LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Morfin Kalceks
(morphine hydrochloride)

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Morfin Kalceks
(morphine hydrochloride)

solution for injection, 10 mg/ml,

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

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

What is Morfin Kalceks and what is it used for?

Morfin Kalceks is a ‘generic medicine’. This means that Morfin Kalceks is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Morfin Meda. Morfin Kalceks is used to relieve severe pain, when other pain relieving medicines do not have sufficient effect.

How does Morfin Kalceks work?

Morfin Kalceks contains the active substamce morphine and belongs to a group of medicines called natural opium alkaloids. Morphine probably exerts its analgesic effect at different levels within the central nervous system.

How is Morfin Kalceks used?

The pharmaceutical form of Morfin Kalceks is solution for injection.

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 Morfin Kalceks have been shown in studies?

No additional studies were needed as Morfin Kalceks is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Morfin Meda.

What are the possible side effects of Morfin Kalceks?

Because Morfin Kalceks 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 Morfin Kalceks approved?

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

A risk management plan has been developed to ensure that Morfin Kalceks 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 Morfin Kalceks, 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 Morfin Kalceks

The marketing authorisation for Morfin Kalceks was granted on 2014-09-11 in Sweden.

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

This summary was last updated in 2016-11.