LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lydagriks
(lidocaine hydrochloride monohydrate)

SE/H/2224/01-02/DC

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Lydagriks
lidocaine hydrochloride monohydrate

Solution for injection, 10 mg/ml, 20 mg/ml

This is a summary of the public assessment report (PAR) for Lydagriks. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lydagriks and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Xylocain utan konserveringsmedel.

The product is a local anaesthetic used to numb parts of the body during small surgical procedures.

How does Lydagriks work?
The product temporarily stops the nerve from being able to pass pain messages to the brain in the area where it is injected.

How is Lydagriks used?
The pharmaceutical form 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 in Sweden.

What benefits of Lydagriks have been shown in studies?
No additional studies were needed as the product is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, Xylocain utan konserveringsmedel.

What are the possible side effects from Lydagriks?
Because the product 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 side effects, see section 4 of the package leaflet.

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

Why is Lydagriks approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered therapeutically equivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Xylocain utan konserveringsmedel, 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 Lydagriks?
A risk management plan has been developed to ensure that the product 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, 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 Lydagriks

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

This summary was last updated in 2024-10.