

XYLOCAINE® VISCOSUS 2%

lidocaine hydrochloride solution

**PART III:
CONSUMER INFORMATION**

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

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

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

XYLOCAINE Viscous 2% could also:

- relieve the pain and discomfort of a sore throat, such as after the tonsils are removed;
- provide relief in other painful diseases of the mouth, throat or esophagus;
- cause a loss of feeling in the throat area, before certain types of examinations are performed by your doctor.

WHAT IT DOES:

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

WHEN IT SHOULD NOT BE USED:

Do not use XYLOCAINE Viscous 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 Viscous 2%) or PABA.

WHAT THE MEDICINAL INGREDIENT IS:

lidocaine hydrochloride 2%

NONMEDICINAL INGREDIENTS:

XYLOCAINE Viscous 2% also contains sodium carboxymethylcellulose, methylparaben, propylparaben, cherry essence, citric acid monohydrate, saccharin sodium, purified water and sodium hydroxide.

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

WHAT DOSAGE FORMS IT COMES IN:

XYLOCAINE Viscous 2%, 100 mL per bottle

WARNINGS AND PRECAUTIONS

XYLOCAINE Viscous 2% should not be used to sooth teething pain in infants and children. Incorrect dosing can lead to serious side effects, including seizures, loss of consciousness, and death.

BEFORE you use XYLOCAINE Viscous 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 Viscous 2% or any other medicines ending with "caine";
- if you think you may be allergic or sensitive to any ingredients in XYLOCAINE Viscous 2% (see above);
- if there is an infection, skin rash, cut or wound at or near the area you want to apply XYLOCAINE Viscous 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**);
- 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, 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 Viscous 2% for a long time;
- fluvoxamine, for depression, if you are going to use high doses of XYLOCAINE Viscous 2% for a long time.

Usage of such medicines at the same time as XYLOCAINE Viscous 2% may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

This medication is for topical use only.

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, or your child, follow the directions below. It is important to follow the instructions on how much, how to apply and, where to apply XYLOCAINE Viscous 2%. Check with your doctor or pharmacist if you have any questions about your directions, or how to calculate or measure the correct dose amounts.

The following are general guidelines for the maximum amount of XYLOCAINE Viscous 2% 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 XYLOCAINE Viscous 2% that you should use.

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)

USUAL DOSE:

Dose for Adults (18 Years of age and older)

- The usual effective dose for adults is 5 - 10 mL (1-2 measured teaspoons) at a time. Use the smallest amount needed to control your symptoms.
- Do not use this amount more than six times in a 24-hour period.
- The **total dose** for a 24-hour period should be no more than 60 mL (12 measured teaspoons, or 4 measured tablespoons).
- Swish the appropriate amount around in your mouth to treat pain in the mouth area. To treat the throat, gargle the liquid in the back of the throat and swallow or spit the liquid out. Adults (but not children) may swallow the solution to treat the esophagus.

Dose for Children over 12 Years of Age, or younger and weighing 50 kg (110 lbs) or more

- The usual effective dose is 5 - 10 mL (1-2 measured teaspoons) at a time. Use the smallest amount needed to control the symptoms.
- After rinsing with the medication to treat the mouth, or gargling to treat the throat, children should not swallow the solution but spit it out.
- No more than four doses should be given during a 24-hour period.

Dose for Children 2-12 Years of Age, or older and weighing less than 50 kg (110 lbs)

- DO NOT use XYLOCAINE Viscous 2% solution to soothe teething pain in infants or children, because serious side effects may occur.
- There may be special considerations for children under 3 years of age. DO NOT use XYLOCAINE Viscous 2% for children in this age group without a doctor's supervision.
- The dose depends on the child's weight. Use the smallest amount possible to treat the pain. The dose should never be more than 10 mL (2 measured teaspoons) at a time.
- For each dose, use no more than 1 mL of Xylocaine Viscous 2% solution per 5 kilogram (11 pounds) of the child's weight. For example, if the child weighs 25 kg (55 pounds), use a maximum of 5 mL (1 measured teaspoon) of Xylocaine Viscous 2% solution per dose.
- Children should swish or gargle the solution and spit it out, not swallow it. For young children who might have trouble spitting it out, and children < 3 years of age, it should be applied with a cotton tip applicator, and only to the affected area.
- No more than four doses should be given during a 24-hour period.
- Do not treat with Xylocaine Viscous for more than 24 hours in children under 2 years of age.

Do not use more XYLOCAINE Viscous 2%; 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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**).

To get the most effect from your dose of medicine:

- Shake the bottle well before using this medicine, so that you get an even dose each time you use it.
- Use only an accurate measuring device, such as a measured cup or a measured teaspoon to dose this medicine correctly.
- When used in the mouth or throat try to increase the length of time XYLOCAINE Viscous 2% is in contact with the affected area. For example, if you are treating mouth sores, swish the liquid around in your mouth and then spit it out. For a sore throat, roll the liquid around at the back of your throat or gargle. Adults (but not children) may swallow the medicine; children should always spit it out or have the dose applied with a cotton tipped applicator.
- Do not drink water or other liquids right after you use XYLOCAINE Viscous 2%, as this will decrease the amount of relief you get from the medicine.
- Avoid contact with your eyes.

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 Viscous 2%.

OVERDOSE:

In case of a suspected drug overdose, immediately contact a hospital emergency department, health care practitioner, or regional Poison Control Centre, even if there are no symptoms.

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, and subsequently unconsciousness may occur.

If not rapidly treated, serious overdosage can lead to death. If you think you or anyone else is experiencing any of the above signs, discontinue use and get emergency help right away.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, XYLOCAINE Viscous 2% may cause side effects in some people.

Avoid eating or chewing gum when XYLOCAINE Viscous 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 gum 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 Viscous 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 Viscous 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 seek immediate emergency assistance
		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 Viscous 2% contact your doctor or pharmacist.

XYLOCAINE Viscous 2% 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 Viscous 2% over a long period of time.

Consult your doctor immediately if any of these symptoms appear.

HOW TO STORE IT

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

Keep XYLOCAINE Viscous 2% at room temperature (15 – 30°C). Protect from freezing. Do not keep XYLOCAINE Viscous 2% in the bathroom medicine cabinet or other warm, moist places. Store in the original package.

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

This leaflet was prepared by:
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REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. 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 Viscous 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.astrazeneca.ca or by contacting the sponsor, AstraZeneca Canada Inc. at:
Customer Inquiries – 1 (800) 668-6000,
Renseignements – 1 (800) 461-3787.