

XYLOCAINE® JELLY 2%
lidocaine hydrochloride USP

**PART III:
CONSUMER INFORMATION**

This leaflet is part III of a two-part "Prescribing Information" published when XYLOCAINE Jelly 2% 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 Jelly 2%. Contact your doctor or pharmacist if you have any questions about the drug.

Before using XYLOCAINE Jelly 2%, read this leaflet carefully.

Please keep this leaflet to refer to until you have used up all your XYLOCAINE Jelly 2%.

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 Jelly 2% is used to produce a temporary loss of feeling or numbness of the skin 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 inflammation of the urinary bladder and the urethra.

WHAT IT DOES:

XYLOCAINE Jelly 2% is the brand name for a topical anesthetic that contains the drug lidocaine. Topical anesthetics are used to produce a temporary loss of sensation or numbness on the area where they are applied.

XYLOCAINE Jelly 2% should start to work within 5 to 15 minutes after you apply it. The effect usually lasts 20 to 30 minutes.

WHEN IT SHOULD NOT BE USED:

Do not use XYLOCAINE Jelly 2% 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 Jelly 2% in tubes) or PABA

WHAT THE MEDICINAL INGREDIENT IS:

lidocaine hydrochloride 2%

NONMEDICINAL INGREDIENTS:

XYLOCAINE Jelly 2% also contains hydroxypropyl methylcellulose, purified water, and sodium hydroxide and/or hydrochloric acid.

Xylocaine Jelly 2% in tubes also contains methylparaben and propylparaben.

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

WHAT DOSAGE FORMS IT COMES IN:

XYLOCAINE Jelly 2% comes in a tube size of 30 millilitres (mL) and in a single-use syringe size of 10 mL.

WARNINGS AND PRECAUTIONS

BEFORE you use XYLOCAINE Jelly 2% 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 Jelly 2% or any other medicines ending with "caine";
- if you think you may be allergic or sensitive to any ingredients in XYLOCAINE Jelly 2% (see above);
- if there is an infection, skin rash, cut or wound at or near the area you want to apply XYLOCAINE Jelly 2%;
- 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 section);
- 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 or pharmacist about any other drugs you take, including:

- drugs you can buy without a prescription;
- anti-arrhythmic drugs for heart problems (e.g. mexiletine, amiodarone) (see PROPER USE OF THIS MEDICATION section);

- other anesthetics (see PROPER USE OF THIS MEDICATION section);
- propranolol for heart problems or cimetidine for gastrointestinal problems, if you are going to use high doses of XYLOCAINE Jelly 2% for a long time;
- fluvoxamine, for depression, if you are going to use high doses of XYLOCAINE Jelly 2% for a long time.

Please inform your doctor/dentist/pharmacist if you are taking or have recently taken any other medicines, even those that can be bought without a prescription. Usage of such medicines at the same time 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, such as for the treatment of pain caused by inflammation of the urethra or urinary bladder, or for self catheterization, follow the directions below and your doctor's or pharmacist's instructions for how to apply the jelly. Check with your doctor or pharmacist if you have any questions about your directions.

The following are general guidelines for the maximum amount of XYLOCAINE Jelly 2% that should be used without a doctor's advice. These guidelines apply only to otherwise healthy people. If you have a special skin or other condition that requires a doctor's supervision ask your doctor about the maximum amount of jelly that you should use.

Do not use more XYLOCAINE Jelly 2%; or more often or for a longer period of time than either your doctor ordered or than these package directions suggest as this may cause unwanted side effects (see SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM).

- If possible, clean the affected area well, before each application of jelly.
- Use the smallest amount of jelly needed to control your symptoms.
- 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 mexiletine)

Dose for Adults:

The dose of the jelly depends on the application site. For oral use of XYLOCAINE Jelly 2% a dose of 20 mL (2/3 tube) is usually safe. For use in the urethra (i.e., before insertion of urinary catheters or urinary procedures), 5 to 20 mL (about 2/3 of a tube) is usually enough. A safe dose for use in the urethra and bladder is 40 mL (1 1/3 tubes).

