LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oxytia Depot
(oxycodone hydrochloride)

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Summary Public Assessment Report

Oxytia Depot
(oxycodone hydrochloride)

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

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

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

What is Oxytia Depot and what is it used for?

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

Oxytia Depot 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 Oxytia Depot work?

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

How is Oxytia Depot used?

The pharmaceutical form of Oxytia Depot 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 Oxytia Depot have been shown in studies?

Because Oxytia Depot 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 Oxytia Depot?

Because Oxytia Depot 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 Oxytia Depot approved?

It was concluded that, in accordance with EU requirements, Oxytia Depot 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 Oxytia Depot?

A risk management plan has been developed to ensure that Oxytia Depot 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 Oxytia Depot, 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 Oxytia Depot

The marketing authorisation for Oxytia Depot was granted on 2014-06-05 in Sweden.

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

This summary was last updated in 2014-06.