EMA/277953/2015
EMEA/H/C/004010

EPAR summary for the public

Pregabalin Sandoz

pregabalin

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

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

What is Pregabalin Sandoz and what is it used for?

Pregabalin Sandoz 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 existing treatment in patients who have partial seizures (epileptic fits starting in one specific part of the brain) that cannot be controlled with their current treatment;
- generalised anxiety disorder (long-term anxiety or nervousness about everyday matters).

Pregabalin Sandoz is a 'generic medicine'. This means that Pregabalin Sandoz is similar to 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.

Pregabalin Sandoz contains the active substance pregabalin.

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How is Pregabalin Sandoz used?

Pregabalin Sandoz 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 up to twice more until the most effective dose is reached. The maximum dose is 600 mg per day. Stopping treatment with Pregabalin Sandoz should also be done gradually, over at least a week. Doctors may need to lower the dose in patients who have kidney problems.

How does Pregabalin Sandoz work?

The active substance in Pregabalin Sandoz, 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 Sandoz been studied?

Because Pregabalin Sandoz is a generic medicine, studies in people have been limited to tests to determine that it is bioequivalent to the reference medicine, Lyrica. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the benefits and risks of Pregabalin Sandoz?

Because Pregabalin Sandoz 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 Sandoz approved?

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

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

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

Further information can be found in the summary of the risk management plan.

Other information about Pregabalin Sandoz

The European Commission granted a marketing authorisation valid throughout the European Union for Pregabalin Sandoz on 19 June 2015.

The full EPAR and risk management plan summary for Pregabalin Sandoz 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 Sandoz, 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 06-2015.