

LIDONOSTRUM® 10% W/V TOPICAL SPRAY

Lidocaine 100 mg/ml

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1. What Lidonostrum 10% w/v Topical Spray is used for

The name of your medicine is 'Lidonostrum 10% w/v Topical Spray'. In this leaflet, it is referred to as 'Lidonostrum 10% w/v Topical Spray'. Lidonostrum 10% w/v Topical Spray contains a medicine called lidocaine. This belongs to a group of medicines called local anaesthetics.

Lidonostrum 10% w/v Topical Spray is used to numb (anaesthetise) parts of the body. It is used as a pain relief during:

- Medical examinations and operations of the nose and throat.
- Childbirth, and after the birth if stitches are needed.
- Treatment at the dentist.

2. How Lidonostrum 10% w/v Topical Spray works

Lidonostrum 10% w/v Topical Spray is used to numb (anaesthetise) parts of the body. The product will usually be given to you by a doctor or dentist.

However, the product can be self-administered. If you are given Lidonostrum 10% w/v Topical Spray to take home, you must use the dose recommended by your doctor or dentist. Always use Lidonostrum 10% w/v Topical Spray exactly as your doctor or dentist has told you. You should check with them if you are not sure

3. Before you use Lidonostrum 10% w/v Topical Spray

When you must not use it

You must not be given Lidonostrum 10% w/v Topical Spray:

- if you are allergic to lidocaine or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to any other local anaesthetics of the same class (such as prilocaine or bupivacaine).

You must not be given Lidonostrum 10% w/v Topical Spray if any of the above apply to you. If you are not sure, talk to your doctor, nurse, dentist or pharmacist before you are given Lidonostrum 10% w/v Topical Spray.

Before you start to use it

Talk to your doctor, nurse, dentist or pharmacist before Lidonostrum 10% w/v Topical Spray is given to you:

- if you have any cuts, sores or ulcers in your throat, mouth or nose.
- if you have a chest infection.
- if you have epilepsy.
- if you have heart problems such as a slow heartbeat.
- if you have very low blood pressure.
- if you have liver or kidney problems.
- if you have ever been told that you have a rare disease of the blood pigment called 'porphyria' or anyone in your family has it.

If you are not sure if any of the above apply to you, talk to your doctor, nurse, dentist or pharmacist before having Lidonostrum 10% w/v Topical Spray.

Taking other medicines

Tell your doctor or dentist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Lidonostrum 10% w/v Topical Spray can affect the way some medicines work and some medicines can have an effect on Lidonostrum 10% w/v Topical Spray.

In particular, tell your doctor or dentist if you are taking or using any of the following medicines:

- Medicines used to treat an uneven heart beat (arrhythmia) such as mexiletine.
- Other medicines that contain lidocaine.

4. How to use Lidonostrum 10% w/v Topical Spray

How much to use

- You should use as few sprays as possible.
- Do not use more than 3 sprays for every 10 kg that you weigh.
- Do not use more than 20 sprays (adults).
- Do not get the spray in your eyes.
- The spray nozzle is bent so that it works properly. Do not try to shorten the nozzle or change its shape as this will affect how it works.

When to use it

Lidonostrum 10% w/v Topical Spray will usually be given to you by a doctor or dentist. The dose that your doctor or dentist gives you will depend on the type of pain relief that you need. It will also depend on your age and physical condition.

If you are given Lidonostrum 10% w/v Topical Spray to take home, you must use the dose recommended by your doctor or dentist.

When Lidonostrum 10% w/v Topical Spray is used in the mouth and throat it causes a loss of feeling. This could result in food or liquid going down the wrong way. Also, this may make it difficult to swallow or cause some people to accidentally bite their tongue or cheek.

Lidonostrum 10% w/v Topical Spray should be used with care in the elderly, in people who are in poor general health and in children.

Routes of administration: dental use; nasal use; vaginal use.

How long to use it

Always use Lidonostrum 10% w/v Topical Spray exactly as your doctor or dentist has told you. You should check with them if you are not sure.

If you forget to use it

Do not take a double dose to make up for a forgotten.

If you use too much (Overdose)

If you think you have used more Lidonostrum 10% w/v Topical Spray than you should, talk to your doctor or dentist immediately.

5. While you are using it

Things you must do

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

Keep this leaflet. You may need to read it again. If you get any side effects, talk to your doctor, nurse, dentist or pharmacist. This includes any possible side effects not listed here.

Things you must not do

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.

Things to be careful of

Lidonostrum 10% w/v Topical Spray may affect your ability to drive or use tools or machines. This depends on where in the body Lidonostrum 10% w/v Topical Spray is used and how much is used. Your doctor or dentist will tell you when it is safe for you to do these activities.

This medicinal product contains small amounts of **ethanol (alcohol)**, less than 100 mg per spray (24.1 mg in each depression). Ethanol is used as a solvent and preservative in this medicine.

Lidonostrum 10% w/v Topical Spray contains **propylene glycol**. This medicine contains 0.4 mg propylene glycol in each delivered dose. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

6. Side effects

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

Severe allergic reactions (rare, may affect up to 1 in 1,000 people):

If you have a severe allergic reaction, tell your doctor immediately. The signs may include sudden onset of:

- Swelling of your face, lips, tongue or throat. This may make it difficult to swallow.
- Severe or sudden swelling of your hands, feet and ankles.

- Difficulty breathing.

- Severe itching of the skin (with raised lumps).

Other possible side effects:

- Irritation where Lidonostrum 10% w/v Topical Spray has been used.
- Feeling nervous.
- Feeling dizzy.
- Feeling sleepy.
- Loss of consciousness.
- Sore throat.

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- Hoarse voice or loss of voice.
- Low blood pressure. This might make you feel dizzy or light-headed.
- Fits (seizures).
- Difficulty breathing or slow breathing.
- Slow heartbeat.
- Stopped breathing or a stopped heartbeat.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

11. Date of revision
10/02/2023

Serial Number
NPRA (R2) 22/170

7. Storage and disposal of Lidonostrum 10% w/v Topical Spray

Storage

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 bottle and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

At temperatures below 8° C the spray solution may start to go solid. This will dissolve when the spray solution is warmed up gently to room temperature.

Your doctor/dentist or the hospital will normally store Lidonostrum 10% w/v Topical Spray.

Disposal

The staff are responsible for the storing, using and disposing of the spray in the correct way.

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.

8. Product Description

What it looks like

Lidonostrum 10% w/v Topical Spray is a pump spray. It comes in a 80 g bottle. It is a clear, colourless to yellowish liquid with a characteristic odour and taste to banana.

Ingredients

Active ingredient: lidocaine. Each dose of spray contains 10 mg of lidocaine.

Inactive ingredients: ethanol (solvent and preservative), polyethylene glycol, banana essence (containing propylene glycol), menthol, saccharin and purified water.

MAL number: XXXXXXXX

9. Manufacturer

SIDEFARMA – Sociedade Industrial de Expansão Farmacêutica, S.A.
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10. Product Registration Holder

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