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Outcome of assessment on use of Moventig (naloxegol) in treatment of constipation due to opioids

The European Medicines Agency (EMA) has finalised an application to change the way Moventig is used, which included a request to extend the medicine's use to include adults who have been previously treated with a laxative regardless of their response to laxative treatment.

Although the company that markets the medicine decided not to continue with the request to extend the medicine's use, EMA concluded that the product information should be updated to reflect certain other changes to the way the medicine is used, based on relevant data submitted with the application.

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 only used in patients who had an inadequate response to laxatives (defined as having symptoms of at least moderate severity on a constipation symptom score).

Moventig contains the active substance naloxegol and is available as tablets to be taken by mouth. It has been authorised in the EU since December 2014.

Further information on Moventig's uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/moventig.

What change had the company applied for?

The company applied for an extension of indication to include use in patients who have previously been treated with a laxative, regardless of whether they had an inadequate response to laxative treatment.

How does Moventig work?

The active substance in Moventig, naloxegol, is derived from naloxone, a well-known substance that is used to block the action of opioids. 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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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 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 did the company present to support its application?

The company did not present new clinical data to support the extension of indication but proposed that the new indication may better reflect recommendations from experts and clinical practice.

The company also presented an analysis of real-world data from three observational studies described in the literature that investigated the safety and effectiveness of naloxegol in patients with cancer-related pain and constipation caused by opioids. In these studies, naloxegol was used with or without laxatives.

What were EMA's conclusions?

The authorised use for Moventig was based on clinical studies in patients with non-cancer pain, which showed that the effect of naloxegol on constipation was mainly seen in patients who had an inadequate response to standard laxative treatment. The Agency noted that the results from the observational studies submitted in the present application were also collected from people with an inadequate response to laxatives and that the company had not submitted any clinical data relevant to support extending the medicine's use to people who had previously received laxative treatment, regardless of whether they had an inadequate response to laxatives.

At the time of the company's decision to no longer pursue this extended use, the Agency's human medicines committee (CHMP) was of the opinion that this use could not have been approved. However, the Committee concluded that the data the company submitted did allay previous concerns about using Moventig together with other laxatives and for treating patients using opioids for cancer pain.

The EMA has therefore agreed on updating the production information for Moventig to remove a recommendation against using the medicine with other laxatives as well as a warning about its use in patients with cancer pain.