

XYLOCAINE® OINTMENT 5%

lidocaine ointment USP

**PART III:
CONSUMER INFORMATION**

This leaflet is part III of a two-part "Prescribing Information" published when XYLOCAINE Ointment 5% was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about XYLOCAINE Ointment 5%. Contact your doctor or pharmacist if you have any questions about the drug.

Before using XYLOCAINE Ointment 5%, read this leaflet carefully.

Please keep this leaflet to refer to until you have used up all your XYLOCAINE Ointment 5%.

This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

XYLOCAINE Ointment 5% is used to produce a temporary loss of feeling or numbness of the area where it is applied in adults and children 2 years of age and older, and can be used:

- before certain types of examinations done by your doctor;
- to help relieve the pain from minor skin abrasions, sunburn or other minor burns, sore nipples, insect bites and hemorrhoids.

WHAT IT DOES:

XYLOCAINE Ointment 5% is the brand name for a topical anesthetic that contains the drug lidocaine. Topical anesthetics are used to produce a temporary loss of feeling or numbness on the area where they are applied.

XYLOCAINE Ointment 5% should start to work within 5 minutes after you apply it. The pain relief effect lasts about 4 hours specifically for wounds caused by burning. When a gauze is used over the cream, it may extend the effect of relief of pain in burn wounds.

WHEN IT SHOULD NOT BE USED:

Do not use XYLOCAINE Ointment 5% if you:

- are allergic to lidocaine, any other "-caine" type anesthetics, or any of the non-medicinal ingredients in the product (see **WHAT THE IMPORTANT NONMEDICINAL INGREDIENTS ARE** below).

WHAT THE MEDICINAL INGREDIENT IS:

lidocaine 5%

WHAT THE IMPORTANT NONMEDICINAL INGREDIENTS ARE:

XYLOCAINE Ointment 5% also contains polyethylene glycol, propylene glycol, and purified water.

Check with your doctor if you think you may be sensitive to any of the above ingredients.

WHAT DOSAGE FORMS IT COMES IN:

XYLOCAINE Ointment 5%, 35g tube

WARNINGS AND PRECAUTIONS

BEFORE you use XYLOCAINE Ointment 5% tell your doctor, or pharmacist:

- about all health problems you have now or have had in the past;
- about other medicines you take, including ones you can buy without a prescription;
- if you are taking other medicines such as drugs used to treat irregular heart activity (anti-arrhythmics);
- if you have ever had a bad, unusual or allergic reaction to XYLOCAINE Ointment 5% or any other medicines ending with "caine";
- if you think you may be allergic or sensitive to any ingredients in XYLOCAINE Ointment 5% (see above);
- if you 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%;
- if you have a skin condition that is severe or that covers a large area;
- if you have a severe heart, kidney or liver disease (see PROPER USE OF THIS MEDICATION);
- if you have epilepsy (there is very low risk if used as per PROPER USE OF THIS MEDICATION section);
- if you are experiencing severe shock;
- if you are pregnant, plan to become pregnant or are breastfeeding.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor or pharmacist about any other drugs you take, or have recently taken, including:

- drugs you can buy without a prescription;
- anti-arrhythmic drugs for heart problems (e.g. mexiletine, amiodarone) (see PROPER USE OF THIS MEDICATION);
- other anesthetics (see PROPER USE OF THIS MEDICATION);
- propranolol for heart problems or cimetidine for gastrointestinal problems, if you are going to use high doses of XYLOCAINE Ointment 5% for a long time;

- fluvoxamine for depression, if you are going to use high doses of XYLOCAINE Ointment 5% for a long time.

Usage of such medicines at the same time as XYLOCAINE Ointment 5% may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

USUAL DOSE:

If this medicine is recommended by your doctor, be sure to follow the directions for use that have been given. If you are treating yourself, follow the directions below. Check with your doctor or pharmacist if you have any questions about your directions.

XYLOCAINE Ointment 5% comes in tube sizes of 35 gram tubes with a special protective seal on the tube opening. If this seal is broken when you buy XYLOCAINE Ointment 5%, exchange it at the pharmacy for a new tube. To break the protective seal the first time you use XYLOCAINE Ointment 5%, firmly press the pointed end of the white cap into the seal.

The following are general guidelines for the maximum amount of XYLOCAINE Ointment 5% that should be used without a doctor's advice. These guidelines apply only to otherwise healthy people. If you have a special skin condition or other condition that requires a doctor's supervision ask your doctor about the maximum amount of ointment that you should use.

