

LIDOCAINE 5 % m/m OINTMENT

Lidocaine

Package leaflet: Information for the user

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to use Lidocaine 5 % m/m Ointment carefully to get the best results from it. Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 24 hours.

What is in this leaflet

1. What Lidocaine Ointment is and what it is used for
2. What you need to know before you use Lidocaine Ointment
3. How to use Lidocaine Ointment
4. Possible side effects
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1 What Lidocaine Ointment is and what it is used for

Lidocaine is a medicine called a local anaesthetic which is used to produce numbness to a part of your body to relieve pain or discomfort.

Lidocaine Ointment is used:

- for numbing gums in dentistry
- for rectal itch or ulcers (pruritus ani or anal fissures)
- for relief of female genital itch (pruritus vulvae)
- for relief of piles (haemorrhoids)
- for relief of shingles (herpes zoster), cold sores (herpes labialis)
- for the relief of sore nipples in nursing mothers
- as a lubricant for rectal or urethral examination (proctoscopy and cystoscopy).

2 What you need to know before you use Lidocaine Ointment

DO NOT use Lidocaine Ointment and consult your doctor or pharmacist if you:

- are allergic (hypersensitive) to lidocaine or any of the other ingredients of this ointment
- are allergic to other similar amide local anaesthetics.

Taking other medicines

Talk to your doctor or pharmacist if you are taking any of the following:

- cimetidine for stomach problems
- propranolol for high blood pressure, anxiety or heart problems.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking any medicine.

Driving and using machines

Lidocaine Ointment may cause drowsiness if it enters your blood stream. If affected, DO NOT drive or operate machinery.

3 How to use Lidocaine Ointment

If your doctor has prescribed this medicine, always use Lidocaine Ointment exactly as your doctor has told you. Otherwise, follow the instructions below. If you are not sure how to use this medicine, talk to your doctor or pharmacist.

- Apply using gauze or barrier gloves, if not available, wash your hands before and after applying Lidocaine Ointment. Note: Lidocaine Ointment is not sterile and should not be used with aseptic techniques.

Adults, the elderly and children:

• Anaesthesia and pain relief

Apply 1 to 2 ml (about 2 to 4 cm when squeezed out of the tube) and gently spread over the affected area (the ointment will soften at body temperature).

Repeat when necessary but use no more than 5 g (one third of a tube) within 24 hours unless instructed otherwise by your doctor.

• **Nursing mothers**

Apply to the nipples using a small piece of lint or gauze, wash off immediately before the next feed.

• **Dentistry**

Apply to dry gum and rub gently.

If you are not sure how to use this medicine talk to your doctor or pharmacist.

If you use more Lidocaine Ointment than you should

If you apply too much ointment, wipe off the excess with a paper towel or similar. If you (or someone else) swallow any of the ointment, or if you think a child has swallowed any of the ointment, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause a low blood pressure and heart problems. Please take this leaflet, any remaining ointment, and the container with you to the hospital or doctor so that they know which ointment has been consumed.

If you forget to use Lidocaine Ointment

If you forget to apply the ointment at the correct time, make the application as soon as possible, and then make your applications at the correct time. If it is 3 hours, or less, to the next application, then ignore the missed dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Lidocaine Ointment can cause side effects, although not everybody gets them.

If the following happens, stop using the ointment and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Most patients using topical lidocaine will have no problems when used in the correct amount for the prescribed time.

- Using Lidocaine Ointment for a prolonged period (longer than prescribed) can cause an allergic reaction.

- If the condition becomes worse during treatment, or you experience any other ill effects, stop using the ointment and tell your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Lidocaine Ointment

Keep this medicine out of the sight and reach of children.

Store the ointment below 25° C.

Do not use Lidocaine Ointment after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Lidocaine Ointment contains

- The active ingredient is lidocaine 5 % m/m.
- The other ingredient is macrogol.

What Lidocaine Ointment looks like and contents of the pack

- Lidocaine Ointment is packed in an internally lacquered aluminium tube fitted with a polythene cap.
- The pack size is 15 g.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer

Merckle GmbH, Graf-Arco-Straße 3, 89079 Ulm, Germany

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