LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Ketamin Abcur
(ketamine)

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Ketamin Abcur

(ketamine)

Solution for injection, 10 mg/ml, 50 mg/ml

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

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

What is Ketamin Abcur and what is it used for?

This medicine contains ketamine which belongs to a group of medicines called anaesthetic agents, which are used to put you to sleep during an surgery. Ketamin Abcur may be used in both routine and emergency surgery. Ketamin Abcur can be given alone or in combination with other anaestehtic agents.

How does Ketamin Abcur work?

Ketamin Abcur contains the active substance ketamine. Ketamine gives a dissociative anaesthesia by selectively interrupting association pathways in the brain. The analgesic effect in sub anaesthetic doses is probably due to interactions with biogenic amine- and endogenous opioid systems.

How is Ketamin Abcur used?

The pharmaceutical form of Ketamin Abcur is solution for injection for intravenous 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 Ketamin Abcur have been shown in studies?

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

What are the possible side effects of Ketamin Abcur?

Because Ketamin 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 Ketamin Abcur approved?

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

A risk management plan has been developed to ensure that Ketamin 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 Ketamin 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 Ketamin Abcur

The marketing authorisation for Ketamin Abcur was granted on 2016-02-25 in Sweden.

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

This summary was last updated in 2016-02