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EPAR summary for the public

Moventig

naloxegol

This is a summary of the European public assessment report (EPAR) for Moventig. 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 Moventig.

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

What is Moventig and what is it used for?

Moventig is a medicine used in adults to treat constipation caused by pain relief medicines called opioids. It is used in patients in whom treatment with laxatives has failed.

Moventig contains the active substance naloxegol.

How is Moventig used?

Moventig is available as tablets (12.5 and 25 mg). The recommended dose is one 25 mg tablet a day. A lower starting dose of 12.5 mg may be prescribed in patients with moderately or severely reduced kidney function or who are taking certain other medicines that increase the effects of Moventig. Before starting treatment with Moventig, treatment with laxatives should be stopped.

The medicine can only be obtained with a prescription.

How does Moventig work?

Opioids relieve pain by attaching to 'opioid receptors' in the brain and spinal cord. However, these receptors are also found in the gut and when opioids attach to the gut receptors, they reduce the movement of the gut and can cause constipation.

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The active substance in Moventig, naloxegol, is a peripheral mu-opioid-receptor antagonist. This means that it attaches to a specific type of opioid receptor called the 'mu-opioid receptor' and blocks opioids from binding to these receptors. Naloxegol is derived from naloxone, a well-known substance that is used to block the action of opioids. Naloxegol is less able to enter the brain than naloxone, meaning that it can block the mu-opioid receptors in the gut but less in the brain. By blocking receptors in the gut, Moventig reduces the constipation due to opioids, but does not interfere with their pain relief effects.

What benefits of Moventig have been shown in studies?

Moventig has been shown to be effective at treating constipation in adults who had an inadequate response to laxatives in two main studies. The studies involved 1,352 adults with constipation caused by opioids that were being used to treat non-cancer pain, half of whom had an inadequate response to laxatives (720). People either received Moventig (at 12.5 and 25 mg) or placebo (a dummy treatment) for 12 weeks. The response to treatment was based on an improvement of the number of spontaneous bowel movements per week which had to be maintained for most of the duration of the study. When looking at the results of both main studies together, 48% (115 out of 241) of adults who previously had an inadequate response to laxatives and who took 25 mg Moventig responded to treatment compared with 30% (72 out of 239) of adults on placebo. For adults who took 12.5 mg Moventig and who previously had an inadequate response to laxatives, 43% (102 out of 240) responded to treatment.

What are the risks associated with Moventig?

The most common side effects with Moventig (which may affect more than 5 in 100 people) are abdominal pain (stomach ache), diarrhoea, nausea (feeling sick), headache and flatulence (passing wind). The majority of side effects affecting the gut were mild to moderate, occurred early in treatment and got better during continued treatment.

Moventig must not be used in patients who have or who are at high risk of bowel obstruction (blockage in the gut) or in patients with cancer who are at a high risk of gastro-intestinal perforation (a hole that develops in the wall of the gut). It must also not be used with certain medicines that affect the way Moventig is broken down in the body.

For the full list of all side effects and restrictions reported with Moventig, see the package leaflet.

Why is Moventig approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Moventig's benefits are greater than its risks and recommended that it be approved for use in the EU. The CHMP considered that Moventig had shown a clinically relevant benefit when used in adults who have not responded adequately to previous treatment with laxatives. Although studies in patients with cancer-related pain had not been conducted, based on the mechanism of action of the medicine, the benefit for these patients was not expected to be different but the safety should be closely monitored. In terms of safety, the side effects were considered acceptable or manageable.

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

A risk management plan has been developed to ensure that Moventig is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and

the package leaflet for Moventig, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Moventig

The European Commission granted a marketing authorisation valid throughout the European Union for Moventig on 8 December 2014.

The full EPAR and risk management plan summary for Moventig 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 Moventig, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 12-2014.