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EPAR summary for the public

Pregabalin Zentiva k.s.

pregabalin

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

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

What is Pregabalin Zentiva k.s. and what is it used for?

Pregabalin Zentiva k.s. 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 herpes zoster (shingles) or nerve disorders caused by diabetes, 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 Zentiva k.s. contains the active substance pregabalin. It is a 'generic medicine'. This means that Pregabalin Zentiva k.s. 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 Zentiva k.s. used?

Pregabalin Zentiva k.s. 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. Doctors may choose lower doses in patients with kidney problems. When stopping treatment with Pregabalin Zentiva k.s. the dose should be reduced gradually, over at least a week.

How does Pregabalin Zentiva k.s. work?

The active substance in Pregabalin Zentiva k.s., pregabalin, is similar in structure to the body's own 'neurotransmitter' gamma-amino butyric acid (GABA), but has very different biological effects. Neurotransmitters are substances that nerve cells use to communicate with neighbouring cells. 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 nerve cells in the brain and spinal cord that are involved in pain, epilepsy and anxiety.

How has Pregabalin Zentiva k.s. 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 Zentiva k.s.

As for every medicine, the company provided studies on the quality of Pregabalin Zentiva k.s. The company also carried out a study 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 Zentiva k.s.?

Because Pregabalin Zentiva k.s. 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 Zentiva k.s. approved?

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

What measures are being taken to ensure the safe and effective use of Pregabalin Zentiva k.s.?

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

Other information about Pregabalin Zentiva k.s.

The European Commission granted a marketing authorisation valid throughout the European Union for Pregabalin Zentiva k.s. on27 February 2017.

The full EPAR for Pregabalin Zentiva k.s. 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 Zentiva k.s., 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 02-2017.