LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Duloxetin Teva B.V. B.V.
(duloxetine hydrochloride)

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gastro-resistant capsule, hard
20 mg, 40 mg

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

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

What is Duloxetin Teva B.V. and what is it used for?

Duloxetin Teva B.V. is a 'generic medicine'. This means that Duloxetin Teva B.V. is similar to a 'reference medicine' already authorised in the European Union (EU) called Yentreve. Duloxetin Teva B.V. 20 mg and 40 mg is used to treat Stress Urinary Incontinence (SUI) in women.

How does Duloxetin Teva B.V. work?

The active substance in Duloxetin Teva B.V., duloxetine, is a serotonin-noradrenaline re-uptake inhibitor. It works by preventing the neurotransmitters 5-hydroxytryptamine (also called serotonin) and noradrenaline from being taken back up into nerve cells in the brain and spinal cord. Duloxetin Teva B.V. increases the levels of serotonin and noradrenaline in the nervous system.

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 these nerve cells, increasing the level of communication between the cells.

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

How is Duloxetin Teva B.V. used?

The pharmaceutical form of Duloxetin Teva B.V. 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 Teva B.V. have been shown in studies?

Because Duloxetin Teva B.V. is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Yentreve. 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 Teva B.V.?

Because Duloxetin Teva B.V. 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 Teva B.V. approved?

It was concluded that, in accordance with EU requirements, Duloxetin Teva B.V. has been shown to have comparable quality and to be bioequivalent to the reference medicine Yentreve. Therefore, the Medical Products Agency in Sweden decided that, as for Yentreve, 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 Teva B.V.?

A risk management plan has been developed to ensure that Duloxetin Teva B.V. 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 Teva B.V., 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 Teva B.V.

The marketing authorisation for Duloxetin Teva B.V. was granted on 2019-10-18 in Sweden.

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

This summary was last updated in 2019-11.