

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

XYLOCAINE® OINTMENT 5%

lidocaine ointment

Read this carefully before you start applying **XYLOCAINE Ointment 5%** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **XYLOCAINE Ointment 5%**.

What is XYLOCAINE Ointment 5% used for?

XYLOCAINE Ointment 5% is a topical ointment that is used in adults and children (2 years of age and older) to lubricate and numb (produce a temporary loss of feeling) the skin. It is used

- by your healthcare professional before certain types of medical procedures;
- to help relieve the pain from:
 - minor scrapes
 - sunburns or other minor burns
 - sore nipples
 - insect bites
 - hemorrhoids

How does XYLOCAINE Ointment 5% work?

XYLOCAINE Ointment 5% belongs to a group of medicines called topical anaesthetics. Topical anaesthetics block nerve signals. This causes a temporary loss of feeling or numbness on the area where the ointment has been applied.

What are the ingredients in XYLOCAINE Ointment 5%?

Medicinal ingredients: lidocaine

Non-medicinal ingredients: polyethylene glycol, propylene glycol, and purified water

XYLOCAINE Ointment 5% comes in the following dosage forms:

Ointment: 50 mg/g

XYLOCAINE Ointment 5% is available in a 35 g tube.

Do not use XYLOCAINE Ointment 5% if:

- you are allergic to:
 - lidocaine or to any other type of anaesthetic ending in “-caine”
 - any of the other ingredients in XYLOCAINE Ointment 5%
- you have a blood disorder called methemoglobinemia
- you have a condition called glucose-6-phosphate dehydrogenase deficiency

- it is to be used for infants who are 12 months of age or younger who are taking medicines that may cause the blood disorder called methemoglobinemia (e.g., sulphonamides)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you apply XYLOCAINE Ointment 5%. Talk about any health conditions or problems you may have, including if you:

- have, or have had in the past, any health problems;
- take any medicines, including ones you can buy without a prescription;
- have problems with your heart, including:
 - A slower than normal heart rate (bradycardia)
 - Irregular heart beat (arrhythmia)
- have ever had a bad, unusual or allergic reaction to XYLOCAINE Ointment 5% or any other medicines ending with "caine";
- think you may be allergic or sensitive to any ingredients in XYLOCAINE Ointment 5%
- have bleeding hemorrhoids and wish to use the ointment in that area;
- if there is an infection, skin rash, cut or wound at or near the area you want to apply XYLOCAINE Ointment 5%;
- have a skin condition that is severe or that covers a large area;
- have problems with your liver or kidneys;
- have epilepsy;
- are experiencing severe shock;
- are pregnant, plan to become pregnant or are breastfeeding.

Other warnings you should know about:

Driving and operating machines: Know how you feel after using XYLOCAINE Ointment 5% before you drive or use heavy machines.

Use in children: Children are at greater risk for serious side effects. Always follow your healthcare professional's instructions for using XYLOCAINE Ointment 5%, especially in young children and infants. It **should not be used on the genitals of children or infants.**

Using XYLOCAINE Ointment 5% in the mouth: When applied in your mouth or throat, topical anesthetics may numb your tongue and the lining of your mouth and make swallowing difficult. This can increase your risk of choking or accidentally biting your tongue or the inside of your cheeks. You should avoid eating or drinking very hot or cold food or drinks or chewing gum until the numbness has worn off.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with XYLOCAINE Ointment 5%:

- Medicines you can buy without a prescription;

- Anti-arrhythmic medicines used to treat heart problems (e.g. mexiletine, amiodarone). Your healthcare professional should monitor you carefully and send you for an electrocardiogram (ECG) if you are taking this medicine and amiodarone.
- Other local anaesthetics;
- Erythromycin used to treat bacterial infections
- Itraconazole used to treat fungal infections
- If you are going to use high doses of this medicine for a long time, the following medications may interact with it:
 - Propranolol used to treat heart problems
 - Cimetidine used to treat gastrointestinal problems
 - Fluvoxamine used to treat depression
- Other medicines which may cause methemoglobinemia, including: sulfonamides, acetanilide, aniline dyes, benzocaine (or other “-caine” type anesthetics), chloroquine, dapsone, naphthalene, nitrates or nitrites, nitrofurantoin, nitroglycerin, nitroprusside, pamaquine, para-aminosalicylic acid, phenacetin, phenobarbital, phenytoin, primaquine, quinine and high doses of acetaminophen.

