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EPAR summary for the public

Prialt

ziconotide

This is a summary of the European public assessment report (EPAR) for Prialt. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Prialt.

What is Prialt?

Prialt is a solution for infusion that contains the active substance ziconotide.

What is Prialt used for?

Prialt is used to treat severe, long-term pain in adults who need a painkiller by intrathecal injection (injection into the space that surrounds the spinal cord and the brain).

Because the number of patients who have long-term pain that requires painkillers to be injected directly into the spine is low, the disease is considered 'rare', and Prialt was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 July 2001.

The medicine can only be obtained with a prescription.

How is Prialt used?

Treatment with Prialt should only be carried out by a doctor who has experience in the intrathecal dosing of medicines.

Prialt must be given as a very slow continuous infusion through an intrathecal catheter (a tube inserted into the spinal canal) using an infusion pump capable of delivering an accurate amount of the medicine. Prialt may need to be diluted before use, especially with the lower doses needed at the start of treatment. The starting dose of Prialt is 2.4 micrograms per day. The dose should be gradually increased, preferably every two days or more, to obtain the best balance between pain relief and

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possible side effects. The dose must not be increased more than once in any 24 hour period. Most patients need doses lower than 9.6 micrograms per day. The maximum dose is 21.6 micrograms per day.

How does Prialt work?

The active substance in Prialt, ziconotide, is a copy of a natural substance called omega-conopeptide, which is found in the venom of a type of sea snail. Ziconotide acts by blocking special pores called calcium channels on the surface of the nerve cells that transmit the pain signals. By blocking the flow of calcium into the nerve cells, ziconotide interferes with the transmission of pain signals within the spine. This helps to bring relief from pain.

How has Prialt been studied?

Prialt has been compared with placebo (a dummy treatment) in 589 patients with severe long-term pain in three main studies. Two of the studies were short-term, lasting five or six days: one in pain due to cancer or AIDS, and one in pain due to other causes such as nerve damage. The third study looked at the use of the medicine over three weeks. In all of the studies, the main measure of effectiveness was the change in the Visual Analog Scale of Pain Intensity (VASPI). This is a score given by the patients of their pain on a scale from 0 mm (no pain) to 100 mm (maximum pain).

What benefit has Prialt shown during the studies?

Prialt was more effective than placebo in the first two studies. Before treatment, patients with cancer or AIDS pain had an average VASPI score of 74 mm, and those with other types of pain had a score of 80 mm. After treatment, the scores in patients receiving Prialt decreased to 35 and 54 mm, respectively, while scores in patients receiving placebo were 61 and 72 mm.

In the third study, there was a trend for Prialt to be more effective than placebo, with the VASPI score changing from 81 mm before treatment to 68 mm in patients receiving Prialt and to 74 mm in patients receiving placebo.

What is the risk associated with Prialt?

The most common side effects with Prialt (seen in more than 1 patient in 10) are confusion, dizziness, nystagmus (uncontrolled eye movement), impaired memory (forgetfulness), headache, somnolence (sleepiness), blurred vision, nausea (feeling sick), vomiting, abnormal gait (difficulty walking) and asthenia (weakness).

Prialt must not be used in patients at the same time as intrathecal chemotherapy (medicines to treat cancer that are injected into the spinal canal). For the full list of all side effects and restrictions with Prialt, see the package leaflet.

Why has Prialt been approved?

The Committee for Medicinal Products for Human Use (CHMP) concluded that Prialt provides an alternative to other intrathecal painkillers, such as opioids. It decided that Prialt's benefits are greater than its risks and recommended that it be given marketing authorisation.

Prialt was originally authorised under 'exceptional circumstances', because, as the disease is rare, limited information was available at the time of approval. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 17 January 2014.

What information is still awaited for Prialt?

The company that makes Prialt is carrying out a study looking at the long-term use of the medicine, looking in particular at the possibility of development of tolerance to treatment (when doses of a medicine that used to be effective become less effective over time).

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

A risk management plan has been developed to ensure that Prialt 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 Prialt, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Prialt

The European Commission granted a marketing authorisation valid throughout the European Union for Prialt on 21 February 2005..

The full EPAR for Prialt 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 Prialt, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Prialt can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 02-2014.