

## **Package leaflet: Information for the user**

### **Lidoposterin 50 mg/g rectal ointment**

lidocaine

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

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 7 days.

#### **What is in this leaflet**

1. What <invented name> is and what it is used for
2. What you need to know before you use <invented name>
3. How to use <invented name>
4. Possible side effects
5. How to store <invented name>
6. Contents of the pack and other information

#### **1. What <invented name> is and what it is used for**

<Invented name> contains the active substance lidocaine, which has an analgesic and local anaesthetic effect. <Invented name> is used in adults aged 18 years and over for the local treatment of discomfort in the anal area, e.g. itching and pain caused by, for example, haemorrhoids.

You should contact your doctor after 7 days if you do not feel better or if you feel worse so that other more serious causes of the symptoms can be ruled out.

#### **2. What you need to know before you use <invented name>**

##### **Do not use <invented name>:**

- if you are allergic to lidocaine or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using <invented name>.

- Do not use more than the highest recommended dose as a higher dose may lead to several side effects. If you use a lot more <invented name>, or if you use it more often than is recommended, serious side effects may occur, e.g. affecting the central nervous system and cardiovascular system.
- Talk to your doctor before starting to use <invented name> if you have an irregular heart rhythm and are taking medication (anti-arrhythmics) for this. Your doctor will decide whether or not <invented name> is suitable for you.
- Do not use the medicine if you have a bleeding from the anal area. Discontinue the treatment and contact your doctor if bleeding occurs during the treatment.
- If you have an infection in the anal area, relevant treatment must be initiated before you start using <invented name>. Ask your doctor for advice.
- Local irritation can sometimes occur in the event of hypersensitivity to lidocaine. In these cases treatment should be discontinued.

- If you have heart, severe liver or kidney dysfunction.

### **Children and adolescents**

The safety and efficacy of Lidoposterin in children under 18 years have not yet been established. No data are available.

### **Other medicines and <invented name>**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

<Invented name> may affect or be affected by certain medicines containing the following active ingredients:

- other local anaesthetic agents: avoid using other local anaesthetic agents at the same time as <invented name>;
- medicines for an irregular heart rhythm (so-called anti-arrhythmics), e.g. amiodarone.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

#### Pregnancy

Lidocaine is passed over into the foetus. The risk to humans is unknown. <Invented name> must therefore only be used during pregnancy when absolutely necessary.

#### Breastfeeding

The active ingredient in <invented name> passes into breast milk, but probably does not affect children who are being breastfed. You should nonetheless ask your doctor for advice in the case of anything more than occasional use of <invented name> while breastfeeding.

### **Driving and using machines**

<Invented name> does not normally affect your ability to drive a motor vehicle or use machinery.

### **<Invented name> contains cetyl alcohol**

May cause local skin reactions (e.g. contact dermatitis).

## **3. How to use <invented name>**

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Start by using the rectal ointment 2–3 times a day, then twice a day (morning and evening), preferably before (about 30 minutes) and after a bowel movement. Use a finger to apply the ointment carefully in a thin layer around the anal area. Use a disposable glove. The anal area should be cleaned thoroughly before use.

The amount of ointment will depend on the areas of skin and mucosa to be treated.

Only small amounts of ointment should be used. A maximum of 9 cm of ointment (or approximately the size of a grape, which corresponds to 2.5 grams of ointment) may be used.

The package includes an applicator with side openings for use in the rectum. The ointment can be applied directly to the site of the pain and itching using the applicator.

#### *Directions for use of the applicator:*

Screw the applicator onto the tube and remove the top of the applicator. Squeeze the tube to push the ointment into the applicator, where it will come out through the side openings. Then carefully insert the applicator into the anus.

Insertion can be made easier by lubricating the applicator with a little ointment. The ointment is introduced into the rectum by squeezing the tube again.

After use, the applicator should be cleaned by squeezing a little ointment through the side openings and wiping the surface dry with a piece of absorbent paper. The top must be screwed on securely again. This prevents the ointment from drying out.

If the ointment is not used for a lengthy period of time, the applicator should be unscrewed and cleaned using warm water.

#### *Duration of use*

Ask a doctor for advice if the symptoms have not improved after 7 days so that the cause of the itching and pain can be determined.

#### *Note:*

Because of your body temperature, the use of ointments in the anal area may lead to soiling of underclothes. It is therefore recommended that you use some form of protection for your underclothes (e.g. a paper handkerchief, cotton, etc.).

#### **If you use more <invented name> than you should**

Overdose: If, by mistake, a small child has ingested the ointment, gastrointestinal poisoning may occur, with stomach pain and nausea. If very high doses of lidocaine are ingested, a reduced level of consciousness, shock, seizures and breathing problems may occur.

If you have occasionally applied <invented name> more often than recommended, no increase in side effects is expected. In that case, continue using at the recommended dose and follow the directions for treatment.

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

## **4. Possible side effects**

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

### Serious side effects

Stop using <invented name> and immediately contact a doctor or go to the nearest emergency department if you experience the following symptoms:

Allergic reactions, in the most serious cases anaphylactic shock (has been reported – occurs in an unknown number of users):

- Palpitations
- Cold sweats
- Breathing difficulties
- Rashes
- Swelling of the face or neck
- Dizziness or collapse

### Other side effects

#### **Very common (may affect more than 1 in 10 people)**

Itching and burning sensation in the anal area. This may be a hypersensitivity reaction.

#### **Common (may affect up to 1 in 10 people)**

Diarrhoea

**Uncommon (may affect up to 1 in 100 people)**

Discomfort and reddening in the anal area.

**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 national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store <invented name>**

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

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Use within six months of opening.

Do not store above 30°C.

To ensure ease of application, store the ointment at room temperature (18°C up to a maximum of 25°C).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information****What <invented name> contains**

- The active substance is lidocaine.
- The other ingredients are cetyl alcohol, macrogol and purified water.

**What <invented name> looks like and contents of the pack**

<Invented name> is a white, homogenous ointment.

Pack size: 25 g tube and applicator.

**Marketing Authorisation Holder and Manufacturer**

[To be completed nationally]

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Sweden: Lidoposterin 50 mg/g rektalsalva

Norway: Lidoposterin 50 mg/g rektalsalve

Denmark: Lidoposterin, rektalsalve 50 mg/g

Germany: Lidocain HWI pharma 50 mg/g Rektalsalbe

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