Summary Public Assessment Report

Generics

Dulodet 30 mg and 60 mg gastro-resistant capsules, hard

(duloxetine)

NL/H/3297/001-002/DC

Date: 30 September 2016

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Active substance: duloxetine

This is a summary of the public assessment report (PAR) for Dulodet. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Dulodet.

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

What is Dulodet and what is it used for?
Dulodet is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Cymbalta.

Dulodet 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).

How does this medicine 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 is this medicine used?
Dulodet is available as gastro-resistant capsules (30 and 60 mg). 'Gastro-resistant' 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.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Dulodet is a generic medicine, studies in patients 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 possible side effects of this medicine?
Because Dulodet is a generic medicine its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Cymbalta, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Dulodet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about this medicine
In the Netherlands, the marketing authorisation for Dulodet was granted on 17 September 2015.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human. For more information about treatment with Dulodet, read the package leaflet (https://mri.cts-mrp.eu/Human/Downloads/NL_H_3297_002_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in September 2016.