

PACKAGE LEAFLET: INFORMATION FOR THE USER

LIDOPROCT

(50.0 + 2.5) mg / g rectal ointment

LIDOCAINE, HYDROCORTISONE ACETATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What LIDOPROCT is and what it is used for
2. Before you take LIDOPROCT
3. How to take use LIDOPROCT
4. Possible side effects
5. How to store LIDOPROCT
6. Further information

1. WHAT LIDOPROCT IS AND WHAT IT IS USED FOR

LIDOPROCT contains two active components: Lidocaine and hydrocortisone acetate.

- Lidocaine (also known as lignocaine) belongs to a group of medicines called local anesthetics. It acts by blocking the transmission of pain impulses, and is applied in order to eliminate pain and itching.
- Hydrocortisone acetate belongs to a group of medicines called corticosteroids.

LIDOPROCT can be used in adults and children of all ages for the following reason:

- reduction of symptoms such as itching in the area of anus or female private parts (genitals);
- reduction of symptoms caused by hemorrhoids and other problems that may occur in the area of the anus, such as pain and inflammation.

2. BEFORE YOU TAKE LIDOPROCT

Do not take LIDOPROCT

- If you have an allergy (hypersensitivity) to Lidocaine, hydrocortisone acetate, aluminium subacetate, zinc oxide, or other ingredient of this medicine (section 6)

- If you have ever had an allergic reaction to other local anesthetics or other corticosteroid medicines
- If you have an infection that does not heal at the site of application
- If you are taking medicines called amiodarone or sotalol

Take special care with LIDOPROCT, so you must tell the doctor if you

- If your skin is very thin or delicate in the area where you intend to apply LIDOPROCT;
- If the area of ointment application is infected, it is required to apply antibacterial, antiviral or antifungal agents (depending on infection).
- If you or someone in your family has a rare disease called porphyria (blood disorder).

If any of the above applies to you or if you are not sure, talk to your doctor or pharmacist before using this medicine.

Taking other medicines

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

Tell your doctor or pharmacist if you are already applying:

- Medicines for the treatment of irregular heartbeat (eg, amiodarone or sotalol);
- Other local anesthetics.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

Your doctor will decide whether you can apply LIDOPROCT during this period.

Driving and using machines

There is no evidence that LIDOPROCT ointment has effect on the ability to drive and use machines. However, depending on the applied quantity, LIDOPROCT can have a slight impact on your alertness and coordination.

Other warnings

LIDOPROCT contains ethyl and stearyl alcohol. Ethyl and stearyl alcohol may cause local skin reaction (dermatitis).

3. HOW TO TAKE LIDOPROCT

When applying LIDOPROCT ointment strictly follow the instructions given to you by your doctor.

Dosage

- Consult your doctor on how much ointment you need to apply and how often.
- Ointment is generally applied to the affected area several times a day.
- The daily dose should not exceed the amount of 6 g (grams) of LIDOPROCT. This is about one-third of the tube.

How long to apply LIDOPROCT

- LIDOPROCT should be used during the time-limited period.
- Treatment in continuity may last no longer than three weeks. If more than three week treatment is required, a break in treatment should be taken, especially if it is suspected that there was an irritation inside the anus and around the site where the ointment is applied.
- If you have irritation, your doctor may want you to do allergy skin test called patch test to determine whether the cause of irritation is LIDOPROCT.

The use of the applicator

- There is the applicator inside the box (used to facilitate the application of rectal fat). Your doctor will tell you whether you need to use it.
- If your doctor has recommended the use of the applicator, be careful not to apply too much ointment inside the anus, especially if the ointment is applied to a child.
- After each use, thoroughly wash the applicator.

If you use more LIDOPROCT than you should

Never apply more LIDOPROCT ointment than you are prescribed.

- If you have applied too much LIDOPROCT rectal ointment, contact your doctor as soon as possible.
- Too much ointment, although rare, can cause convulsions in children, and in this case it is especially important to seek medical assistance as soon as possible.

If you forget to take LIDOPROCT

If you forgot to apply LIDOPROCT ointment do it as soon as possible and then continue as usual. Do not apply double dose to make up for a forgotten dose.

If you stop applying LIDOPROCT rectal ointment

If you suddenly stop applying this medicine, it should not have a damaging effect on your body.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Stop applying LIDOPROCT and immediately contact your doctor if you notice any of the following side effects - you may need urgent medical treatment:

- Sudden rash, itching or hives on the skin;
- Swelling of the face, lips, tongue or other parts of the body;
- Shortness of breath, wheezing when breathing or shortness of breath.

This may mean that you have an allergic reaction.

Stop applying LIDOPROCT and consult your doctor if you notice any of the following side effects:

- Pain in the anus;
- Bleeding from the back passage.

Other possible side effects

- Redness, swelling and itching at the site administration of LIDOPROCT.

Reporting of suspected side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE LIDOPROCT

Keep out of the reach and sight of children.

Store in the refrigerator at 2 ° C - 8 ° C, until the opening.

After opening, store at room temperature.

Ointment is usable 3 months after opening.

Shelf life: 18 months.

Do not use LIDOPROCT after the expiry date which is stated on the label.

6. FURTHER INFORMATION

What LIDOPROCT contains

1 g of LIDOPROCT rectal ointment contains:

Lidocaine 50.00 mg

Hydrocortisone Acetate 2.50 mg

LIDOPROCT contains the following excipients: Macrogol 400, zinc oxide, Macrogol 4000, aluminum subacetate, cetyl alcohol, stearyl alcohol, and purified water.

What LIDOPROCT looks like and contents of the pack

LIDOPROCT is white to slightly yellow fat.

LIDOPROCT rectal ointment is packed into a box with a tube containing 20 g of ointment, and the applicator for easier application of rectal ointment.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

BOSNALIJEK d.d.,
Jukićeva 53, Sarajevo
Bosna i Hercegovina

Manufacturer of the medicinal product

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