No more than four doses should be given during a 24-hour period.

Dose for Children Under 12 Years of Age:

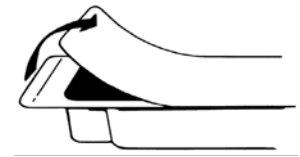
The dose depends on the child's weight. No more than 3 mL of jelly per 10 kilograms of the child's weight should be used per dose. For a 10 kg child the dose should be no more than 1/10 of the tube.

No more than four doses should be given during a 24-hour period.

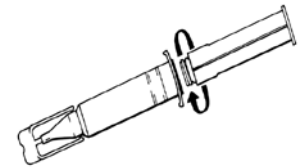
- For use in children under 2 years of age, consult a doctor.
- If you have any questions about how to measure the above amounts, be sure to ask your pharmacist.
- If you are treating yourself and your condition does not seem to improve within three to five days, check with your doctor about continuing to use XYLOCAINE Jelly 2%.

Instructions for Use – Syringe

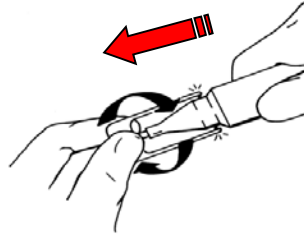
1. Tear off the paper cover.



2. Screw plunger rod clockwise into grey rubber until rubber rotates.

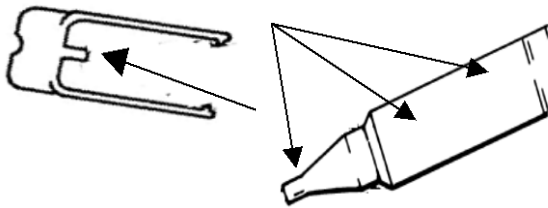


3. Twist the protective tab and **then, without bending, pull slightly** to break the seal.



4. Extrude a small amount (i.e. 1 cm) of Jelly. Inspect the syringe to ensure that there is no plastic fragment present in the Jelly.

Note: upon visual inspection, a clear plastic fragment in clear jelly may be difficult to detect and may look like an air pocket.



If the protective tab is broken, do not use the syringe.

5. The syringe must not be used and must be discarded if there is **any** suspicion of a broken plastic fragment.
6. If the protective tab is intact and no plastic fragment is found in the Jelly, the syringe is ready for use.

For further assistance please contact Aspen Pharmacare Canada at 1-844-330-1213.

OVERDOSE:

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

If the early signs of overdose are noticed and no further XYLOCAINE Jelly 2% is given, the risk of serious adverse 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 Jelly 2% may cause side effects in some people.

Avoid eating or chewing gum when XYLOCAINE Jelly 2% 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 Jelly 2% 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 Jelly 2%, stop using it and check with your doctor or pharmacist 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 (frequency greater than or equal to 0.01% but less than 0.1% of patients)			
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 Jelly 2% contact your doctor or pharmacist.

XYLOCAINE Jelly 2% can cause serious side effects if too much is applied. 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 side effects are extremely rare, but can occur when too much XYLOCAINE 2% Jelly is used at one time and when large amounts are used over a long period of time.

Consult your doctor immediately if any of these symptoms appear.

HOW TO STORE IT

Remember to **keep XYLOCAINE Jelly 2% well out of the reach of children** when you are not using it.

Keep XYLOCAINE Jelly 2% at room temperature. Protect from freezing. Do not keep XYLOCAINE Jelly 2% in the bathroom medicine cabinet or other warm, moist places. Store in the original package.

Do not use XYLOCAINE Jelly 2% after the expiry date marked on the package.

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 Jelly 2%.

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.

This leaflet was prepared by:

Aspen Pharmacare Canada Inc, 111 Queen Street East, Suite 450, Toronto, Ontario, M5C 1S2

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Last revised: August 09, 2017