

Rizmoic[®] 200 micrograms film-coated tablets

naldemedine

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking 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

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2. What you need to know before you take Rizmoic
3. How to take Rizmoic
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1. What Rizmoic is and what it is used for

Rizmoic contains the active substance naldemedine.

It is a medicine used in adults to treat **constipation caused by pain medicines**, called opioids (e.g morphine, oxycodone, fentanyl, tramadol, codeine, hydromorphone, methadone).

Your opioid pain medicine may cause the following symptoms:

- reduction in how often you pass stools
- hard stools
- stomach ache
- pain in the rectum when pushing hard stools out
- a feeling that the bowel is still not empty after passing stools.

Rizmoic can be used in patients using an opioid medicine for cancer pain or long term non-cancer pain after they have previously been treated with a laxative.

2. What you need to know before you take Rizmoic

Do not take Rizmoic:

- if you are allergic to naldemedine or any of the other ingredients of this medicine (listed in section 6).
- if your bowel is blocked or perforated, or if there is a high risk of your bowel becoming blocked, as a blockage may cause a hole to develop in the bowel wall.

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Rizmoic.

Warnings and precautions

Talk to your doctor or pharmacist **before taking** Rizmoic:

- if you suffer from a disease which may affect your bowel wall such as:
 - a stomach ulcer;
 - an enlarged colon due to a condition known as Ogilvie's syndrome;
 - diverticulitis (an illness where your gut is inflamed);
 - cancer of the bowel or peritoneum. The peritoneum is the lining of your gut area.
 - a disease causing severe inflammation of the digestive tract such as Crohn's disease .
- if you have cancer of the brain or central nervous system, multiple sclerosis, or Alzheimer's disease. If you have these conditions and develop opioid withdrawal symptoms (see section 4) or if the opioid medicine no longer controls your pain, contact your doctor immediately.
- if you have had a heart attack within the last 3 months or if you have other severe problems with your heart which cause daily symptoms
- if you have severe liver disease such as alcoholic liver disease, viral liver infection or impaired liver function.

- if you are taking certain medicines such as itraconazole to treat fungal infections, or an antibiotic called rifampicin to treat tuberculosis and other infections. See 'Other medicines and Rizmoic'.

If any of the above apply to you, or you are not sure, talk to your doctor or pharmacist before taking Rizmoic.

Talk to your doctor or pharmacist immediately **whilst taking** Rizmoic:

- if you develop **severe, lasting or worsening stomach pain** as this could be a symptom of developing a hole in your bowel wall and can be life-threatening. Speak to your doctor immediately and stop taking Rizmoic.
- if you suffer from **symptoms of opioid withdrawal syndrome** (see section 4 Possible side effects) which can develop within minutes to several days after taking a medicine such as Rizmoic. Stop taking Rizmoic and contact your doctor if you develop opioid withdrawal symptoms.
- if you have **severe diarrhoea or stomach ache**, tell your doctor, so that the doctor can monitor you and treat you with rehydration and appropriate medicines if needed.

Children and adolescents

This medicine is not for children or adolescents under the age of 18 years because the effects of the medicine in children and adolescents are not known.

Other medicines and Rizmoic

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

Talk to your doctor or pharmacist if you are taking any of the following medicines:

- Rifampicin, clarithromycin or telithromycin (antibiotic medicines)
- Itraconazole or ketoconazole (medicines to treat fungal infections)
- Ritonavir, indinavir or saquinavir (medicines for HIV infection)
- Phenytoin, carbamazepine, phenobarbital (medicines to treat epilepsy)
- St John's wort (*Hypericum perforatum*), a herbal medicine used for depression

Using these medicines with Rizmoic may affect the way naldemedine works or increase its side effects.

Rizmoic with drink

You should not drink large amounts of grapefruit juice whilst taking Rizmoic.

Pregnancy and breast-feeding

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. The effects of the medicine in pregnant women are not known. Your doctor will advise you about whether you can use Rizmoic if you are pregnant.

Do not breast-feed during treatment with Rizmoic as it is not known if naldemedine passes into breast milk. Talk to your doctor if you are already breast-feeding.

Driving and using machines

Rizmoic has no influence on your ability to drive or to use machines.

Rizmoic contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Rizmoic

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

- The recommended dose is one 200 microgram tablet once daily.
- You can take Rizmoic with or without laxatives.
- You can take Rizmoic at any time of the day, with food or between meals. However, once you start taking the medicine, take it at around the same time each day.
- There is no need to alter the dose of your opioid medicine before starting Rizmoic.

If you stop taking your opioid medicine

You should stop taking Rizmoic when you stop taking your opioid pain medicine.

If you take more Rizmoic than you should

If you have taken more Rizmoic than you should, talk to your doctor or go to the hospital. You will be monitored for opioid withdrawal symptoms (see section 2, under 'Warnings and Precautions', and section 4).

If you forget to take Rizmoic

If you miss a tablet of Rizmoic, take it as soon as you remember.

However if it is less than 12 hours until your next dose, skip the missed dose, and wait until it is time to take your next tablet.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Rizmoic

Stopping Rizmoic while continuing to take your opioid medicine may cause the constipation to return. Talk to your doctor if you stop taking Rizmoic.

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.

Stop taking Rizmoic and contact your doctor if you get a combination of 3 or more of the following symptoms of **opioid withdrawal** on the same day:

- feeling depressed
- nausea (feeling sick) or vomiting
- achy muscles
- watery eyes or runny nose
- pupils dilating
- hairs of the skin standing on end
- sweating
- diarrhoea
- yawning
- fever
- inability to sleep

The following side effects may happen with this medicine:

If you are being treated with an opioid medicine for chronic non-cancer pain.

Rare (may affect up to 1 in 1,000 people):

- If you experience a serious allergic reaction, stop taking Rizmoic and see a doctor or go to a hospital straight away. Serious allergic reactions include: swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty swallowing or breathing, itching of the skin and nettle rash.

Common (may affect up to 1 in 10 people):

- diarrhoea
- stomach pain
- nausea (feeling sick)
- vomiting

If you are being treated with an opioid medicine for cancer.

Very common (may affect more than 1 in 10 people):

- diarrhoea

Common:

- stomach pain

Not Known (frequency cannot be estimated from the available data)

- Gastrointestinal perforation (a hole developing in the bowel wall)

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:

Yellow Card Scheme

Website: 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 Rizmoic

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 blisters after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect the tablets from light and moisture.

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 protect the environment.

6. Contents of the pack and other information

What Rizmoic contains

- Each tablet contains 200 micrograms of naldemedine (as tosylate).
- The other ingredients are:
Tablet core: Mannitol, croscarmellose sodium (see section 2 under 'Rizmoic contains sodium') and magnesium stearate.
Film coating: hypromellose, talc and yellow iron oxide (E172).

What Rizmoic looks like and contents of the pack

Rizmoic is a round, approximately 6.5 mm diameter, yellow film-coated tablet debossed with '222' and the Shionogi logo on one side and '0.2' on the other side.

The medicine is available in aluminium blisters, containing 7, 10 or 14 tablets. Pack sizes of 7, 10, 28, 30, 84 or 100 tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder

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