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EPAR summary for the public

Pregabalin Mylan

pregabalin

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

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

What is Pregabalin Mylan and what is it used for?

Pregabalin Mylan 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 Mylan contains the active substance pregabalin.

Pregabalin Mylan is a 'generic medicine'. This means that Pregabalin Mylan 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 Mylan used?

Pregabalin Mylan 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 three to seven days, 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 Mylan 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 Mylan work?

The active substance in Pregabalin Mylan, 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 that 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 Mylan 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 Mylan.

As for every medicine, the company provided studies on the quality of Pregabalin Mylan. 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 Mylan?

Because Pregabalin Mylan 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 Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Pregabalin Mylan 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 Mylan be approved for use in the EU.

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

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

Other information about Pregabalin Mylan

The European Commission granted a marketing authorisation valid throughout the European Union for Pregabalin Mylan on 25 June 2015.

The full EPAR for Pregabalin Mylan 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 Mylan, 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 05-2017.