

PART III: CONSUMER INFORMATION

**PrVerapamil Hydrochloride Injection USP
2.5 mg/mL
Sterile Solution**

This leaflet is PART III of a three-part “Product Monograph” published when Verapamil Hydrochloride 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 Verapamil Hydrochloride Injection USP. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

Verapamil Hydrochloride Injection USP is used to control life threatening:

- Abnormal heart rhythms
- Rapid heartbeat

What it does:

Verapamil Hydrochloride Injection USP is a calcium channel blocker. Calcium channel blockers change the amount of calcium getting into the muscle cells of your heart and blood vessels. This can change the strength and speed at which your heart beats. It also opens up the blood vessels so that blood can be pumped around your body more easily. This helps to lower your blood pressure.

When it should not be used:

Verapamil Hydrochloride Injection USP should not be used if:

- you are allergic to any component of Verapamil Hydrochloride Injection USP (see What the nonmedicinal ingredients are).
- you have had a heart attack
- you have heart failure
- you have serious heart or circulation problems
- you have a slow or irregular heartbeat.
- you have very low blood pressure or feel faint when you get up.
- you are breast-feeding while taking this medication.
- you have serious heart disease and are taking beta blockers. You can recognize beta blockers because their medicinal ingredient ends in ‘-lol’.
- you are taking ivabradine, a drug that lowers your heart rate
- you are taking flibanserin, a medicine to treat generalized hypoactive sexual desire disorder. You must wait at least 2 weeks after your last dose of Verapamil Hydrochloride Injection USP before starting flibanserin. You must wait at least 2 days

after your last dose of flibanserin before starting Verapamil Hydrochloride Injection USP.

What the medicinal ingredient is:

Each mL contains 2.5 mg verapamil hydrochloride

What the non-medicinal ingredients are:

Each mL contains sodium chloride, hydrochloric acid and water for injection

What dosage forms it comes in:

Verapamil Hydrochloride Injection USP is available in 2.5 mg/mL in 2 mL (5 mg/2 mL,) ampoules, sleeves of 10, and 2.5 mg/mL in 2 mL (5 mg/2 mL,) fliptop vials, cartons of 5

LATEX-FREE STOPPER: Stopper contains no dry natural rubber.

WARNINGS AND PRECAUTIONS

BEFORE Verapamil Hydrochloride Injection USP is used, tell your doctor if:

- you have heart failure
- you have low blood pressure and slow heart rate
- you have kidney disease.
- you have liver disease.
- you are taking beta-blocker to treat high blood pressure, angina and heart failure.
- you have a neuromuscular disease (i.e. myasthenia gravis or Duchenne muscular dystrophy).
- you are pregnant or planning to become pregnant
- you are breast-feeding
- you are under 18 years of age
- you are 65 years of age or older
- you are taking any other medications

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor if you are taking or have recently taken any other medications, including non-prescription medicines, vitamins, minerals, natural supplements, or alternative medicines.

Additional monitoring of your dose or condition may be needed if you are taking other drugs.

The following may interact with Verapamil Hydrochloride Injection USP:

- Anti-anxiety drugs, including busprione and midazolam
- Antibiotics such as clarithromycin,

- erythromycin, telithromycin, rifampicin,
- Dabigatran, rivaroxaban, apixaban, and edoxaban (blood thinners)
- Anti-diabetic medications, e.g. glyburide
- Anti-epilepsy drugs (e.g. carbamazepine, phenytoin, phenobarbital)
- Asthma medications e.g. theophylline,
- Blood pressure lowering drugs, including alpha blockers (e.g. prazosin, terazosin); beta-blockers (e.g. propranolol, metoprolol, atenolol); diuretics (e.g. hydrochlorothiazide);
- Cholesterol lowering medications (e.g. simvastatin, atorvastatin, lovastatin);
- Dantrolene, used for severe muscle spasms or severe fever
- Doxorubicin, a cancer medication
- Drugs that affect your immune system (e.g. cyclosporine, sirolimus, tacrolimus, everolimus);
- Drugs used to control heart rate (e.g. amiodarone, digoxin, disopyramide, flecainide, lidocaine, quinidine);
- Cimetidine, an ulcer medication
- Gout medications including colchicine, sulfapyrazone
- Imipramine, an antidepressant
- Lithium for the treatment of bipolar disease
- Migraine medication, e.g. almotriptan,
- Nitrous oxide and other inhalation anesthetics
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. e.g. acetylsalicylic acid, ibuprofen, naproxen, and celecoxib.
- Neuromuscular blocking agents (e.g. atracurium);
- HIV-anti-viral medication (e.g. ritonavir);
- Grapefruit juice;
- Alcohol;
- St John's Wort.
- Ivabradine (a drug that lowers your heart rate).

