LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lindoxa
(oxycodone hydrochloride)

SE/H/1703/01/DC

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(oxycodone hydrochloride)

Solution for injection/infusion 10 mg/ml

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

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

What is Lindoxa and what is it used for?

Lindoxa is a ‘generic medicine’. This means that Lindoxa is similar to a ‘reference medicine’ already authorised in the European Union (EU) called OxyNorm.

Lindoxa 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 Lindoxa work?

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

How is Lindoxa used?

The pharmaceutical form of Lindoxa is solution for injection/infusion.

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 Lindoxa have been shown in studies?

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

What are the possible side effects of Lindoxa?

Because Lindoxa 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 Lindoxa approved?

It was concluded that, in accordance with EU requirements, Lindoxa 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 Lindoxa?

A risk management plan has been developed to ensure that Lindoxa 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 Lindoxa, 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 Lindoxa

The marketing authorisation for Lindoxa was granted on 2018-07-11 in Sweden.

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

This summary was last updated in 2018-09.