LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Duloxetin Pensa
(duloxetine hydrochloride)

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Summary Public Assessment Report

Duloxetin Pensa

(duloxetine hydrochloride)

Gastro-resistant capsules, hard, 30 mg and 60 mg

This is a summary of the public assessment report (PAR) for Duloxetin Pensa. It explains how Duloxetin Pensa 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 Duloxetin Pensa.

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

What is Duloxetin Pensa and what is it used for?

Duloxetin Pensa is a 'generic medicine'. This means that Duloxetin Pensa is similar to a 'reference medicine' already authorised in the European Union (EU) called Cymbalta. Duloxetin Pensa is used in adults to treat:

- depression
- generalised anxiety disorder (chronic feeling of anxiety or nervousness)
- diabetic neuropathic pain (often described as burning, stabbing, stinging, shooting or aching or like an electric shock. There may be loss of feeling in the affected area, or sensations such as touch, heat, cold or pressure may cause pain)

How does Duloxetin Pensa work?

Duloxetin Pensa contains the active substance duloxetine which increases the levels of serotonin and noradrenaline in the nervous system.

How is Duloxetin Pensa used?

The pharmaceutical form of Duloxetin Pensa is gastro-resistant capsules, hard, for oral use.

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

The medicine can only be obtained with a prescription.

What benefits of Duloxetin Pensa have been shown in studies?

Because Duloxetin Pensa 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 Duloxetin Pensa?

Because Duloxetin Pensa is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine. For the full list of restrictions, see the package leaflet.

Why is Duloxetin Pensa approved?

It was concluded that, in accordance with EU requirements, Duloxetin Pensa has been shown to have comparable quality and to be bioequivalent to the reference medicine Cymbalta. Therefore, the Medical Products Agency in Sweden decided that, as for Cymbalta, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Duloxetin Pensa?

A risk management plan has been developed to ensure that Duloxetin Pensa 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 Duloxetin Pensa, 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 Duloxetin Pensa

The marketing authorisation for Duloxetin Pensa was granted on 2015-07-02 in Sweden.

The full PAR for Duloxetin Pensa can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Duloxetin Pensa, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2015-07.