LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Aritavi
(duloxetine hydrochloride)

SE/H/1466/01-02/DC

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Summary Public Assessment Report

Aritavi

(duloxetine hydrochloride)

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

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

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

What is Aritavi and what is it used for?

Aritavi is a 'generic medicine'. This means that Aritavi is similar to a 'reference medicine' already authorised in the European Union (EU) called Cymbalta.
Aritavi contains the active substance duloxetine. Aritavi increases the levels of serotonin and noradrenaline in the nervous system.

Aritavi 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 Aritavi work?

Aritavi 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 Aritavi 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 is Aritavi used?

The pharmaceutical form of Aritavi 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 Aritavi have been shown in studies?

Because Aritavi 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 Aritavi?

Because Aritavi 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 Aritavi approved?

It was concluded that, in accordance with EU requirements, Aritavi 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 Aritavi?

A risk management plan has been developed to ensure that Aritavi 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 Aritavi, 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 Aritavi

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

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

This summary was last updated in 2015-07.