LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Oxycodone G.L.
(oxycodone hydrochloride)

SE/H/1704/01-03/DC

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Oxycodone G.L

(oxycodone hydrochloride)

Solution for injection/infusion 10 mg/ml
Oral solution 1 mg/ml and 10 mg/ml

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

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

What is Oxycodone G.L. and what is it used for?

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

Oxycodone G.L. is used to treat severe pain in adults (18 years and older), which requires treatment with an opioid analgesics because other painkillers have not been effective.

How does Oxycodone G.L. work?

Oxycodone G.L contains the active substance oxycodone hydrochloride which belongs to a group of medicines called opioids and has a strong analgesic (painkilling) effect.

How is Oxycodone G.L. used?

The pharmaceutical form of Oxycodone G.L. is solution for injection/infusion and oral solution

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 G.L. have been shown in studies?

It was justified and accepted that no additional studies were needed to determine that Oxycodone G.L. is similar to the reference medicine OxyNorm.

What are the possible side effects of Oxycodone G.L.?

Because Oxycodone G.L. is a generic 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 G.L. approved?

It was concluded that, in accordance with EU requirements, Oxycodone G.L. has been shown to have comparable quality and to be similar 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 G.L.?

A risk management plan has been developed to ensure that Oxycodone G.L. 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 G.L., 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 G.L.

The marketing authorisation for Oxycodone G.L. was granted on 2018-06-05 in Sweden.

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

This summary was last updated in 2018-09.