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EPAR summary for the public

Relistor

methylnaltrexone bromide

This is a summary of the European public assessment report (EPAR) for Relistor. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Relistor.

For practical information about using Relistor, patients should read the package leaflet or contact their doctor or pharmacist.

What is Relistor and what is it used for?

Relistor is used to treat constipation caused by opioid painkillers (such as morphine) when laxative medicines have not worked well enough.

Relistor contains the active substance methylnaltrexone bromide.

How is Relistor used?

Relistor can only be obtained with a prescription. It is available as a solution for injection in vials or in prefilled syringes.

In patients who are receiving palliative care (treatment of the symptoms of a serious disease that is not intended to lead to cure), Relistor is given as an injection under the skin, once every two days, in addition to the usual laxative medicines. The dose depends on the patient's body weight. In patients not on palliative care, Relistor is given as an injection under the skin at a dose of 12 mg once a day, for at least 4 days per week and up to 7 days per week as needed; treatment with usual laxatives should be stopped when starting Relistor. Relistor is usually injected under the skin of the upper legs, belly or upper arms.

The dose of Relistor should be reduced in patients who have severe kidney problems. Relistor is not recommended for patients who have very severe kidney problems that require dialysis (a blood clearance technique).

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Patients can inject Relistor themselves once they have been trained appropriately.

How does Relistor work?

Opioids relieve pain by attaching to 'opioid receptors' in the brain and spinal cord. These receptors are also found in the gut. When opioids attach to the gut receptors, the mobility of the gut is reduced, leading to constipation.

The active substance in Relistor, methylnaltrexone bromide, is a 'mu-opioid receptor antagonist'. This means that it blocks a specific type of opioid receptor called the 'mu-opioid receptor'. Methylnaltrexone bromide is derived from naltrexone, a well-known substance that is used to block the action of opioids. Methylnaltrexone bromide is less able to enter the brain than naltrexone, meaning that it blocks the mu-opioid receptors in the gut but not in the brain. By blocking these receptors, Relistor reduces the constipation due to opioids, but does not interfere with their painkilling effects.

What benefits of Relistor have been shown in studies?

Relistor was shown to be more effective than placebo (a dummy treatment) at stimulating bowel movement in two main studies involving a total of 288 patients with an advanced illness and constipation caused by opioids. The main measure of effectiveness in both studies was the number of patients who had a bowel movement within four hours of the first dose. The second study also looked at the number of patients who had a bowel movement at least twice within four hours of the first four doses. Looking at the results of the two studies taken together, 55% of the patients receiving Relistor had a bowel movement within four hours of the first dose (91 out of 165), compared with 15% of the patients receiving placebo (18 out of 123). In the second study, 52% of the patients receiving Relistor had a bowel movement at least twice within four hours of the first four doses (32 out of 62), compared with 8% of those receiving placebo (6 out of 71).

Relistor has also been compared with placebo in a third study involving 496 patients with constipation caused by opioids, but no advanced illness. The main measures of effectiveness were the number of patients who had a bowel movement within four hours of the first dose, and the percentage of injections that were successful in producing a bowel movement. Results showed that 34% of patients receiving Relistor (102 out of 298) had a bowel movement within four hours after the first injection, compared with 10% of those receiving placebo (16 out of 162). The percentages of successful injections for the two groups were around 30% and 9%, respectively.

What are the risks associated with Relistor?

The most common side effects with Relistor (seen in more than 1 patient in 10) are abdominal pain (stomach ache), nausea (feeling sick), diarrhoea and flatulence. These side effects are generally mild or moderate. For the full list of all side effects reported with Relistor, see the package leaflet.

Relistor must not be used in patients whose bowel is blocked, who are at risk of recurrent bowel blockage or who have a condition that needs immediate bowel surgery. For the full list of restrictions, see the package leaflet.

Why is Relistor approved?

The Agency's Committee for Medicinal Products for Human Use decided that Relistor's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

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

Other information about Relistor

The European Commission granted a marketing authorisation valid throughout the European Union for Relistor on 2 July 2008.

The full EPAR for Relistor can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Relistor, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2016.