discard the product and start again using another vial and syringe.

With the needle still in the vial, turn the vial upside-down. Hold the syringe at eye level so that you can see the dosing marks and make sure the tip of the needle is in the fluid all of the time. Slowly pull the plunger down to the 0.4 mL or 0.6 mL mark on the syringe or as advised, depending on the dose prescribed by your doctor, nurse or pharmacist. You may see some fluid or bubbles inside the vial when the syringe is properly filled. This is normal.

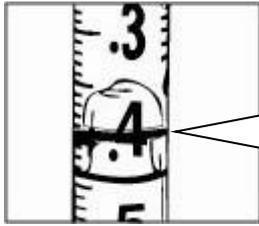


7. With the needle still inserted in the upside down vial, check for air bubbles in the syringe. Gently tap the syringe to make any air bubbles rise to the top of the syringe; be sure that you still hold onto the vial and syringe. Slowly push the plunger up until all air bubbles are removed. If you push solution back into the vial, slowly pull back the plunger to draw the correct amount of solution back into the syringe. Due to the safety design of the syringe, a small air bubble may be resistant to removal. There is no need to worry about this as it will not affect the accuracy of the dose or pose any risk to your health.



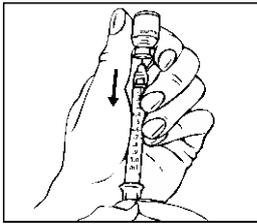
Tap the upside down syringe and push out any air bubbles with the plunger

8. Always make sure you have the correct dose in the syringe. If unsure, please contact your doctor, nurse or pharmacist.



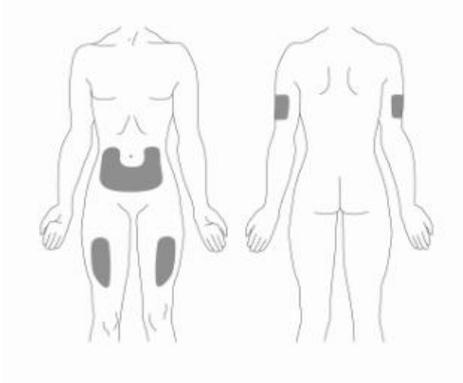
Ensure you have the correct dose level in the syringe (e.g. 0.4 mL if you have been prescribed 8 mg)

9. Remove the syringe and needle from the vial. Keep the needle attached to the syringe. Do not touch the needle or allow the needle to touch any surface. Once you have drawn the medicine into the syringe, it must be used within 24 hours because Relistor is affected by light and may not work properly if it is left in the syringe for longer than 24 hours.

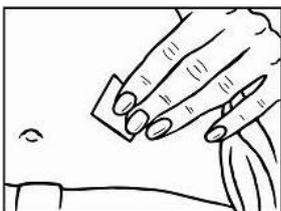


### Step 3: Choosing and preparing an injection site

1. The three areas of the body recommended for injection of Relistor are: (1) your upper legs (thighs), (2) your abdomen (stomach), and (3) your upper arm (only if injecting another person).

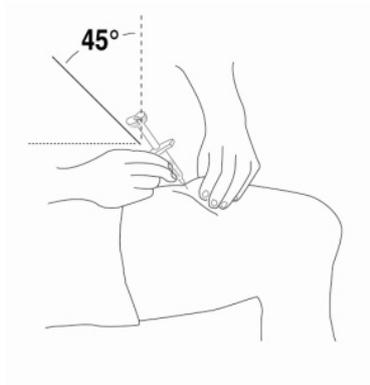


2. It is recommended to move to a different site each time an injection is given. Avoid repeated injections at the exact same spot previously used. Do not inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. To prepare the area of skin where Relistor is to be injected, wipe the injection site with an alcohol swab. **DO NOT TOUCH THIS AREA AGAIN BEFORE GIVING THE INJECTION.** Allow the injection site to air-dry before injecting.



#### **Step 4a: Injecting Relistor using a pack containing injection syringe with retractable injection needle**

1. Holding the filled syringe with the needle pointing up, recheck the syringe for air bubbles. If there are bubbles, gently tap the syringe with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.
2. Hold the syringe in one hand like a pencil. Use the other hand to gently pinch the cleaned area of skin and hold it firmly.
3. Push the full length of the needle into the skin at a slight angle (45 degrees) with a quick, short motion.

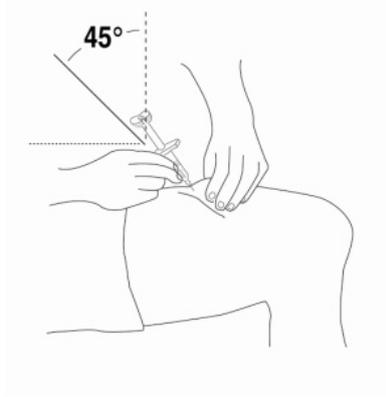


4. After the needle is inserted, let go of the skin and slowly push the plunger all the way down until the syringe is empty and you hear a click to inject Relistor.
5. When you hear a click sound that means the entire contents were injected. The needle will automatically retract from the skin and be capped. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site. Do not rub the injection site. If needed, you may cover the injection site with a plaster.



#### **Step 4b: Injecting Relistor using a standard injection syringe and injection needle**

1. Holding the filled syringe with the needle pointing up, recheck the syringe for air bubbles. If there are bubbles, gently tap the syringe with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.
2. Hold the syringe in one hand like a pencil. Use the other hand to gently pinch the cleaned area of skin and hold it firmly.
3. Push the full length of the needle into the skin at a slight angle (45 degrees) with a quick, short motion.



4. After the needle is inserted, let go of the skin and slowly push the plunger all the way down to inject Relistor.
5. When the syringe is empty, quickly pull the needle out of the skin, being careful to keep it at the same angle as inserted. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site. Do not rub the injection site. If needed, you may cover the injection site with a plaster.



#### **Step 5: Disposing of supplies**

The capped syringe or syringe and needle should NEVER be reused. NEVER recap the needle. Dispose of the capped syringe or needle and syringe in a closable puncture-resistant container as instructed by your doctor, nurse or pharmacist.