LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lidocaine Accord
(lidocaine 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.lakemedelsverket.se E-mail: registrator@mpa.se

Summary Public Assessment Report

Lidocaine Accord
(lidocaine hydrochloride)

solution for injection 10mg/ml and 20mg/ml

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

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

What is Lidocaine Accord and what is it used for?

Lidocaine Accord is a 'generic medicine'. This means that Lidocaine Accord is similar to a 'reference medicine' already authorised in the European Union (EU) called Xylocain.

Lidocaine Accord is a local anaesthetic. It is used to numb parts of the body during small surgical procedures.

How does Lidocaine Accord work?

Lidocaine Accord stops the nerves from being able to pass pain messages to the brain and so stops you feeling pain. It starts to work a few minutes after being injected and slowly wears off when the surgical procedure is over.

How is Lidocaine Accord used?

The pharmaceutical form of Lidocaine Accord 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 Lidocaine Accord have been shown in studies?

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

What are the possible side effects of Lidocaine Accord?

Because Lidocaine Accord 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 Lidocaine Accord approved?

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

A risk management plan has been developed to ensure that Lidocaine Accord 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 Lidocaine Accord, 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 Lidocaine Accord

The marketing authorisation for Lidocaine Accord was granted on 2015-07-16 in Sweden.

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

This summary was last updated in 2015-07-16