LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Morfin Abcur
(morphine hydrochloride)

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Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelverket.se E-mail: registrator@mpa.se

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Morfin Abcur

(morphine hydrochloride)

solution for injection, 10 mg/ml

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

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

What is Morfin Abcur and what is it used for?

Morfin Abcur is a ‘generic medicine’. This means that Morfin Abcur is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Morfin Meda. Morfin Abcur is used to relieve severe pain.

How does Morfin Abcur work?

Morfin Abcur belongs to a group of medicines called natural opium alkaloids, which have strong effect on pain relief.

How is Morfin Abcur used?

The pharmaceutical form of Morfin Abcur 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 Abcur have been shown in studies?

No additional studies were needed as Morfin Abcur 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 Abcur?

Because Morfin Abcur 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 Abcur approved?

It was concluded that, in accordance with EU requirements, Morfin Abcur 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 Abcur?

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

The marketing authorisation for Morfin Abcur was granted on 2012-06-14 in Sweden.

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

This summary was last updated in 2014-12.