LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Lidocaine Grindeks
# (lidocaine hydrochloride)

# SE/H/982/01/DC

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# Summary Public Assessment Report

Lidocaine Grindeks
(lidocaine hydrochloride)

Solution for injection, 20 mg/ml

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

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

## What is Lidocaine Grindeks and what is it used for?

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

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

## How does Lidocaine Grindeks work?

Lidocaine Grindeks 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 Grindeks used?

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

No additional studies were needed as Lidocaine Grindeks 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 Grindeks?

Because Lidocaine Grindeks 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 Grindeks approved?

It was concluded that, in accordance with EU requirements, Lidocaine Grindeks 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 Grindeks?

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

The marketing authorisation for Lidocaine Grindeks was granted on 2011-05-27 in Sweden.

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

This summary was last updated in 2015-06-12.