LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oxikodon Depot Actavis
(oxycodone hydrochloride)

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Prolonged release tablets

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

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

What is Oxikodon Depot Actavis and what is it used for?

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

Oxikodon Depot Actavis 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 Oxikodon Depot Actavis work?

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

How is Oxikodon Depot Actavis used?

The pharmaceutical form of Oxikodon Depot Actavis 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 Oxikodon Depot Actavis have been shown in studies?

Because Oxikodon Depot Actavis 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 Oxikodon Depot Actavis?

Because Oxikodon Depot Actavis 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 Oxikodon Depot Actavis approved?

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

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

The marketing authorisation for Oxikodon Depot Actavis was granted on 2014-05-15 in Sweden.

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

This summary was last updated in 2014-05