LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Duloxetin Actavis
(duloxetine hydrochloride)

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Summary Public Assessment Report

Duloxetin Actavis

(duloxetine hydrochloride)

Gastro-resistant capsule, hard, 20 mg and 40 mg

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

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

What is Duloxetin Actavis and what is it used for?

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

Duloxetin Actavis is a medicine to be taken by mouth to treat Stress Urinary Incontinence (SUI) in women.

Stress urinary incontinence is a medical condition in which patients have accidental loss or leakage of urine during physical exertion or activities such as laughing, coughing, sneezing, lifting, or exercise.

How does Duloxetin Actavis work?

Duloxetin Actavis is believed to work by increasing the strength of the muscle that holds back urine when you laugh, sneeze, or perform physical activities.

The efficacy of Duloxetin Actavis is reinforced when combined with a training program called Pelvic Floor Muscle Training (PFMT).

How is Duloxetin Actavis used?

The pharmaceutical form of Duloxetin Actavis 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 Duloxetin Actavis have been shown in studies?

Because Duloxetin Actavis 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 Actavis?

Because Duloxetin Actavis 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 Actavis approved?

It was concluded that, in accordance with EU requirements, Duloxetin Actavis 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 Actavis?

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

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

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

This summary was last updated in 2015-07.