

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

XYLOCAINE® Parenteral Solutions

Lidocaine Hydrochloride Injection and Lidocaine Hydrochloride and Epinephrine Injection.

Read this carefully before you start taking **XYLOCAINE Parenteral Solutions** 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 Parenteral Solutions**.

What is XYLOCAINE Parenteral Solutions used for?

XYLOCAINE Parenteral Solutions are used in adults and children (2 years of age or older), to provide pain relief by producing a temporary loss of feeling or numbness to the area that it is injected. It can be used:

- to numb the area of the body where surgery is to be performed;
- to provide pain relief in labour and after surgery

XYLOCAINE Parenteral Solution should be used with caution in children younger than 2 years of age.

How does XYLOCAINE Parenteral Solutions work?

XYLOCAINE Parenteral Solutions belong to a group of medicines called 'local anesthetics'. XYLOCAINE Parenteral Solutions prevent the nerves in the injected area from transmitting signals to the brain. This causes a temporary loss of feeling or numbness, so you do not feel sensations such as pain, heat or cold.

What are the ingredients in XYLOCAINE Parenteral Solutions?

Lidocaine Hydrochloride Injection:

Medicinal ingredients: lidocaine hydrochloride.

Non-medicinal ingredients: sodium chloride, water for injection, sodium hydroxide and/or hydrochloric acid (to adjust pH).

Lidocaine Hydrochloride and Epinephrine Injection:

Medicinal ingredients: lidocaine hydrochloride and epinephrine bitartrate.

Non-medicinal ingredients: sodium chloride, sodium metabisulfite, water for injection, sodium hydroxide and/or hydrochloric acid (to adjust pH). Certain vial presentations may contain citric acid, please refer to the product label.

All multidose vials also contain methylparaben (as preservative).

XYLOCAINE Parenteral Solutions comes in the following dosage forms:

Lidocaine Hydrochloride Injection:

Solution: 0.5%, 1% and 2% lidocaine hydrochloride.

Lidocaine Hydrochloride and Epinephrine Injection:

Solution: 1% lidocaine hydrochloride with 1:200,000 epinephrine, 1% lidocaine hydrochloride with 1:100,000 epinephrine and 2% lidocaine hydrochloride with 1:200,000 epinephrine.

Do not use XYLOCAINE Parenteral Solutions if:

- you are allergic to lidocaine, any other "-caine" type anesthetics, or any of the non-medicinal ingredients in the product;
- you are allergic to sodium metabisulfite and/or citric acid;
- you are allergic to methylparaben and/or propylparaben (preservative used in some solutions) or para amino benzoic acid (PABA).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take XYLOCAINE Parenteral Solutions. Talk about any health conditions or problems you may have, including if you:

- are allergic to any other drugs, including any other local anesthetics;
- have a sulfite sensitivity, XYLOCAINE Parenteral Solutions with epinephrine contain sodium metabisulfite;
- have an irregular heartbeat (arrhythmias) or other heart problems such as heart block;
- have inflammation and/or sepsis in the region of the injection;
- have sepsis;
- have liver disease;
- have severe kidney problems;
- have untreated heart disease;
- have untreated or severe high blood pressure;
- have a neurological disease, or spinal deformities
- have uncontrolled hyperthyroidism (an overactive thyroid) or diabetes
- have epilepsy;
- have or have a family history of porphyria;
- have a condition called hypovolemia;
- have a blood circulation condition called 'peripheral vascular disorder';
- have problems with the blood supply to your brain because of obstructed arteries;
- are experiencing severe shock;
- are pregnant, think you are pregnant, or plan to become pregnant;
- are breastfeeding.

Other warnings you should know about:

Driving and using machines: In addition to the temporary loss of feeling and numbness, XYLOCAINE Parenteral Solutions may have an effect on your mental function and coordination. This may impair your ability to move and decrease your alertness. Avoid driving or operating machinery on the day you receive XYLOCAINE Parenteral Solutions.

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 Parenteral Solutions:

- other local anesthetics;
- erythromycin, a medication used to treat bacterial infections;
- itraconazole, a medication used to treat fungal infections;
- propranolol, a medication used to treat high blood pressure;
- cimetidine, a medication used to treat heartburn and peptic ulcers;
- medications used to treat irregular heartbeat such as mexiletine or amiodarone;
- medications used to treat depression such as fluvoxamine, imipramine, triptyline drugs and monoamine oxidase inhibitors;
- certain medications used to treat headaches and migraines
- medications used to treat psychosis such as phenothiazine or butyphenones
- sedative medications
- inhaled anesthetics such as halothane or enflurane

How to take XYLOCAINE Parenteral Solutions:

Usual dose:

XYLOCAINE Parenteral Solutions are given to you by a healthcare professional who is experienced in the use of anesthesia. The dose is decided by the healthcare professional and is based on the clinical need and your physical condition. In children, the dose is based on the child's weight, age and physical condition.

Overdose:

XYLOCAINE Parenteral Solutions are only given by healthcare professionals who are well experienced in the use of anesthesia. If you experience an overdose or any serious side effects after receiving XYLOCAINE Parenteral Solutions, the proper equipment and personnel will be immediately available to help you. Symptoms of an overdose may include:

- numbness of the lips and around the mouth,
- light-headedness or dizziness
- blurred vision
- hearing problems or tingling in the ears

In the event of a serious overdosage or a misplaced injection, trembling, seizures or unconsciousness may occur.

If the early signs of overdosage are noticed and no further XYLOCAINE Parenteral Solution is given, the risk of serious side effects occurring rapidly decreases. If you have any of these symptoms, **tell your healthcare professional immediately.**

If you think you, or a person you are caring for, have been given too much XYLOCAINE Parenteral Solution, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using XYLOCAINE Parenteral Solutions?

These are not all the possible side effects you may have when taking XYLOCAINE Parenteral Solutions. If you experience any side effects not listed here, tell 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	
COMMON			
Bradycardia (abnormally slow heartbeat)		X	
Dizziness, abnormal sensations (pins and needles)		X	
Feeling of sickness/nausea, vomiting (These side effects occur more frequently after epidural block).	X		
Hypertension (high blood pressure): shortness of breath, fatigue, dizziness or fainting, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or heart palpitations		X	
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		X	
UNCOMMON			
Toxicity symptoms: convulsions, seizures, light-headedness, numbness of the lips and around the mouth, hearing, visual, or speech disturbances, trembling			X
RARE			
Allergic reaction: difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat,			X
Cardiac arrest and/or irregular heartbeat			X
Double vision		X	

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	
Nervous system disorders: weakness or paralysis of limbs or face, tingling of extremities, difficulty speaking, confusion, disorientation, trembling		X	
UNKNOWN			
Kounis syndrome (heart problems caused by an allergic reaction): chest pain, chest pressure or discomfort, heart palpitations, sweating, shortness of breath (may occur with symptoms of an allergic reaction; see above in this table)			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, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- 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.

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.

Storage:

The healthcare professional is responsible for storing XYLOCAINE Parenteral Solutions.

XYLOCAINE Parenteral Solutions are stored at controlled room temperature (15-25°C) and protected from freezing. XYLOCAINE Parenteral Solutions containing epinephrine are also protected from light.

If you want more information about XYLOCAINE Parenteral Solutions:

- Talk to your healthcare professional

XYLOCAINE Parenteral Solutions, lidocaine hydrochloride / lidocaine hydrochloride and epinephrine bitartrate

- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.aspenpharma.ca, or by calling 1-844- 330-1213.

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