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EPAR summary for the public

Pregabalin Accord

pregabalin

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

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

What is Pregabalin Accord and what is it used for?

Pregabalin Accord is a medicine used to treat adults with the following conditions:

- neuropathic pain (pain due to nerve damage), including peripheral neuropathic pain, such as the pain experienced by patients with diabetes or herpes zoster (shingles), and central neuropathic pain, such as the pain experienced by patients who have had a spinal cord injury;
- epilepsy, where it is used as an 'add-on' to other epilepsy treatment in patients who have partial seizures (epileptic fits starting in one specific part of the brain);
- generalised anxiety disorder (long-term anxiety or nervousness about everyday matters).

Pregabalin Accord contains the active substance pregabalin.

Pregabalin Accord is a 'generic medicine'. This means that Pregabalin Accord contains the same active substance and works in the same way as a 'reference medicine' already authorised in the European Union (EU) called Lyrica. For more information on generic medicines, see the question-and-answer document here.

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How is Pregabalin Accord used?

Pregabalin Accord is available as capsules (25, 50, 75, 100, 150, 200, 225 and 300 mg) and can only be obtained with a prescription. The recommended starting dose is 150 mg per day, divided into two or three doses. After one week, the dose can be increased to 300 mg per day. Doses can be increased further until the most effective dose is reached. The maximum dose is 600 mg per day. To stop treatment with Pregabalin Accord, the dose should be reduced gradually, over at least a week. Patients who have kidney problems may need to take lower doses.

How does Pregabalin Accord work?

The active substance in Pregabalin Accord, pregabalin, is similar in structure to the body's own 'neurotransmitter' gamma-amino butyric acid (GABA), but has very different biological effects. Neurotransmitters are chemicals that allow nerve cells to communicate with each other. The exact way in which pregabalin works is not fully understood, but it is thought to affect the way that calcium enters nerve cells. This reduces the activity of some of the nerve cells in the brain and spinal cord, reducing the release of other neurotransmitters that are involved in epilepsy and anxiety.

How has Pregabalin Accord been studied?

Studies on the benefits and risks of the active substance in the approved uses have already been carried out with the reference medicine, Lyrica, and do not need to be repeated for Pregabalin Accord.

As for every medicine, the company provided studies on the quality of Pregabalin Accord. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Pregabalin Accord?

Because Pregabalin Accord is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Pregabalin Accord approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Pregabalin Accord has been shown to have comparable quality and to be bioequivalent to Lyrica. Therefore, the CHMP's view was that, as for Lyrica, the benefit outweighs the identified risk. The Committee recommended that Pregabalin Accord be approved for use in the EU.

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

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

Other information about Pregabalin Accord

The European Commission granted a marketing authorisation valid throughout the European Union for Pregabalin Accord on 28 August 2015.

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

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 06-2017.