

Summary Public Assessment Report

Duloxetine Teva (duloxetine hydrochloride)

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(duloxetine hydrochloride)

gastro-resistant capsule, hard
20 mg, 40 mg

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

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

What is Duloxetine Teva and what is it used for?

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

How does Duloxetine Teva work?

The active substance in Duloxetine Teva, 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. Duloxetine Teva 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. Duloxetine Teva 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 Duloxetine Teva used?

The pharmaceutical form of Duloxetine Teva 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 Teva have been shown in studies?

Because Duloxetine Teva 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 Duloxetine Teva?

Because Duloxetine Teva 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 Teva approved?

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

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

The marketing authorisation for Duloxetine Teva was granted on 2019-10-18 in Sweden.

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

This summary was last updated in 2019-11.