

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

XYLOCAINE® Jelly 2%
Lidocaine hydrochloride Jelly

Read this carefully before you start taking **XYLOCAINE® Jelly 2%** 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® Jelly 2%**.

What is XYLOCAINE® Jelly 2% used for?

XYLOCAINE Jelly 2% is a topical jelly 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 doctor before certain types of medical procedures;
- to help relieve the pain from inflammation of the bladder and the urethra

How does XYLOCAINE® Jelly 2% work?

XYLOCAINE Jelly 2% 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 jelly has been applied.

What are the ingredients in XYLOCAINE® Jelly 2%?

Medicinal ingredients: lidocaine hydrochloride 2%

Non-medicinal ingredients: hydroxypropyl, methylcellulose, purified water, and sodium hydroxide and/or hydrochloride acid (to adjust pH).

XYLOCAINE Jelly 2% in tubes also contain the preservatives methylparaben and propylparaben.

XYLOCAINE® Jelly 2% comes in the following dosage forms:

Jelly: 20 mg /mL

XYLOCAINE® Jelly 2% is available:

- in a 30 mL tube with applicator nozzle that contains a total of 600 mg of lidocaine hydrochloride / tube
- as a single-use 10mL syringe that contains a total of 200 mg of lidocaine hydrochloride / syringe

Do not use XYLOCAINE® Jelly 2% if:

- you are allergic to:
 - lidocaine, prilocaine or to any other type of anaesthetic ending in “-caine”
 - any of the other ingredients in XYLOCAINE Jelly 2% (see list of Non-medicinal ingredients above)
 - methylparaben and/or propylparaben (preservatives used tube format) or to para amino benzoic acid (PABA) – a substance that is made from the breakdown of methylparaben and propylparaben
- you have a blood disorder called methemoglobinemia
- 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 take XYLOCAINE® Jelly 2%. Talk about any health conditions or problems you may have, including if you:

- Take other medications, including ones you can buy without prescription;
- Have problems with your heart including:
 - A slower than normal heart rate (bradycardia);
 - Irregular heart beat (arrhythmia);
- Ever had a bad, unusual, or allergic reaction to XYLOCAINE Jelly 2% or any other medicines ending with “-caine”;
- Think you may be allergic or sensitive to any ingredients in XYLOCAINE Jelly 2% (see list of ingredients above);
- Have an infection, skin rash, cut, or wound at or near the area you want to apply XYLOCAINE Jelly 2%;
- Have a skin condition that is severe or that covers a large area;
- Have problems with your liver or kidneys;
- Have epilepsy;
- You or someone in your family has been diagnosed with a disorder that can cause nerve or skin problems (porphyria);
- Are experiencing 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 Jelly 2% before you drive or use heavy machines.

Use in children: Children are at greater risk for serious side effects. Always follow your doctor’s instructions for using XYLOCAINE Jelly 2%, especially in young children and infants. **It should not be used on the genitals of children or infants.**

Using XYLOCAINE Jelly 2% 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® Jelly 2%:

- Drugs you can buy without a prescription;
- Anti-arrhythmic drugs used to treat heart problems (e.g. mexiletine, amiodarone). Your doctor should monitor you carefully and send you for an electrocardiogram (ECG) if you are taking XYLOCAINE Jelly 2% 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 problem
 - 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 use XYLOCAINE® Jelly 2%:

XYLOCAINE Jelly 2% can be:

- applied by your doctor when you or your child arrive for the medical procedure
- for your own use to treat certain conditions such as:
 - pain caused by inflammation of the urethra or urinary bladder, or
 - self-catheterization

When used by a Healthcare Professional:

- Your dose or your child’s dose will depend on:
 - what part of the body XYLOCAINE Jelly 2% 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 Jelly 2%; or more often or for a longer period of time than your doctor ordered or than these package directions suggest. This may cause unwanted and serious side effects.**
- **ONLY** apply the jelly on unbroken skin. If you have a special skin condition or other conditions that require a doctor’s supervision, talk to your doctor before you use XYLOCAINE Jelly 2%.
- XYLOCAINE Jelly 2% should start to work within 5 to 15 minutes after you apply it. The numbing effect usually lasts 20 to 30 minutes.
- You should:
 - clean the area well, before each application of jelly
 - use the smallest amount of the jelly to control your symptoms
 - avoid contact with your eyes
- Check with your doctor or pharmacist if you:
 - have any questions about how to apply or measure the amount of XYLOCAINE Jelly 2% you need to use
 - are treating yourself and your condition does not seem to improve within 3 to 5 days
 - feel that the effect of XYLOCAINE Jelly 2% is too strong or too weak

Children dose (2 years of age and older): Follow the doctor’s instructions on how much of the jelly to use, how often it should be applied to the affected area and how to apply it.

