LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lidokain Aguettant
(lidocaine hydrochloride)

SE/H/1975/01/DC

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@lakemedelsverket.se

Summary Public Assessment Report

Lidokain Aguettant
lidocaine hydrochloride

Solution for injection/infusion, 20 mg/ml

This is a summary of the public assessment report (PAR) for Lidokain Aguettant. 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 Lidokain Aguettant and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance.

The reference medicine for the product is Xylocain utan konserveringsmedel.

The company has provided additional own data to demonstrate therapeutic equivalence between the product and the reference medicine.

The product can be used in adults to numb part of the body during small surgical procedures.

How does Lidokain Aguettant work?

It stops the nerves from being able to pass pain messages to the brain and so stops the feeling of pain.

How is Lidokain Aguettant used?

The pharmaceutical form is solution for injection/infusion for injection into a vein, under the skin, or into the epidural space near the spinal cord.

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 Lidokain Aguettant have been shown in studies?

Because the product is a hybrid application and is considered to be therapeutically equivalent to the reference product Xylocain utan konserveringsmedel, the benefits and risks are taken as being the same as those of the reference medicine.

What are the possible side effects from Lidokain Aguettant?

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 Lidokain Aguettant approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalent to the reference medicine Xylocain utan konserveringsmedel. 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 Lidokain Aguettant?

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 Lidokain Aguettant

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

This summary was last updated in 2022-08.