

PART III: CONSUMER INFORMATION**Pr PRO-VERAPAMIL SR****Verapamil Hydrochloride Sustained-Release Tablet, USP
240 mg**

This leaflet is part III of a three-part "Product Monograph" published when PRO-VERAPAMIL SR was approved for sale in Canada and is designed specifically for consumers. This leaflet is a summary and will not tell you everything about PRO-VERAPAMIL SR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

PRO-VERAPAMIL SR is used to treat hypertension (high blood pressure).

What it does:

PRO-VERAPAMIL SR 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:

PRO-VERAPAMIL SR should not be used if:

- you are allergic to any component of PRO-VERAPAMIL SR including the active ingredient or the nonmedicinal ingredients. (See What the nonmedicinal ingredients are).
- you have certain serious heart disease or problems.
- you feel faint when you get up.
- you have symptoms such as rapid pulse and breathing, anxiety, weakness, decreased urine production, cool hands and feet and loss of alertness. See your doctor immediately.
- you have had a heart attack.
- you have slow heartbeat or irregular heartbeat.
- you are breast-feeding while taking this medication.

Ask your doctor for advice.

What the medicinal ingredient is:

Verapamil hydrochloride.

What the non-medicinal ingredients are:

Carnauba wax, D&C Yellow No. 10 lake, FD&C Blue No. 1 lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium alginate, titanium dioxide.

For a full listing of non-medicinal ingredients see PART 1 of the Product Monograph.

What dosage forms it comes in:

Tablets: 240 mg

WARNINGS AND PRECAUTIONS

BEFORE you use PRO-VERAPAMIL SR talk to your doctor or pharmacist if:

- you are pregnant or planning to become pregnant
- you have any heart disease.
- you have kidney disease.
- you have liver disease.
- you are taking beta-blockers. (See Interactions With This Medication).
- you have neuromuscular disease (i.e. myasthenia gravis or Duchenne muscular dystrophy).

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with PRO-VERAPAMIL SR include:

- beta-blockers (e.g. propranolol, metoprolol, atenolol, timolol);
- any other treatment for hypertension (high blood pressure) or an arrhythmia (abnormal heart beat) (e.g. hydrochlorothiazide, disopyramide, flecainide, quinidine, prazosin, terazosin);
- dabigatran (a blood thinner);
- digoxin, digitoxin, cimetidine, lithium, rifampicin, theophylline, sulfapyrazone, clarithromycin, erythromycin, telithromycin, glyburide, almotriptan, colchicine;
- carbamazepine, phenobarbital, phenytoin;
- any of the group of medicines known as major tranquilizers, or an antidepressant of the tricyclic group (e.g. imipramine);
- any of the group of medicines known as benzodiazepines or other anti-anxiety treatment (e.g. buspirone, midazolam);
- any of the group of medicines known as non-steroidal anti-inflammatory drugs (e.g. acetylsalicylic acid);
- anti-cancer medication (e.g. doxorubicin);
- some medication that can affect your immune system (e.g. cyclosporine, sirolimus, tacrolimus, everolimus);
- any neuromuscular blocking agent (e.g. atracurium);
- some anti-cholesterol products (e.g. simvastatin, atorvastatin, lovastatin);
- some HIV-antiviral medication (e.g. ritonavir);
- grapefruit juice;
- alcohol;
- St John's Wort.

PROPER USE OF THIS MEDICATION**Usual dose:**

Always take your tablets exactly as your doctor has told you. The usual starting adult dose for PRO-VERAPAMIL SR is 180 to 240 mg per day, taken at the same time every day. Dosage is individualized and your doctor will adjust your dose as needed. The maximum dose to treat high blood pressure is 480 mg each day. This is usually taken as one PRO-VERAPAMIL SR 240 mg

tablet in the morning and one in the evening, leaving a gap of about 12 hours between each dose.

Tablets should be taken with sufficient liquid, preferably with or shortly after meals. Do not crush or chew the tablets.

The PRO-VERAPAMIL SR 240 mg tablets are scored. It may be cut in half without damaging the modified release formulation.

Overdose:

If you think you have taken too much PRO-VERAPAMIL SR, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you or someone you know accidentally takes more than stated dose, contact your doctor immediately or go to the nearest hospital with the tablets.

In case of accidental drug overdose, contact a health care practitioner, hospital emergency department or regional poison control centre immediately, even if there are no symptoms. Tell your doctor or hospital how much was taken. Treat even small overdoses seriously.

Missed Dose:

If you forget to take one tablet, take another as soon as you remember, unless it is almost time for your next dose. If it is, do not take the missed tablet at all.

Never double-up on a missed dose.

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

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
		Only if severe	In all cases	
Common	Feeling dizzy and faint or your blood pressure is too low		✓	
	Difficulty breathing		✓	
	Swelling in the arms or legs		✓	
Uncommon	Feeling an irregular heart beat		✓	
	Rash or other skin irritation		✓	
	Muscle weakness		✓	

This is not a complete list of side effects. For any unexpected effects while taking PRO-VERAPAMIL SR, contact your doctor or pharmacist.

HOW TO STORE IT

- Keep PRO-VERAPAMIL SR and all other medicines out of sight and reach of children
- PRO-VERAPAMIL SR tablets should be stored between 15°C and 30°C, in airtight containers. Protect from light and moisture.
- Do not take your tablets after the expiry date shown on the label
- It is important to keep the PRO-VERAPAMIL SR tablets in the original package.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its needed effects, a medicine may cause some unwanted effects. These are referred to as “side effects”. Although not all of these side effects may occur, if they do occur they may need medical attention.

The most common side effects with PRO-VERAPAMIL SR are constipation, dizziness and feeling sick (nausea). Other less common side effects may include headache and tiredness.

Check with your physician or pharmacist if you experience any unexpected effects, or are concerned by the above side effects.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect \(http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php\)](http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php).

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.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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