LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oxycodone Teva
(oxycodone hydrochloride)

SE/H/1423/01-03/DC

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Summary Public Assessment Report

Oxycodone Teva

oxycodone hydrochloride

Capsules; 5 mg, 10 mg, 20 mg

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

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

What is Oxycodone Teva and what is it used for?

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

Oxycodone Teva is used in the treatment of severe pain, which can only be adequately managed with opioid analgesics.

How does Oxycodone Teva work?

Oxycodone Teva is a centrally acting, strong painkiller from the group of opioids. Oxycodone Teva is used to treat severe pain, which can only be adequately managed with opioid analgesics.

How is Oxycodone Teva used?

The pharmaceutical form of Oxycodone Teva is 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 Oxycodone Teva have been shown in studies?

Because Oxycodone Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, OxyNorm. 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 Teva?

Because Oxycodone 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 Oxycodone Teva approved?

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

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

The marketing authorisation for Oxycodone Teva was granted on 2015-03-12 in Sweden.

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

This summary was last updated in 2015-03.