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Rizmoic

An overview of Rizmoic and why it is authorised in the EU

What is Rizmoic and what is it used for?

Rizmoic is a medicine for treating constipation caused by opioid pain relief medicines in patients who have previously been treated with a laxative (a medicine that triggers bowel movements).

It contains the active substance naldemedine.

How is Rizmoic used?

Rizmoic is available as 200 microgram tablets. The recommended dose is one tablet once daily, which the patient can take with or without a laxative.

The patient must stop taking Rizmoic when they are no longer taking an opioid. Rizmoic can only be obtained with a prescription. For more information about using Rizmoic, see the package leaflet or contact your doctor or pharmacist.

How does Rizmoic work?

The active substance in Rizmoic, naldemedine, works by attaching to and blocking receptors in the gut (mu-, delta- and kappa-opioid receptors), through which opioid medicines cause constipation.

Because molecules of naldemedine were designed not be able to enter into the brain, the medicine does not block opioids from working on pain receptors in the brain and therefore does not interfere with pain relief.

What benefits of Rizmoic have been shown in studies?

Studies have shown that Rizmoic is effective at improving bowel movement in patients who are currently taking laxatives or had taken laxatives in the past.

The studies compared Rizmoic with placebo (a dummy treatment) to see if treatment would consistently increase the number of patients who can pass stools and allow them to do so at least 3 times a week during treatment.

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In two of the studies, involving 1095 patients taking opioids for chronic (long-term) pain caused by a condition other than cancer, 50% of patients taking Rizmoic for 12 weeks achieved the desired outcome, compared with 34% of patients taking placebo.

In two other studies, involving 307 patients taking opioids for cancer pain, 74% of patients taking Rizmoic for two weeks achieved the desired outcome compared with 36% of patients taking placebo.

What are the risks associated with Rizmoic?

The most common side effects with Rizmoic in patients without cancer (which may affect up to 1 in 10 people) are abdominal pain (belly ache), diarrhoea, nausea and vomiting. In patients with cancer, the most common side effects were diarrhoea (seen in more than 1 in 10 people) and abdominal pain (seen in up to 1 in 10 people). The majority of side effects in patients with or without cancer were mild to moderate.

Rizmoic must not be used in patients with a blocked or perforated bowel or patients at high risk of bowel blockage. For the full list of side effects and restrictions, see the package leaflet.

Why is Rizmoic authorised in the EU?

Constipation is the most common side effect of opioid pain medicines and many standard laxatives are not effective in treating the condition.

Rizmoic has been shown to improve bowel movement in patients taking opioids pain medicines for long-term pain (including cancer pain). Furthermore, the side effects of Rizmoic, which mainly affected the gut, were mostly mild or moderate.

The European Medicines Agency therefore decided that Rizmoic's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Rizmoic?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rizmoic have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rizmoic are continuously monitored. Side effects reported with Rizmoic are carefully evaluated and any necessary action taken to protect patients.

Other information about Rizmoic

Rizmoic received a marketing authorisation valid throughout the EU on 18 February 2019.

Further information on Rizmoic can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rizmoic

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