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EPAR summary for the public

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Pregabalin Mylan Pharma

pregabalin

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

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

What is Pregabalin Mylan Pharma and what is it used for?

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

- 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 Pharma contains the active substance pregabalin.

Pregabalin Mylan Pharma is a 'generic medicine'. This means that Pregabalin Mylan Pharma 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.

How is Pregabalin Mylan Pharma used?

Pregabalin Mylan Pharma 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

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increased further until the most effective dose is reached. The maximum dose is 600 mg per day. To stop treatment with Pregabalin Mylan Pharma 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 Pharma work?

The active substance in Pregabalin Mylan Pharma, 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 pain, epilepsy and anxiety.

How has Pregabalin Mylan Pharma 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 Pharma.

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

Because Pregabalin Mylan Pharma 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 Pharma approved?

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

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

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

Other information about Pregabalin Mylan Pharma

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

The full EPAR for Pregabalin Mylan Pharma can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about

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treatment with Pregabalin Mylan Pharma, 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.

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