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EPAR summary for the public

Duloxetine Zentiva

duloxetine

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

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

What is Duloxetine Zentiva and what is it used for?

Duloxetine Zentiva is used to treat adults with the following diseases:

- major depression;
- pain due to diabetic peripheral neuropathy (damage to the nerves in the feet, legs, hands and arms that can occur in patients with diabetes);
- generalised anxiety disorder (long-term anxiety or nervousness about everyday matters).

Duloxetine Zentiva contains the active substance duloxetine and is is a 'generic medicine'. This means that Duloxetine Zentiva is similar to a 'reference medicine' already authorised in the European Union (EU) called Cymbalta. For more information on generic medicines, see the question-and-answer document here.

How is Duloxetine Zentiva used?

Duloxetine Zentiva is available as gastroresistant capsules (30 and 60 mg). 'Gastroresistant' means that the capsules' contents pass through the stomach without being broken down until they reach the intestine. This prevents the active substance being destroyed by the acid in the stomach. The medicine can only be obtained with a prescription.

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For major depression, the recommended dose of Duloxetine Zentiva is 60 mg once a day. A response is usually seen in two to four weeks. In patients who respond to Duloxetine Zentiva, treatment should continue for several months to prevent the disease coming back, or for longer in patients who have had repeated periods of depression in the past.

For diabetic neuropathic pain, the recommended dose is 60 mg per day but some patients may need a higher dose of up to 120 mg per day. The response to treatment should be assessed regularly.

For generalised anxiety disorder, the recommended starting dose is 30 mg once a day, but the dose can be increased to 60, 90 or 120 mg depending on the patient's response. Most patients will need to take 60 mg per day. Patients who also have major depression should start with 60 mg once a day. In patients who respond to Duloxetine Zentiva, treatment should continue for several months, to prevent the disorder coming back.

The dose of Duloxetine Zentiva should be reduced gradually when stopping treatment.

How does Duloxetine Zentiva work?

The active substance in this medicine, duloxetine, is a serotonin-noradrenaline re-uptake inhibitor. It works by preventing the neurotransmitters serotonin (5-hydroxytryptamine) and noradrenaline from being taken back up into nerve cells in the brain and spinal cord.

Neurotransmitters are chemicals that allow nerve cells to communicate with one another. By blocking their re-uptake, duloxetine increases the amount of these neurotransmitters in the spaces between nerve cells, increasing the level of communication between the cells. Since these neurotransmitters are involved in maintaining mood and reducing the sensation of pain, blocking their re-uptake into nerve cells can improve the symptoms of depression, anxiety and neuropathic pain.

How has Duloxetine Zentiva been studied?

Because Duloxetine Zentiva is a generic medicine of Cymbalta, its benefits and risks are taken as being the same as the reference medicine's.

What are the benefits and risks of Duloxetine Zentiva?

Because Duloxetine 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 Duloxetine Zentiva approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Duloxetine Zentiva has been shown to have comparable quality to Cymbalta and to be bioequivalent to Cymbalta. Therefore, the CHMP's view was that, as for Cymbalta, the benefit outweighs the identified risk. The Committee recommended that Duloxetine Zentiva be approved for use in the EU.

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

A risk management plan has been developed to ensure that Duloxetine 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 Duloxetine 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 Duloxetine Zentiva

The European Commission granted a marketing authorisation valid throughout the European Union for Duloxetine Zentiva on 20 August 2015.

The full EPAR and risk management plan summary for Duloxetine 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 Duloxetine 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 08-2015.