

PACKAGE LEAFLET: INFORMATION FOR THE USER

LIDOKAIN

Belupo 100 mg / ml spray

LIDOCAINE

• 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 LIDOKAIN Belupo 100 mg / ml spray is and what it is used for
2. Before you use LIDOKAIN Belupo 100 mg / ml spray
3. How to use LIDOKAIN Belupo 100 mg / ml spray
4. Possible side effects
5. How to store LIDOKAIN Belupo 100 mg / ml spray
6. Further information

1. WHAT LIDOKAIN BELUPO 100 MG / ML SPRAY IS AND WHAT IS IT USED FOR

- Active substance of BELUPO lidocaine 100 mg / ml spray contains is lidocaine. Lidocaine is one of the medicines called local anesthetics. BELUPO lidocaine 100 mg / ml spray is used for anesthesia of body parts. Removes pain during:
 - Medical examination and surgery of the nose and throat
 - Delivery, as well as with sewing, if it is necessary after the birth.
 - Treatment at the dentist.

2. BEFORE YOU USE LIDOKAIN BELUPO 100 MG / ML SPRAY

Do not use LIDOKAIN Belupo 100 mg / ml spray

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed inSection6)
- If you are allergic to any other local anesthetics of the same group (such as prilocaine or bupivacaine).

Take special care with LIDOKAIN Belupo 100 mg / ml spray

Before you start taking LIDOKAIN Belupo 100 mg / ml spray tell your doctor or dentist if you have got anything listed below:

- you have cuts, sores or ulcers in the throat, mouth or nose
- You have an infection of the airways
- You have epilepsy
- You have problems with the heart, for example. slow heartbeat
- You have very low blood pressure
- You have problems with your liver or kidneys
- You or one of your relatives has porphyria, a rare disease of the blood pigment.

If any of the above applies to you or else you are not sure, contact your doctor or dentist.

Children and adolescents

Dose of LIDOKAIN Belupo 100 mg / ml spray should be adjusted according to age, body weight, physical condition and the type of medical procedure (see section 3. How to use LIDOKAIN Belupo 100 mg / ml spray).

Using other medicines

- Tell your doctor, dentist or pharmacist if you are taking, have recently taken or could take any other medicines. This also applies to medicines that you buy without a prescription, including herbal medicines.
- BELUPO lidocaine 100 mg / ml aerosol may impact the effect of other drugs, but some drugs can affect the way LIDOKAIN Belupo 100 mg / ml spray affects. It is particularly important to tell your doctor or dentist if you are taking medicines to treat cardiac arrhythmias (arrhythmias), such as eg. Mexiletine

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant, are planning to have a baby or breast-feeding, tell your doctor or dentist before applying LIDOKAIN Belupo 100 mg / ml spray.

Driving and using machines

LIDOKAIN Belupo 100 mg / ml spray can affect the ability to drive and use machinery, depending on the body part where the spray was applied and the amount used. Your doctor or dentist will tell you when you should not drive or operate machinery.

What LIDOKAIN Belupo 100 mg / ml spray contains

- ethanol. This drug contains ethanol in an amount of 39.6% by volume of ethanol (alcohol), ie. up to 625 mg per dose, corresponding to 15.84 ml of beer, wine or 6.6 ml per dose. Harmful for alcoholics. It should be taken into account in pregnant women, nursing mothers, children and high risk groups of people, such as patients with liver disease or epilepsy.
- Propylene glycol. This medicine contains propylene glycol, which can irritate the skin.

3. HOW TO USE LIDOKAIN BELUPO 100 MG / ML SPRAY

- Depending on the type of pain that you should act and your age and physical condition.
- If you apply LIDOKAIN Belupo 100 mg / ml spray at home, you should take the dose prescribed by your doctor or dentist. Always follow LIDOKAIN Belupo 100 mg / ml spray exactly as you were told by your doctor or dentist. Check with your doctor or dentist or pharmacist if you are unsure.

Do not use more than 20 thrusts pump in adults.

Use the smallest possible number of presses.
Do not spray in eyes.

How to apply LIDOKAIN Belupo spray 100 mg / ml in the oral cavity and the pharynx

- LIDOKAIN Belupo 100 mg / ml spray causes numbness sensation in the mouth and throat due to which food or liquid can get into the respiratory tract. It may also cause difficulty in swallowing or cause you to accidentally bite your tongue or to get cheek mucosa. In elderly people, disabled people and in children, LIDOKAIN Belupo spray 100 mg / ml must be used with caution.

If you use more LIDOKAIN Belupo spray 100 mg / ml than you should

- If you take more LIDOKAIN Belupo spray 100 mg / ml than you should, immediately tell your doctor or pharmacist!

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you notice any side effects, please inform your doctor or pharmacist about it.

Severe allergic reactions:

If you notice any of the following serious side effects, stop taking this medicine and inform your doctor or contact your nearest medical emergency:

- Swelling of the face, lips, tongue and throat, which can cause difficulty swallowing
- Strong or sudden swelling of the hands, feet or ankles
- hard breathing
- Severe itching of the skin (with blisters).

Other possible side effects:

- Irritation at the injection site
- jitters
- dizziness
- drowsiness
- Loss of consciousness
- sore throat
- Hoarseness or loss of voice
- Low blood pressure which can cause dizziness or light-headedness
- Seizures (convulsions)
- Difficult or slowed breathing
- Slow heart rate
- Cessation of breathing or heart rate.

If you notice any side effects, please tell your doctor or dentist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE LIDOKAIN BELUPO 100 MG / ML SPRAY

Keep out of the reach and sight of children.

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

Do not store above 25°C. Store in the original carton

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. FURTHER INFORMATION

What LIDOKAIN Belupo 100 mg / ml spray contains

- Active ingredients: lidocaine
- Other ingredients: ethanol (96 percent); propylene glycol; levomenthol; eucalyptus essential oil; saharinnatrij; water, purified
- A positive displacement dose (0.1 ml) of the spray solution contains 10 mg of lidocaine

Packing

LIDOKAIN Belupo 100 mg / ml spray is a clear, colorless to light yellow solution, with characteristic smell.

50 ml of a solution in a brown glass bottle with a pump dispenser or a spray, in a box.

The regime of dispensing

The drug is issued on prescription.

Manufacturer

Belupo, medications and cosmetics, Ltd.

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