

Summary Public Assessment Report

Oxycodone Depot Teva Sweden (oxycodone hydrochloride)

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(oxycodone hydrochloride)

Prolonged-release tablets; 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg

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

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

What is Oxycodone Depot Teva Sweden and what is it used for?

Oxycodone Depot Teva Sweden is a 'generic medicine'. This means that Oxycodone Depot Teva Sweden is similar to a 'reference medicine' already authorised in the European Union (EU) called Oxycontin.

Oxycodone Depot Teva Sweden is used to relieve severe pain, which can only be controlled by opioid analgesics in adults and adolescents 12 years of age and older.

How does Oxycodone Depot Teva Sweden work?

Oxycodone Depot Teva Sweden contains the active ingredient oxycodone hydrochloride, which belongs to a group of medicines called opioids. These are strong painkillers.

How is Oxycodone Depot Teva Sweden used?

The pharmaceutical form of Oxycodone Depot Teva Sweden is prolonged-release tablets 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 Oxycodone Depot Teva Sweden have been shown in studies?

Because Oxycodone Depot Teva Sweden is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Oxycontin. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Oxycodone Depot Teva Sweden?

Because Oxycodone Depot Teva Sweden 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 Oxycodone Depot Teva Sweden approved?

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

A risk management plan has been developed to ensure that Oxycodone Depot Teva Sweden 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 Oxycodone Depot Teva Sweden, 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 Oxycodone Depot Teva Sweden

The marketing authorisation for Oxycodone Depot Teva Sweden was granted on 2016-07-06 in Sweden.

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

This summary was last updated in 2016-09.