

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

### **Lidokain Isdin 40 mg/g cream**

#### **Lidocaine**

**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. See section 4.

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

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

#### **1. What Lidokain Isdin is and what it is used for**

Lidokain Isdin 40 mg/g cream contains lidocaine and is a medicine for local numbing (local anaesthesia) of the skin.

Lidokain Isdin is used to numb the skin in connection with needle insertion (e.g. prior to blood sampling).

#### **2. What you need to know before you use Lidokain Isdin**

##### **Do not use Lidokain Isdin**

- if you are allergic to lidocaine, or any of the other ingredients of Lidokain Isdin this medicine (listed in section 6).
- if you are allergic (hypersensitive) to local anaesthetics, soya or peanuts.
- on infants born too early (born before the 37<sup>th</sup> full week of pregnancy).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Lidokain Isdin

- in surgical interventions in the ear canal or inner ear as there is a risk of damage to the inner ear.
- if you suffer from severe underlying disease e.g. heart disease or severely reduced liver function.
- if you take medicines for heart rhythm disorders (see Using other medicines).

- near the eyes, as lidocaine may cause eye irritation. In addition, with the loss of protective reflexes, corneal irritation or grazing may occur. If Lidokain Isdin comes into contact with the eyes, rinse them immediately with lukewarm water and protect them until sensation returns.
- if you are about to receive a vaccination with live vaccine (e.g. tuberculosis vaccine). Vaccines should not be administered in areas where Lidokain Isdin has been applied as the effect of the vaccine may be affected.

Please inform your doctor if any of the above applies to you.

Lidokain Isdin should only be used on undamaged skin (not on mucous membranes, wounds or eczema).

#### **Other medicines and Lidokain Isdin**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important for your doctor to know if you are already being treated with any of the medicines mentioned below, as the risk of side effects may be increased:

- lidocaine in high doses for other reasons
- other local anaesthetics
- medicines for arrhythmia (heart rhythm disorders) e.g. tocainide, mexiletine and 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 taking any medicine.

Temporary use of Lidokain Isdin during pregnancy is unlikely to cause harmful effects to the foetus.

Lidokain Isdin passes into breast milk but is unlikely to affect the breast fed child.

#### **Driving and using machines**

Lidokain Isdin has no known effect on the ability to drive or operate machinery.

#### **Lidokain Isdin contains propylene glycol, benzyl alcohol, hydrogenated soy lecithin and polysorbate 80.**

Lidokain Isdin contains 75 mg propylene glycol in each gram of cream. Propylene glycol may cause skin irritation.

Lidokain Isdin contains 15 mg of benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

Lidokain Isdin contains 7,5 mg polysorbate 80 that can cause allergic reactions.

Lidokain Isdin contains hydrogenated soy lecithin. If you are allergic to peanut or soya, do not use this medicinal product.

### **3. How to use Lidokain Isdin**

Always use Lidokain Isdin exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

*Children from 6 to 12 years:*

The single application dose is 2-3g. Recommended application time, i.e. the time the cream should be on the skin, is 60 minutes, but no longer than two hours.

*Adolescents over 12 years and Adults:*

The single application dose is 2-3g. The maximum daily dose is 5 grams. The recommended application time is 60 minutes, but no longer than two hours.

