LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lidokain/Adrenalin Aguettant (lidocaine hydrochloride monohydrate, adrenaline tartrate)

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lidocaine hydrochloride monohydrate, adrenaline tartrate

Solution for injection, 10 mg/ml + 5 mikrogram/ml, 20 mg/ml + 5 mikrogram/ml

This is a summary of the public assessment report (PAR) for Lidokain/Adrenalin 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/Adrenalin Aguettant 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 adrenalin.

The product is used to numb parts of the body during surgical procedures. The product can be used for local or regional anaesthesia.

How does Lidokain/Adrenalin Aguettant work?
The product contains the active substance lidocaine hydrochloride which is a local anaesthetic and the active substance adrenaline which prolongs the effect of lidocaine. It temporarily blocks the nerve signals in the area where it is injected from being able to pass pain messages to the brain, which prevents you from feeling pain.

How is Lidokain/Adrenalin Aguettant used?
The pharmaceutical form is a 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 in Sweden.

What benefits of Lidokain/Adrenalin Aguettant have been shown in studies?
No additional studies were needed as the product is a generic medicine that is given by infiltration anaesthesia, intravenous regional anaesthesia, nerve block or epidural anaesthesia and contains the same active substance as the reference medicine, Xylocain adrenalin.

What are the possible side effects from Lidokain/Adrenalin Aguettant?
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 Lidokain/Adrenalin 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 similar to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Xylocain adrenalin, 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/Adrenalin 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/Adrenalin Aguettant
The full PAR for Lidokain/Adrenalin Aguettant can be found on the following website: MRI - Home. For more information about treatment with Lidokain/Adrenalin Aguettant, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-09