

PART III: CONSUMER INFORMATION

PrISOPTIN® SR verapamil hydrochloride sustained-release tablet Manufacturer's Standard

This leaflet is PART III of a three-part "Product Monograph" published when ISOPTIN® 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 ISOPTIN® SR. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

- ISOPTIN® SR is used to treat hypertension (high blood pressure).

What it does:

ISOPTIN® 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:

ISOPTIN® SR should not be used if:

- you are allergic to any component of ISOPTIN® 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.
- you are taking ivabradine, a drug that lowers your heart rate.

Ask your doctor for advice.

What the medicinal ingredient is:

ISOPTIN® SR contains verapamil hydrochloride.

What the non-medicinal ingredients are:

hydroxypropyl methylcellulose, indigo carmine (240 mg tablet only), macrogol 400, macrogol 6000, magnesium stearate,

microcrystalline cellulose, montan glycol wax, povidone, purified water, quinoline yellow (240 mg tablet only), red iron oxide (180 mg tablet only), sodium alginate, talc, titanium dioxide

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

What dosage forms it comes in:

ISOPTIN® SR is available as sustained-release tablets in the following strengths: 120 mg, 180 mg, 240 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use ISOPTIN® 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 ISOPTIN® 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.
- ivabradine (a drug that lowers your heart rate).

PROPER USE OF THIS MEDICATION

Usual dose:

Always take your tablets exactly as your doctor has told you. The usual starting adult dose for ISOPTIN® 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 ISOPTIN® 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 ISOPTIN® SR 180 mg and 240 mg tablets are scored. Only the 240 mg tablets may be cut in half without damaging the modified release formulation.

Overdose:

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.

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 ISOPTIN® 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.

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 call your doctor or pharmacist
		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 ISOPTIN® SR, contact your doctor or pharmacist.

HOW TO STORE IT

Keep ISOPTIN® SR and all other medicines out of reach of children.

ISOPTIN® SR tablets should be stored at 15° to 25°C.

Do not take your tablets after the expiry date shown on the label.

It is important to keep the ISOPTIN® SR tablets in the original package.

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 on line 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
 - Mail to : Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON 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

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:
1-844-596-9526

This leaflet was prepared by BGP Pharma ULC.

Last revised: August 10, 2017