

Summary Public Assessment Report

Duloxetine Orion (duloxetine hydrochloride)

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Duloxetine Orion

(duloxetine (as hydrochloride))

Hard gastro-resistant capsules; 30 mg and 60 mg

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

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

What is Duloxetine Orion and what is it used for?

Duloxetine Orion is a 'generic medicine'. This means that Duloxetine Orion is similar to a 'reference medicine' already authorised in the European Union (EU) called Cymbalta.

Duloxetine Orion 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).

Duloxetine Orion starts to work in most people with depression or anxiety within two weeks of starting treatment, but it may take 2–4 weeks before you feel better. Tell your doctor if you do not start to feel better after this time. Your doctor may continue to give you Duloxetine Orion when you are feeling better to prevent your depression or anxiety from returning.

In people with diabetic neuropathic pain it can take some weeks before you feel better. Talk to your doctor if you do not feel better after 2 months.

How does Duloxetine Orion work?

Duloxetine Orion increases the levels of serotonin and noradrenaline in the nervous system.

How is Duloxetine Orion used?

The pharmaceutical form of Duloxetine Orion is hard gastro-resistant capsules 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 Duloxetine Orion have been shown in studies?

Because Duloxetine Orion 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 Duloxetine Orion?

Because Duloxetine Orion 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 Duloxetine Orion approved?

It was concluded that, in accordance with EU requirements, Duloxetine Orion 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 Duloxetine Orion?

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

The marketing authorisation for Duloxetine Orion was granted on 2015-07-02 in Sweden.

The full PAR for Duloxetine Orion can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Duloxetine Orion, please read the [\[package leaflet\]](#) or contact your doctor or pharmacist.

This summary was last updated in 2015-07.