

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

PrXYLOCARD®

Lidocaine hydrochloride
Solution, 20 mg/mL, Intravenous

(Ph Eur)

Antiarrhythmic ATC CO1BB01

Aspen Pharmacare Canada Inc.
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READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

XYLOCARD®
lidocaine hydrochloride injection

Read this carefully before you start taking **XYLOCARD** 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 **XYLOCARD**.

What is XYLOCARD used for?

XYLOCARD is used to treat abnormally fast heart rhythms that may occur during:

- heart surgery or other procedures
- a heart attack or other heart conditions.

How does XYLOCARD work?

XYLOCARD is an antiarrhythmic drug. It works to reduce the number of heartbeats per minute and helps return the heartbeat to normal.

What are the ingredients in XYLOCARD?

Medicinal ingredients: lidocaine hydrochloride

Non-medicinal ingredients: Sodium chloride, sodium hydroxide (and/or hydrochloric acid) and water for injection

XYLOCARD comes in the following dosage forms:

Solution: 20 mg/mL

Do not use XYLOCARD if you:

- are allergic or sensitive to lidocaine hydrochloride, to any of the nonmedicinal ingredients in XYLOCARD or other local anaesthetics (e.g. prilocaine, mepivacaine or bupivacaine).
- have a heart condition such as, Adams-Stokes syndrome, or severe degrees of sinoatrial, atrioventricular or intraventricular block.

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

- have a slow heartbeat.
- have low levels of potassium in your blood.
- have been taking a drug called digitalis.
- have epilepsy.
- have low blood pressure.
- have problems with your heart, liver or kidneys.
- have been diagnosed with acute porphyria.
- are experiencing severe shock.
- are pregnant or plan to become pregnant.
- are breastfeeding or planning to breastfeed.

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 XYLOCARD:

- Antiarrhythmic drugs used to treat heart problems such as; mexiletine, amiodaraone.
- Cimetidine used for stomach problems.
- Fluvoxamine used to treat depression.
- Beta-blockers, used to treat heart problems, such as; metoprolol, nadolol, propranolol.
- Drugs used to treat epilepsy and seizures such as; carbamazepine, phenobarbital, phenytoin, primidone.

How to take XYLOCARD?:

- XYLOCARD will be given as an intravenous injection by a healthcare professional.
 - Your heart rate and blood pressure will be monitored while you are receiving XYLOCARD.
- Your doctor may give you one single injection of XYLOCARD. Depending on your condition, you may need a continuous infusion of XYLOCARD.

Usual dose:

The doctor will determine your dose based on your individual needs.

Overdose:

Serious side effects can occur if you are given too much XYLOCARD. Early signs that you have been given too much XYLOCARD include:

- numbness of the lips and around the mouth,
- lightheadedness or dizziness,
- blurred vision,
- hearing problems and/ or ringing in the ears.

If you think you have been given too much XYLOCARD, contact your doctor, nurse, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using XYLOCARD?

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

Side effects may include:

- nausea, vomiting
- dizziness, lightheadedness
- drowsiness
- sensations of heat, cold or numbness
- sensitivity to sounds, ringing in the ears

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			

Abnormal sensations: pins and needles, numbness around the mouth and/or of the tongue		√	
Slow or irregular heartbeat		√	
Low blood pressure: dizziness, fainting, lightheadedness, fatigue May occur when you go from lying or sitting to standing up.		√	
RARE			
Prolonged dizziness		√	
Heart attack: severe crushing chest pain, irregular heartbeat, shortness of breath			√
Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Nerve injury: tingling of the arms and legs		√	
Blurred vision		√	
Nervous system disorders: nervousness, apprehension, euphoria, confusion, twitching, tremors, convulsions, unconsciousness			√
Respiratory arrest: severe trouble breathing, unconsciousness			√

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.

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:

Store at room temperature (15 - 25°C).
Keep out of reach and sight of children.

If you want more information about XYLOCARD:

- 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 www.aspenpharma.ca, or by calling 1- 844-330-1213.

This leaflet was prepared by
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