Instructions for Use - XYLOCAINE Jelly 2%, Tube

The following are general directions for the maximum amount of XYLOCAINE Jelly 2% that

should be used **without a doctor's advice for adults**. These guidelines apply only to healthy people. If you have a special skin condition or other conditions that require a doctor's supervision, talk to your doctor before you use XYLOCAINE Jelly 2%.

Adult dose:

- For oral use: a dose of 20 mL (about 2/3 of the tube) is recommend as usually safe
- For use in the urethra before insertion of urinary catheters: 5 to 20 mL (up to about 2/3 of a tube) is recommended as usually safe
- For use in the urethra and bladder: 40 mL (about 1 full tube plus 1/3 of another tube) is recommended as usually safe.

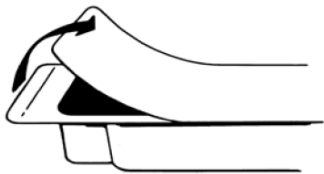
Do not use more than 4 doses in a 24-hour period.

Instructions for Use – XYLOCAINE Jelly 2%, Syringe

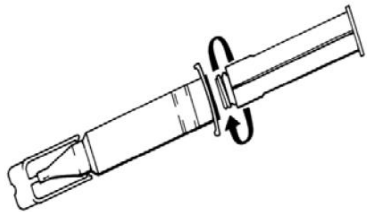
Adult dose (Pre-filled syringe): If you are using the pre-filled syringe to treat your condition, follow the **Instructions for Use – XYLOCAINE Jelly 2%, Syringe** (below) and your doctor or pharmacist's instructions on how much to use.

- The syringe is graduated (there are lines on it that indicate the volume of jelly in the syringe). A 3 mm line of the jelly is equal to about 1 mL of jelly (20 mg lidocaine hydrochloride).

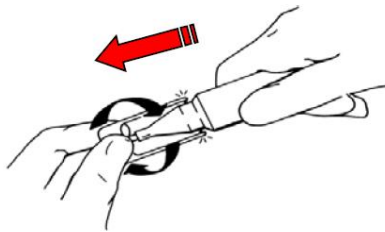
1. Tear off the paper cover.



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

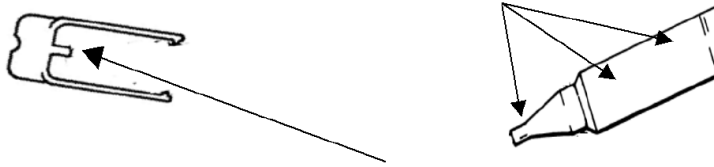


3. Twist the protective tab and **then, without bending, pull slightly** to break the seal.



4. **Force a small amount (i.e. about 1 cm) of jelly out of the syringe. Inspect the syringe to ensure that there are no pieces of plastic in the jelly.**

Note: when you inspect the syringe, a clear piece of plastic may be difficult to see in clear jelly. It may look like an air pocket.



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

- 5. Throw the syringe away and do NOT use it if you think that the jelly contains any broken pieces of plastic.**
- 6. If the protective tab is intact and there are no plastic pieces found in the jelly, the syringe can be used.**

If you have any questions or concerns contact Aspen Pharmacare Canada Inc. at 1-(844)-330-1213.

Overdose:

If you think you have used too much XYLOCAINE Jelly 2%, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Symptoms of an overdose include:

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

What are possible side effects from using XYLOCAINE® Jelly 2%?

These are not all the possible side effects you may feel when taking XYLOCAINE® Jelly 2%. If you experience any side effects not listed here, contact your healthcare professional.

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.	X		X
RARE Methemoglobinemia Brownish or greyish skin especially around lips and nails			X
EXTREMELY 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 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.			X

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

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <p>Visiting the Web page on Adverse Reaction Reporting:</p> <ul style="list-style-type: none"> • 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. <p><i>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.</i></p>
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Store:

At room temperature (15-30°C). Protect from freezing. Store it in its original package. Keep out of the reach and sight of children.

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

If you want more information about XYLOCAINE® Jelly 2%:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://aspenpharma.ca/>, or by calling 1-844-330-1213.

This leaflet was prepared by Aspen Pharmacare Canada Inc.

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