LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Morphine Unimedic
(morphine hydrochloride)

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Summary Public Assessment Report

Morphine Unimedic
(morphine hydrochloride)

Solution for injection, 1 mg/ml

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

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

What is Morphine Unimedic and what is it used for?

Morphine Unimedic is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but in a different strength.

The reference medicine for Morphine Unimedic is Morfin Epidural Meda 0,4 mg/ml solution for injection. Morphine Unimedic is used for severe pain such as cancer pain and for pain relief after surgery or injuries after external violence.

How does Morphine Unimedic work?

Morphine Unimedic contains the active substance morphine hydrochloride which has a substantial analgesic effect.

How is Morphine Unimedic used?

The pharmaceutical form of Morphine Unimedic is solution for injection for intravenous, epidural, subcutaneous or intramuscular 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 Morphine Unimedic have been shown in studies?

Because Morphine Unimedic is a hybrid application and is considered to be equivalent to the reference product Morfin Epidural Meda, their benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects of Morphine Unimedic?

For the full list of all side effects reported with Morphine Unimedic, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Morphine Unimedic approved?

This medicine is similar to a reference medicine containing the same active substance, but in a different strength. The company has provided additional own data to demonstrate the safety and efficacy of Morphine Unimedic regarding this difference from the reference medicine. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Morphine Unimedic's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Morphine Unimedic?

A risk management plan has been developed to ensure that Morphine Unimedic 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 Morphine Unimedic, 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 Morphine Unimedic

The marketing authorisation for Morphine Unimedic was granted on 2018-04-06 in Sweden.

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

This summary was last updated in 2018-04-06.