EMA/276795/2015
EMEA/H/C/003981

EPAR summary for the public

Duloxetine Mylan

duloxetine

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

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

What is Duloxetine Mylan and what is it used for?

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

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

Duloxetine Mylan contains the active substance duloxetine and is a 'generic medicine'. This means that Duloxetine Mylan 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 Mylan used?

Duloxetine Mylan 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.

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

For major depression, the recommended dose of Duloxetine Mylan is 60 mg once a day. A response is usually seen in two to four weeks. In patients who respond to Duloxetine Mylan, 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 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 Mylan, treatment should continue for several months, to prevent the disorder coming back.

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

How does Duloxetine Mylan 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 these nerve cells, increasing the level of communication between the cells. Since these neurotransmitters are involved in maintaining high 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 Mylan been studied?

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

What are the benefits and risks of Duloxetine Mylan?

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

Why is Duloxetine Mylan approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Duloxetine Mylan has been shown to have comparable quality 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 Mylan be approved for use in the EU.

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

A risk management plan has been developed to ensure that Duloxetine Mylan 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 Mylan, 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 Mylan

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

The full EPAR and risk management plan summary for Duloxetine Mylan 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 Mylan, 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.