

IMPORTANT: PLEASE READ

XYLOCAINE® PARENTERAL SOLUTIONS

Lidocaine Hydrochloride Injection USP

Lidocaine Hydrochloride and Epinephrine Bitartrate Injection USP

PART III: CONSUMER INFORMATION

This leaflet is part III of a three-part "Package Insert" published when XYLOCAINE Parenteral Solutions 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 Parenteral Solutions. Contact your doctor if you have any questions about the drug.

ABOUT THIS MEDICATION

WHAT THE MEDICATION IS USED FOR:

XYLOCAINE Parenteral Solutions are used to anesthetize part of the body for surgical operations and also for pain relief and can be used:

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

WHAT IT DOES:

XYLOCAINE Parenteral Solutions act by preventing the nerves in the injected area from transmitting sensations of pain, heat or cold. However, you may still experience sensations such as pressure and touch. In this way, the nerve(s) is anesthetised in the part of the body, which will be subjected to surgery. In many cases this means that the nerves to the muscles in the area will also be blocked, causing temporary weakness or paralysis.

WHEN IT SHOULD NOT BE USED:

XYLOCAINE Parenteral Solutions should not be used in patients who:

- 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 sodium metabisulfite
- are allergic to methylparaben (preservative used in some solutions) or PABA

XYLOCAINE Parenteral Solutions containing methylparaben should not be used for epidural or spinal anesthesia.

Because of the potential for irreversible joint damage, pain following joint surgery should not be managed by infusing XYLOCAINE into the joint (i.e. by use of a post-operative "pain pump").

WHAT THE MEDICINAL INGREDIENTS ARE:

Sterile solutions of 0.5%, 1% and 2% lidocaine hydrochloride contain 5, 10 or 20 mg/mL lidocaine hydrochloride. Sterile solutions of 1% and 2% lidocaine hydrochloride with epinephrine contain 10 or 20 mg/mL lidocaine hydrochloride with 0.010 mg/mL (1:100,000) or 0.005 mg/mL (1:200,000) epinephrine base, as epinephrine bitartrate.

NONMEDICINAL INGREDIENTS:

XYLOCAINE Parenteral Solutions also contain sodium chloride, water for injection, and sodium hydroxide and/or hydrochloric acid.

XYLOCAINE Parenteral Solutions with epinephrine also contain sodium chloride, sodium metabisulphite, water for injection, and sodium hydroxide and/or hydrochloric acid. Certain vial presentations may contain citric acid. Please refer to the product label.

Multidose vials contain methylparaben.

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

WHAT DOSAGE FORMS IT COMES IN:

XYLOCAINE Parenteral Solutions are available in plastic ampoules, single use and multidose glass vials.

WARNINGS AND PRECAUTIONS

You should talk to your doctor prior to surgery:

- 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 think you may be allergic or sensitive to any ingredients in XYLOCAINE Parenteral Solutions (see above). Sodium metabisulphite might cause allergic reactions (e.g., facial swelling and respiratory difficulties) in susceptible people, especially those with a history of asthma or allergy;
- if you have a severe heart, kidney or liver disease;
- if you have neurological disease, spinal deformities, septicaemia and severe hypertension (in case of Lumbar and caudal epidural anesthesia);
- if you have poorly controlled hyperthyroidism and diabetes (in case of use of solutions with epinephrine);
- if you have epilepsy;
- 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;
- if you are planning to drive or operate any tools or machinery on the day of surgery, because XYLOCAINE Parenteral Solutions may temporarily interfere with your reactions and muscle coordination.

INTERACTIONS WITH THIS MEDICATION

Tell your doctor/dentist/pharmacist if you are taking or have recently taken any medicines, even those that can be bought without a prescription.

Drugs that may interact with XYLOCAINE Parenteral Solutions include:

- anti-arrhythmic drugs for heart problems (e.g. mexiletine, amiodarone);
- other anesthetics;
- propranolol for heart problems or cimetidine for gastrointestinal problems;
- fluvoxamine for depression, if using high doses of XYLOCAINE Parenteral Solutions for long time and other medicines for depression;
- antimigraine therapy;
- antipsychotic therapy;
- medicines for high blood pressure.

Usage of such medicines at the same time as XYLOCAINE Parenteral Solutions may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

USUAL DOSE:

XYLOCAINE Parenteral Solutions should be administered by a doctor. The dose to be given is decided by the doctor, based on the clinical need and your physical condition.

OVERDOSE:

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

Serious side effects resulting from getting too much XYLOCAINE Parenteral Solution need special treatment and the doctor treating you is trained to deal with these situations. Early signs that too much XYLOCAINE Parenteral Solution has been given include:

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

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

If the early signs of overdose are noticed and no further XYLOCAINE Parenteral Solutions is given, the risk of serious side effects occurring rapidly decreases. If you have any of these symptoms, or you think you have received too much XYLOCAINE Parenteral Solutions, **tell your doctor immediately.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, XYLOCAINE Parenteral Solutions may cause side effects in some people.

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 after exposure to XYLOCAINE Parenteral solutions, check with your doctor as soon as possible.

XYLOCAINE Parenteral Solutions may temporarily interfere with your reactions and muscle co-ordination; therefore do not drive or use machines on the day of surgery.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor		Seek immediate emergency assistance
	Only if severe	In all cases	
Common			
Dizziness, abnormal sensations (pins and needles)		X	
Feeling of sickness/nausea*, vomiting*	X		
Decreased heart rate		X	
Increased blood pressure, decreased blood pressure*		X	
Uncommon			
Toxicity symptoms such as: convulsions, seizures, light-headedness, numbness of the lips and around the mouth, numbness of the tongue, hearing disturbances, visual disturbances, speech disturbances, trembling and other signs of central nervous system depression.			X
Rare			
Cardiac arrest and/or irregular heartbeat			X

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor		Seek immediate emergency assistance
	Only if severe	In all cases	
Allergic reactions such as: facial swelling and difficulties with breathing/respiratory shock			X
Nervous system disorders such as: nerve injury, paralysis or tingling of extremities		X	
Double vision		X	

*These side effects occur more frequently after epidural block.

This is not a complete list of side effects. Consult your doctor immediately if any of these symptoms or any unexpected effects appear.

HOW TO STORE IT

XYLOCAINE should be stored at controlled room temperature (15-25°C). XYLOCAINE containing epinephrine should be protected from light. Protect from freezing. Keep out of the reach and sight of children.

Your doctor or the hospital will normally store, XYLOCAINE. The staff is responsible for storing, dispensing and disposing of, XYLOCAINE in the correct way.

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 Parenteral Solutions.

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 Package Insert, 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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