Do not use more XYLOCAINE Ointment 5%; or more often or for a longer period of time than either your doctor ordered or than these package directions recommend as this may cause unwanted side effects (see SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

- If possible, clean the affected area well, before each application of ointment.
- Use the smallest amount of ointment needed to control your symptoms.
- Apply a thin layer, using only enough to cover the affected area, and reapply it only when you need it.
- For broken or burned skin: To avoid touching the affected area with your hands, apply the ointment to a sterile gauze pad. Then secure the gauze pad in place over the affected area.
- If used on sore nipples it is essential that you clean the nipple area completely before each feeding. This will ensure that the baby does not take in any of this medicine.
- Avoid contact with your eyes.

Conditions where dose adjustments may be required:

- elderly patients
- acutely ill patients
- patients with severe liver disease
- patients with severe kidney disease
- patients also treated with other anesthetics or certain antiarrhythmic drugs (such as amiodarone or melixitine)

Dose for Adults:

No more than 10 grams of ointment should be used for any single application.

The minimum time between doses should be at least 8 hours.

The **total dose** for a 24-hour period should be no more than 20 grams.

Dose for Children 2-12 Years of Age:

The dose depends on the child's weight. No more than 1 gram of ointment per 10 kilograms of the child's weight. The minimum time between doses should be at least 8 hours.

- For use in children under 2 years of age, consult a doctor.
- If you have any questions about how to measure the above amounts, be sure to ask your pharmacist.
- 10 grams of ointment administered from the 35 g tube is approximately 1/3 of the tube.
- If you have the impression that the effect of XYLOCAINE Ointment 5% is too strong or too weak, talk to your doctor or pharmacist.

The ointment can easily be removed from the site of application and from clothing by washing with water.

If you are treating yourself and your condition does not seem to improve within three to five days, check with your doctor about continuing to use XYLOCAINE Ointment 5%.

OVERDOSE:

Early signs of overdosage are numbness of the lips and around the mouth, lightheadedness, dizziness and sometimes blurred vision. In the event of a serious overdosage, trembling, seizures or unconsciousness may occur.

If the early signs of overdosage are noticed and no further XYLOCAINE Ointment 5% is given, the risk of serious side effects occurring rapidly decreases. If you think you or anyone else is experiencing any of the above signs, telephone your doctor or go to the nearest hospital right away.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, XYLOCAINE Ointment 5% may cause side effects in some people.

Propylene glycol (one of the other ingredients of the ointment) may cause skin irritation.

Avoid eating or chewing gum when XYLOCAINE Ointment 5% is used in the mouth or throat since numbness in these areas may interfere with swallowing and could potentially cause choking. Numbness of the tongue or gums may also increase the danger of injury due to biting.

Avoid exposure to extreme hot or cold temperatures (e.g. food, drink) until complete sensation has returned.

Avoid contact with the eyes because numbness in the eyes may prevent you from noticing if you get something in your eye.

With the recommended doses, XYLOCAINE Ointment 5% has no effect on the ability to drive and use machines.

Medicines affect different people in different ways. Just because side effects have occurred in some patients, does not mean that you will get them. If any side effects bother you, or if you experience any unusual effects while you are using XYLOCAINE Ointment 5%, stop using it and check with your doctor or pharmacist as soon as possible.

Consult your doctor immediately if any of these symptoms appear.

HOW TO STORE IT

Remember to **keep XYLOCAINE Ointment 5% well out of the reach of children** when you are not using it.

Keep XYLOCAINE Ointment 5% at room temperature. Protect from freezing. Do not keep XYLOCAINE Ointment 5% in the bathroom medicine cabinet or other warm, moist places. Store in the original package.

Do not use XYLOCAINE Ointment 5% after the expiry date marked on the package.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Health Canada by:

Toll-free telephone: 866-234-2345
 Toll-free fax: 866-678-6789
 By email: cadmp@hc-sc.gc.ca

By regular mail:
 National AR Centre
 Marketed Health Products Safety and Effectiveness
 Information Division
 Marketed Health Products Directorate
 Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Before contacting Health Canada, you should contact your physician or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Allergic reaction such as: redness, itching or swelling of your skin, hives, burning, stinging, or any other skin problems, swelling of the neck area, or any difficulty with breathing, not present before using this medicine	X		X

This is not a complete list of side effects. For any unexpected effects while taking XYLOCAINE Ointment 5% contact your doctor or pharmacist

XYLOCAINE Ointment 5% can cause serious side effects if too much is used. These include: 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.

The above are extremely rare and usually require large amounts of XYLOCAINE Ointment 5% over a long period of time.

MORE INFORMATION

Important Note: This leaflet alerts you to some of the times you should call your doctor. Other situations which cannot be predicted may arise. Nothing about this leaflet should stop you from calling your doctor with any questions or concerns you have about using XYLOCAINE Ointment 5%.

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

For the most current information, the Consumer Information Leaflet plus the full Prescribing Information, prepared for health professionals can be found at: www.aspenpharma.ca or by contacting the sponsor, Aspen Pharmacare Canada Inc. at 1-844-330-1213.

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