

Package leaflet: Information for the user

Relistor 8 mg solution for injection in pre-filled syringe Relistor 12 mg solution for injection in pre-filled syringe 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 breastfeeding, 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 methylnaltrexone 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 8 mg pre-filled syringe will only be used to treat these patients if the dose needs to be decreased because of another medical problem.

The recommended dose for patients receiving supportive care in 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.

If you weigh less than 38 kg or more than 114 kg you should use Relistor vials because the correct dose cannot be accurately delivered with these pre-filled syringes.

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 of 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 (belly 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 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, tray lid and syringe label after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Keep the pre-filled syringe 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 that 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 syringe of 0.4 mL contains 8 mg methylnaltrexone bromide. Each syringe 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.

The following packs are available:

Pack containing 4, 7, 8 or 10 pre-filled syringes with a needle shield.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Bausch Health Ireland Limited
3013 Lake Drive
Citywest Business Campus
Dublin 24, D24PPT3
Ireland

Manufacturer

Bausch Health Poland Sp. z o. o.,
ul. Kosztowska 21,
41-409 Mysłowice,
Poland

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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: Preparing for an injection

Step 2: Choosing and preparing an injection site

Step 3: Injecting Relistor pre-filled syringe

Step 4: Disposing of supplies

Introduction

The following instructions explain how to prepare and give an injection of Relistor when using a pre-filled syringe. Please read and follow them step by step. You will be instructed by your doctor, nurse or pharmacist on the techniques of self-injection. Do not attempt to administer an injection until you are sure that you understand how to prepare and give an injection.

Important notes:

- **Do not use a Relistor pre-filled syringe more than one time, even if there is medicine in the syringe.**
- **Safely throw away the Relistor pre-filled syringe after use (Step 4).**
- **To avoid needle-stick injuries, do not recap used needles.**

Gather the supplies you will need for your injection:

1. Relistor pre-filled syringe
2. Alcohol swab
3. Cotton ball or gauze
4. Adhesive plaster

Step 1: Preparing 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. Look at the pre-filled syringe. Make sure that the dose prescribed by your doctor matches the dose on the pre-filled syringe label.

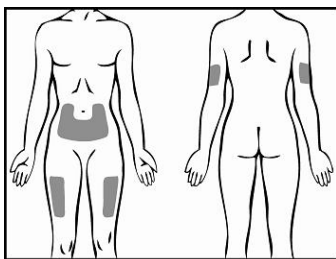


4. Make sure the liquid in the pre-filled syringe is clear and colourless to pale yellow, and does not have any particles in it. If not, do not use the pre-filled syringe and call your nurse, doctor or pharmacist.
5. Firmly hold the barrel of the pre-filled syringe and pull the needle cap straight off. Do not touch the needle or allow it to touch any surface.

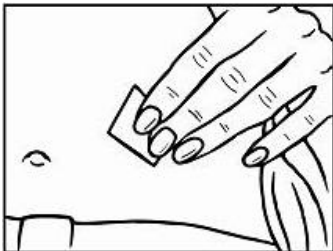


Step 2: Choosing and preparing an injection site

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. Clean the injection site with an alcohol swab and let it dry. Do not touch this area again before giving the injection.



Step 3: Injecting Relistor pre-filled syringe

1. 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.



2. Push the full length of the needle into the skin at a slight angle (45 degrees) with a quick, short motion.



3. After the needle is inserted, let go of the skin and slowly push the plunger all the way down until the pre-filled syringe is empty.



4. Quickly pull the needle out of the skin, being careful to keep it at the same angle as it was inserted. Release your thumb from the plunger to allow the protective sleeve to cover the needle. There may be a little bleeding at the injection site.



5. 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 4: Disposing of supplies

The pre-filled syringe should NEVER be reused. NEVER recap the needle. Dispose of the pre-filled syringe as instructed by your doctor, nurse or pharmacist.

Place used pre-filled syringe in a closable, puncture-resistant container. You may use a sharps container (such as a yellow biohazard container). Ask your doctor, nurse or pharmacist for instructions on the right way to throw away (dispose of) the container. There may be local laws about how you should throw away used needles and syringes.