

Summary Public Assessment Report

Lidokain GALENpharma (lidocaine)

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lidocaine

Rectal ointment, 50 mg/g

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

The product is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of the product is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

The product is used in adults for:

- Relief of pain in the anal region before local examination,
- Treatment of itching and pain in the anal area caused by, for example, haemorrhoids.

How does Lidokain GALENpharma work?

The product has a pain-relieving (analgesic) and local anesthetic effect.

Lidocaine blocks the formation and transmission of nerve impulses by reversibly reducing the membrane permeability of peripheral nerve cells for sodium ions, which is increased during nerve impulse transmission.

Onset of action is within a few minutes and lasts for several hours. The duration of contact determines the duration of action of the drug.

By inhibiting the excitability of the pain-transmitting sensory end organs, lidocaine locally limits and reversibly reduces pain sensation. Individually to a very different extent, this also applies to the sensation of cold, warmth, touch and pressure.

How is Lidokain GALENpharma used?

The pharmaceutical form is rectal ointment for use in the anal area.

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 GALENpharma have been shown in studies?

As *lidocaine* is a well-known substance, and its use in the treatment of “*adults for the treatment of:*

- *Relief of pain in the anal region before proctological examination,*
- *Symptomatic treatment of itching and pain in the anal area caused by, for example, haemorrhoids.”*

is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of *lidocaine* in the treatment of the above-mentioned indication.

What are the possible side effects from Lidokain GALENpharma?

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 GALENpharma approved?

The Swedish Medical Products Agency decided that 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 GALENpharma?

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 GALENpharma

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

This summary was last updated in 2023-10.