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EPAR summary for the public

Pregabalin Zentiva

pregabalin

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

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

What is Pregabalin Zentiva and what is it used for?

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

- 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 is a 'generic medicine'. This means that Pregabalin Zentiva 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 Zentiva contains the active substance pregabalin.

How is Pregabalin Zentiva used?

Pregabalin Zentiva 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

day. Stopping treatment with Pregabalin Zentiva 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 Zentiva work?

The active substance in Pregabalin Zentiva, 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 Zentiva been studied?

Because Pregabalin Zentiva 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 Zentiva?

Because Pregabalin Zentiva 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 approved?

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

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

A risk management plan has been developed to ensure that Pregabalin Zentiva 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 Zentiva, 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 Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Pregabalin Zentiva on 17 July 2015.

The full EPAR and risk management plan summary for Pregabalin Zentiva 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, 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 July-2015.