

PART III: CONSUMER INFORMATION

Lidocaine Hydrochloride and Epinephrine Injection USP

Lidocaine Hydrochloride (10 mg/mL) and Epinephrine (0.01 mg/mL)

Lidocaine Hydrochloride (20 mg/mL) and Epinephrine (0.01 mg/mL)

Lidocaine Hydrochloride (20 mg/mL) and Epinephrine (0.005 mg/mL)

Sterile Solution

Local Anesthetic

This leaflet is part III of a three-part “Package Insert” published when Lidocaine Hydrochloride and Epinephrine Injection USP was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Lidocaine Hydrochloride and Epinephrine Injection USP. Contact your doctor if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Lidocaine Hydrochloride and Epinephrine Injection USP is used to anesthetize part of the body for surgical operations and also for pain relief and can be used:

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

What it does:

Lidocaine Hydrochloride and Epinephrine Injection USP acts 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 anesthetized 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:

Lidocaine Hydrochloride and Epinephrine Injection USP 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 **Non-medicinal ingredients** below);
- are allergic to sodium metabisulfite;
- are allergic to methylparaben (preservative used in some solutions) or PABA.

Lidocaine Hydrochloride and Epinephrine Injection USP 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

Lidocaine Hydrochloride and Epinephrine Injection USP into the joint (i.e., by use of a post-operative “pain pump”).

What the medicinal ingredients are:

Sterile solutions of Lidocaine Hydrochloride and Epinephrine Injection USP contains 10 mg/mL lidocaine hydrochloride and 0.01 mg/mL (1:100 000) epinephrine; 20 mg/mL lidocaine hydrochloride and 0.01 mg/mL (1: 100 000) epinephrine; and 20 mg/mL lidocaine hydrochloride and 0.005 mg/mL (1: 200 000).

Non-medicinal ingredients:

Lidocaine Hydrochloride and Epinephrine Injection USP also contains sodium chloride, sodium metabisulfite, methylparaben for multi-dose vials only, water for injection, sodium hydroxide and/or hydrochloric acid, and citric acid.

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

What dosage forms it comes in:

Lidocaine Hydrochloride and Epinephrine Injection USP is available in single-use and multidose 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 Lidocaine Hydrochloride and Epinephrine Injection USP (see above). Sodium metabisulfite 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, septicemia 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 Lidocaine Hydrochloride and Epinephrine Injection USP 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 Lidocaine Hydrochloride and Epinephrine Injection USP 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 Lidocaine Hydrochloride and Epinephrine Injection USP for a long time and other medicines for depression;
- antimigraine therapy;
- antipsychotic therapy;
- medicines for high blood pressure;
- opioid medicines, such as fentanyl (used to treat severe pain during and/or following surgery);
- other medicines that decrease the nervous system, breathing and blood pressure activities.

Usage of such medicines at the same time as Lidocaine Hydrochloride and Epinephrine Injection USP may increase the risk of serious side effects.

PROPER USE OF THIS MEDICATION

Usual dose:

Lidocaine Hydrochloride and Epinephrine Injection USP 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:

If you think you have taken too much Lidocaine Hydrochloride and Epinephrine Injection USP, contact your health care professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Serious side effects resulting from getting too much Lidocaine Hydrochloride and Epinephrine Injection USP need special treatment and the doctor treating you is trained to deal with these situations. Early signs that too much Lidocaine Hydrochloride and Epinephrine Injection USP 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 Lidocaine Hydrochloride and Epinephrine Injection USP 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 Lidocaine Hydrochloride and Epinephrine Injection USP, **tell your doctor immediately.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any medication, Lidocaine Hydrochloride and Epinephrine Injection USP 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 Lidocaine Hydrochloride and Epinephrine Injection USP, check with your doctor as soon as possible.

Lidocaine Hydrochloride and Epinephrine Injection USP 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 or pharmacist		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
Common			
Dizziness, abnormal sensations (pins and needles)		√	
Feeling of sickness/nausea*, vomiting*	√		
Decreased heart rate		√	
Increased blood pressure, decreased blood pressure*		√	
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.			√
Rare			
Cardiac arrest and/or irregular heartbeat			√
Allergic reactions such as: facial swelling and difficulties with breathing/respiratory shock			√

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

Symptom / effect	Talk with your doctor or pharmacist		Stop taking the drug and get immediate medical help
	Only if severe	In all cases	
Nervous system disorders such as: nerve injury, paralysis or tingling of extremities		√	
Double vision		√	
Unknown frequency			
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)			√

* 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.***

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.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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.

HOW TO STORE IT

Lidocaine Hydrochloride and Epinephrine Injection USP should be stored at controlled room temperature (20°C to 25°C). Lidocaine Hydrochloride and Epinephrine Injection USP 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 Lidocaine Hydrochloride and Epinephrine Injection USP. The staff is responsible for storing, dispensing and disposing of Lidocaine Hydrochloride and Epinephrine Injection USP in the correct way.

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 Lidocaine Hydrochloride and Epinephrine Injection USP.

NOTE: This CONSUMER INFORMATION leaflet provides you with the most current information at the time of printing.

This document, plus the full Prescribing Information prepared for health professionals, can be found by contacting the sponsor, Pfizer Canada ULC, at: 1-800-463-6001 or by visiting their website at www.pfizer.ca.

This leaflet was prepared by:
Pfizer Canada ULC
Kirkland, Québec H9J 2M5

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