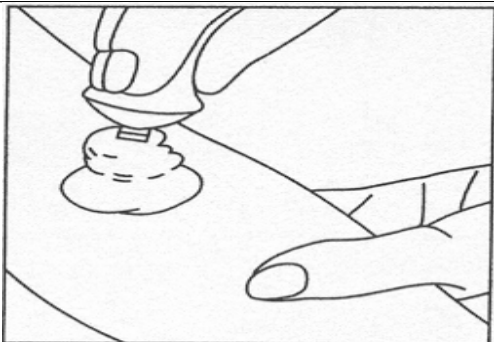
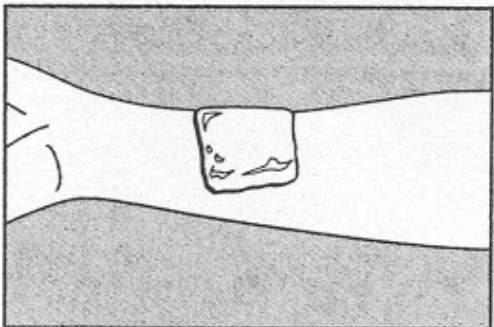
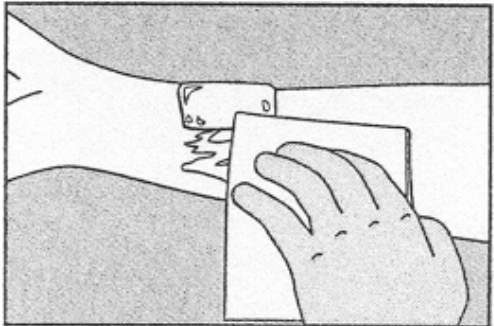
*Children from 2 to 6 years:*

As there is insufficient experience, Lidokain Isdin is not recommended in this age group.

*Children from 0 to 2 years:*

As there is no experience, Lidokain Isdin should not be used in this age group.

1 g of cream corresponds to a strand of approximately 2.5 cm.

|                                                                                     |                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | 1) A thick, even layer of cream should be applied to the skin area being treated.                                                                                                                         |
|  | 2) Leave the cream on the skin according to above application times.<br><br>Use of a covering (e.g. plaster) is recommended to avoid the cream accidentally coming off before the application time is up. |
|  | 3) Wipe off the cream afterwards. The skin area should be washed prior to surgery.<br><br>Close the tube after use.                                                                                       |

If you have the impression that the effect of Lidokain Isdin is too strong or too weak, please talk to your doctor or pharmacist.

**If you use more Lidokain Isdin than you should**

Overdose is unlikely in normal use on undamaged skin.

If you have used more Lidokain Isdin than you should, or if a child has taken the medicine by accident or got too much on the skin, please contact your doctor or the hospital to get a risk assessment and advice.

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

#### **4. Possible side effects**

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

*Uncommon (1 to 10 users in 1,000):*

Local skin reactions (pallor, redness, itching and stinging) in the treated area. The symptoms are usually temporary and mild.

*Rare (1 to 10 users in 10,000):*

Allergic contact eczema.

*Very rare (less than 1 user in 10,000):*

Allergic reactions (in severe cases, anaphylactic shock)

Stop using Lidokain Isdin and contact your doctor immediately if you get any of the following symptoms (anaphylactic shock)

- Swelling of the face, tongue or throat
- Difficulty swallowing
- Urticaria and trouble breathing.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **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 <To be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Lidokain Isdin**

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 the tube after EXP. The expiry date refers to the last day of that month. After opening the tube, the shelf life is 6 months.

Do not store above 30°C.

After opening the tube, the shelf life is 6 months.

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 Lidokain Isdin contains**

- The active substance is lidocaine. 1 gram cream contains 40 mg lidocaine.
- The other ingredients are purified water, propylene glycol, hydrogenated soy lecithin, benzyl alcohol, polysorbate 80, carbomer 940, trolamine, cholesterol.

**What Lidokain Isdin looks like and contents of the pack**

Lidokain Isdin is a white to yellowish cream.

Pack sizes: 5 g, 10 g, 20 g, 30 g, 40 g and 50 g in aluminium tubes. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

[to be completed nationally]

**Manufacturer:**

Medinfar Manufacturing S.A.  
Parque Industrial Armando Martins Tavares  
Rua Outeiro da Armada, 5  
Condeixa-a-Nova  
3150-194 Sebal  
Portugal

**This leaflet was last approved in 2025-05-08**

Detailed information on this medicine is available on the website of {name of MS Agency (link)}.