

XYLOCAINE® TOPICAL 4%
lidocaine hydrochloride topical solution USP

**PART III:
CONSUMER INFORMATION**

This leaflet is part III of a two-part "Prescribing Information" published when XYLOCAINE Topical 4% solution 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 Topical 4% solution. Contact your doctor or pharmacist if you have any questions about the drug.

Before using XYLOCAINE Topical 4% solution, read this leaflet carefully.

Please keep this leaflet to refer to until you have used up all your XYLOCAINE Topical 4% solution.

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 Topical 4% solution may be used to produce temporary loss of feeling or numbness of the area where it is applied in adults and children, and can be used:

- before certain types of examination and instrumentation are performed by your doctor, e.g., bronchial examination.

WHAT IT DOES:

XYLOCAINE Topical 4% solution is the brand name for a topical anesthetic that contains the drug lidocaine hydrochloride. Topical anesthetics are used to produce a temporary loss of feeling or numbness on the area where they are applied. XYLOCAINE Topical 4% should start to work within 5 minutes after it is applied and its effect should last about 15 to 30 minutes.

WHEN IT SHOULD NOT BE USED:

Do not use XYLOCAINE Topical 4% solution if you:

- are allergic to lidocaine, any other "-caine" type anesthetics, or any of the non-medicinal ingredients in the product (see **NONMEDICINAL INGREDIENTS** below)
- are allergic to methylparaben and/or propylparaben (preservatives used in XYLOCAINE Topical 4%) or PABA.

WHAT THE MEDICINAL INGREDIENT IS:

lidocaine hydrochloride 4%

NONMEDICINAL INGREDIENTS:

XYLOCAINE Topical 4% solution also contains methylparaben, sodium hydroxide and/or hydrochloric acid and water for injection.

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

WHAT DOSAGE FORMS IT COMES IN:

XYLOCAINE Topical 4% solution, 50 mL bottle.

WARNINGS AND PRECAUTIONS

BEFORE you use XYLOCAINE Topical 4% solution tell your doctor or dentist:

- 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 Topical 4% solution or any other medicines ending with "caine";
- if you think you may be allergic or sensitive to any ingredients in XYLOCAINE Topical 4% solution (see above);
- if there is an infection, skin rash, cut or wound at or near the area you want to apply XYLOCAINE Topical 4%;
- 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 or someone in your family has been diagnosed with porphyria;
- if you are experiencing severe shock;
- if you are pregnant, plan to become pregnant or are breastfeeding.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor 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 high doses of XYLOCAINE Topical 4% will be used for a long time;
- fluvoxamine, for depression, if high doses of XYLOCAINE Topical 4% will be used for a long time.

Usage of such medicines at the same time as XYLOCAINE Topical 4% may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

USUAL DOSE:

A doctor/nurse will give you XYLOCAINE Topical 4% solution. The dose given is decided by the doctor. If you have the impression that the effect of XYLOCAINE Topical 4% solution is too strong or too weak, talk to your doctor.

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 mexiletine)

Dose for Adults:

The recommended dose of XYLOCAINE Topical 4% solution is:

- 2-7.5 mL (80-300 mg lidocaine hydrochloride);
- During long procedures (more than 5 minutes), up to 400 mg may be used;
- When combined with other lidocaine products, the total dose should not exceed 400 mg;
- No more than 5 mL (200 mg) should be used when applied to the upper respiratory tract;
- When inhaled from a nebulizer, 5-10 mL (200-400 mg) may be used.

Dose for Children (Unser 12 Years of Age):

The dose depends on the child's weight and physical condition.

- No more than 3 mg/kg of body weight should be used.

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 Topical 4% 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 Topical 4% solution may cause side effects in some people.

Methylparaben (one of the other ingredients of the topical solution) may also cause allergic reaction.

Avoid eating or chewing gum when XYLOCAINE Topical 4% solution 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 Topical 4% 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 Topical 4% solution, stop using it and check with your doctor or dentist as soon as possible.

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 Topical 4% , contact your doctor or pharmacist.

XYLOCAINE Topical 4% solution 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 Topical 4% solution over a long period of time.
Consult your doctor immediately if any of these symptoms appear.

HOW TO STORE IT

Keep XYLOCAINE Topical 4% solution at room temperature. Protect from freezing. Your doctor or the hospital will normally store XYLOCAINE Topical 4% solution. The staff are responsible for the storing, using and disposing of the solution in the correct way.

REPORTING SUSPECTED SIDE EFFECTS

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

By toll-free telephone: 866-234-2345
By toll-free fax: 866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and
Effectiveness Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

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 Topical 4% solution.

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.astrazeneca.ca or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.

This leaflet was prepared by:
AstraZeneca Canada Inc. Mississauga, Ontario L4Y 1M4
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