Please check with your doctor before taking any other medications with Verapamil Hydrochloride Injection USP.

PROPER USE OF THIS MEDICATION

Verapamil hydrochloride Injection USP will be administered by a healthcare professional

Usual dose :

Adult

Initial Dose: 5 to 10 mg (0.075 to 0.15 mg/kg body weight) given as an IV bolus over at least 2 minutes.

Repeat Dose: 10 mg (0.15 mg/kg body weight) 30

minutes after the first dose if the initial response is not adequate. An optimal interval for subsequent IV doses has not been determined, and should be individualized for each patient.

Older Patients (65 years or older):

The dose should be administered over at least 3 minutes to minimize the risk of untoward drug effects.

Children

Initial Dose:

0 to 1 year: 0.1 to 0.2 mg/kg body weight (usual single dose range 0.75 to 2 mg) should be administered as an IV bolus over at least 2 minutes under continuous ECG monitoring.

1 to 15 years: 0.1 to 0.3 mg/kg body weight (usual single dose range 2 to 5 mg) should be administered as an IV bolus over at least 2 minutes. Do not exceed 5 mg.

Repeat Dose:

0 to 1 year: 0.1 to 0.2 mg/kg body weight (usual single dose range 0.75 to 2 mg) 30 minutes after the first dose if the initial response is not adequate (under continuous ECG monitoring). An optimal interval for subsequent doses has not been determined, and should be individualized for each patient.

1 to 15 years: 0.1 to 0.3 mg/kg body weight (usual single dose range 2 to 5 mg) 30 minutes after the first dose if the initial response is not adequate. An optimal interval for subsequent doses has not been determined, and should be individualized for each patient. Do not exceed 10 mg as a single dose.

Oral treatment should replace intravenous therapy as soon as possible, when the physician wishes to continue treatment with verapamil hydrochloride. Duration of treatment will depend on the underlying cause and history of recurrence.

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.

Missed dose:

Your healthcare professional will ensure that this product is administered properly and doses are not missed.

SIDE EFFECTS AND WHAT TO DO ABOUT

THEM

Side effects may include:

- constipation,
- headache
- nausea
- unusual tiredness or weakness

If any of these affects you severely, tell your doctor, nurse or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	Low blood pressure: dizziness, fainting, lightheadedness. May occur when you go from lying or sitting to standing up		√	
	Fast, slow or irregular heart beat		√	
	Difficulty breathing, coughing or wheezing		√	
	Swelling in the arms, legs, ankles or feet		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
Uncommon	Angioedema and Severe Allergic Reaction (anaphylaxis): swelling of the face, eyes, lips, tongue or throat, difficulty swallowing or breathing, nausea or vomiting, wheezing, rash, hives itching, fever, abdominal cramps, chest discomfort or tightness			√
	Muscle weakness		√	
	Seizures			√

This is not a complete list of side effects. For any unexpected effects while taking Verapamil Hydrochloride Injection USP, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 20 °C and 25°C. Protect from light and freezing

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>) 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.

FOR MORE INFORMATION

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 Product Monograph, prepared for health professionals can be found at: www.pfizer.ca, under Prescription Products, or by contacting the sponsor, Pfizer Canada ULC at: 1-800-463-6001.

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