How to apply XYLOCAINE Ointment 5%:

XYLOCAINE Ointment 5% can be:

- applied by your healthcare professional when you or your child arrive for the medical procedure
- for your own use to treat certain conditions such as:
 - minor scrapes
 - sunburns or other minor burns
 - sore nipples
 - insect bites
 - hemorrhoids

When used by a Healthcare Professional:

- Your dose or your child’s dose will depend on:
 - what part of the body XYLOCAINE Ointment 5% will be applied; and
 - age, any health or medical conditions and medications you or child are taking

When treating yourself or your child:

- **Do NOT use more XYLOCAINE Ointment 5%; or more often or for a longer period of time than your healthcare professional ordered or than these package directions suggest. This may cause unwanted and serious side effects.**
- **ONLY** apply the ointment on unbroken skin. If you have a special skin condition or other conditions that require a healthcare professional’s supervision, talk to your healthcare professional before you use XYLOCAINE Ointment 5%.

- XYLOCAINE Ointment 5% should start to work within 5 to 15 minutes after you apply it. The numbing effect usually last 20 to 30 minutes.
- You should:
 - clean the area well, before each application of ointment
 - apply a thin layer, using only enough to cover the affected area and reapply it only when you need it
 - avoid contact with your eyes
- For broken or burnt skin – avoid touching the affected area with your fingers. Apply the ointment to a sterile gauze pad and place the pad over the affected area. The pain relief effect lasts about 4 hours specifically for wounds caused by burning.
- If you are using the ointment on sore nipples, it is important that you clean the nipple area completely before each feeding. This will ensure that your baby does not take in any of the medicine.
- Check with your doctor or pharmacist if you:
 - have any questions about how to apply or measure the amount of XYLOCAINE Ointment 5% you need to use
 - are treating yourself or your child and you do not see any improvement within 3 to 5 days
 - feel that the effect of XYLOCAINE Ointment 5% is too strong or too weak

Instructions for Use:

The tube has a special protective seal on the tube opening. If this seal is broken, do NOT use the ointment. Go to the pharmacy and exchange for a new tube.

To use the tube for the first time: break the protective seal by firmly pressing the pointed end of the white cap into the seal.

The ointment can easily be removed from the area where it was applied and from clothing by washing with water.

Usual dose:

Child dose (2 years of age and older): Follow the healthcare professional's instructions on how much of the ointment to use, how often it should be applied to the affected area and how to apply it.

The following are general directions for the maximum amount of XYLOCAINE Ointment 5% that should be used **without a healthcare professional's advice for adults**. These guidelines apply only to healthy people. If you have a special skin condition or other conditions that require a healthcare professional's supervision, talk to your healthcare professional before you use XYLOCAINE Ointment 5%.

Adult dose: Apply no more than 1/3 of the tube (10 g) to the affected area. If you need to reapply the ointment, wait at least 8 hours before you reapply it again. Do NOT use more than 2/3 of the tube (20 g) in a 24-hour period.

Overdose:

Symptoms of an overdose with XYLOCAINE Ointment 5% may include:

- numbness of the lips and around the mouth
- feeling lightheaded
- dizziness and
- blurred vision
- trembling
- seizures or
- losing consciousness

If you think you, or a person you are caring for, have applied too much or accidentally swallowed XYLOCAINE Ointment 5%, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using XYLOCAINE Ointment 5%?

These are not all the possible side effects you may have when applying XYLOCAINE Ointment 5%. If you experience any side effects not listed here, tell your healthcare professional.

XYLOCAINE Ointment 5% may cause skin irritation where it was applied.

| Serious side effects and what to do about them | | | |
|--|---|---------------------|--|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| RARE | | | |
| Allergic reaction: difficulty swallowing or breathing, wheezing; drop in blood pressure; feeling sick to your stomach and throwing up; hives or rash; swelling of the face, lips, tongue or throat. | | | √ |
| Methemoglobinemia (blood disorder): brownish or greyish skin especially around the lips and nails | | | √ |

| Serious side effects and what to do about them | | | |
|--|--------------------------------------|--------------|---|
| Symptom / effect | Talk to your healthcare professional | | Stop taking drug and get immediate medical help |
| | Only if severe | In all cases | |
| VERY RARE | | | |
| drowsiness, numbness of your tongue, light-headedness, ringing in your ears, blurred vision, vomiting, dizziness, unusually slow heart beat, fainting, nervousness, unusual sweating, trembling or seizures. These symptoms usually require large amounts of XYLOCAINE Ointment 5% over a long period of time. | | | √ |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at room temperature (15-30°C). Protect from freezing.
- Keep out of reach and sight of children.
- Do not use XYLOCAINE Ointment 5% after the expiry date marked on the package.

If you want more information about XYLOCAINE Ointment 5%:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <https://aspenpharma.ca/>, or by calling 1-844-330-1213.

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