

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrISOPTIN® SR

Verapamil Hydrochloride Sustained-Release Tablets

Read this carefully before you start taking **ISOPTIN® SR** 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 **ISOPTIN® SR**.

What is ISOPTIN® SR used for?

ISOPTIN® SR is used to treat high blood pressure (hypertension) in adults (18 years of age or older) that:

- cannot take diuretics (medicines used to increase the amount of water released in your urine),
- cannot take beta blockers (medicines used to treat high blood pressure), or
- experience serious side effects when taking diuretics or beta blockers.

How does ISOPTIN® SR work?

ISOPTIN® SR belongs to a group of medicines known as calcium channel blockers. 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.

What are the ingredients in ISOPTIN® SR?

Medicinal ingredient: verapamil hydrochloride.

Non-medicinal ingredients: 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, and titanium dioxide.

ISOPTIN® SR comes in the following dosage forms:

Sustained-release tablets: 120 mg, 180 mg, and 240 mg of verapamil hydrochloride.

Do not use ISOPTIN® SR if:

- you are allergic to verapamil hydrochloride or to any other ingredients in ISOPTIN® SR.
- you have any of the following heart conditions:
 - left ventricular dysfunction (a weakness to part of the heart that pumps oxygen-rich blood to the rest of the body);
 - cardiogenic shock (heart is not able to pump enough blood to the body);
 - second or third degree heart block (a type of irregular heart beat and rhythm);
 - sick sinus syndrome (heart's natural pacemaker is unable to create normal heartbeats at the normal rate);
 - bradycardia (abnormally slow heart beat); or
 - atrial flutter or atrial fibrillation (abnormal heart rhythm which is rapid and irregular), and you

also have an accessory bypass tract (e.g., Wolff-Parkinson-White and Lown-Ganong-Levine syndromes).

- you have had a heart attack, and you also have heart failure.
- you are taking ivabradine, medicine used to treat chronic heart failure by lowering the heart rate.
- you are taking or have recently taken (within the last 2 days) flibanserin, a medicine used to treat a condition known as hypoactive sexual desire disorder (HSDD) in women.

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

- are pregnant or planning to become pregnant. ISOPTIN® SR is not recommended during pregnancy.
- are breastfeeding or planning to breastfeed. ISOPTIN® SR can be passed in your breast milk and is not recommended during breastfeeding.
- have any heart problems.
- have kidney problems.
- have liver problems.
- are taking beta blockers. ISOPTIN® SR should not be taken with beta blockers as this can cause serious adverse effects.
- have neuromuscular disease (e.g. myasthenia gravis, Lambert-Eaton syndrome, or Duchenne muscular dystrophy).
- have high levels of calcium in your blood.
- are 65 years of age or older.

Other warnings you should know about:

Taking ISOPTIN® SR can cause the following:

- **Hypotension** (low blood pressure): This can occur after a single dose and even after several months of treatment. If you develop hypotension, your healthcare professional may reduce your dose of ISOPTIN® SR.
- **Heart problems:** This includes:
 - heart block (a type of irregular heartbeat and rhythm). ISOPTIN® SR may worsen a first-degree heart block to the second- or third-degree;
 - bradycardia (abnormally slow heartbeat); and
 - asystole (no electrical activity in the heart and the heart stops beating).

If you develop a heart problem, your healthcare professional may decide to reduce or stop your treatment with ISOPTIN® SR. A therapy may also be recommended by your healthcare professional to treat the heart problem.

- **Liver problems:** This includes an increase of certain liver enzymes that can result in the injury or death of liver cells. Your healthcare professional will monitor your liver enzyme levels throughout treatment. If you develop any liver problems, your healthcare professional may reduce your dose of ISOPTIN® SR.

See the **Serious side effects and what to do about them** table, below, for more information on these and other serious side effects.

Monitoring and testing: If you are prescribed ISOPTIN® SR, your healthcare professional may conduct various tests depending on your health and the other medicines you take. This includes blood tests, blood pressure checks, and electrocardiogram tests (used to evaluate your heart). Your healthcare professional will interpret your results and may adjust your dose or stop your treatment with ISOPTIN® SR.

Driving and using machines: ISOPTIN® SR may affect your ability to react. This may be more likely to occur at the start of your treatment and when your dose is raised. You should not drive or use machines until you know how ISOPTIN® SR affects you.

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 ISOPTIN® SR:

Serious Drug Interactions

Serious drug interactions with ISOPTIN® SR include:

- ivabradine, a medicine used to treat chronic heart failure by lowering the heart rate. Do not take ISOPTIN® SR if you are taking ivabradine.
- flibanserin, a medicine used to treat a condition known as hypoactive sexual desire disorder (HSDD) in women. Do not take ISOPTIN® SR if you are taking or have recent taken (within 2 days) discontinuing flibanserin. In addition, if you plan to start taking flibanserin, you must wait at least 2 weeks after your last dose of ISOPTIN® SR.

- alcohol.
- almotriptan, a medicine used to treat acute migraine headaches.
- anesthetics, medicines used to prevent pain during surgery.
- antiarrhythmics, medicines used to treat or prevent irregular heartbeats (e.g., disopyramide, flecainide, and quinidine).
- anticoagulants, medicines used to prevent blood clotting (e.g., dabigatran, rivaroxaban, apixaban, and edoxaban).
- anticonvulsants also known as antiepileptics, medicines used to prevent epilepsy or seizures (e.g., carbamazepine and phenytoin).
- antidepressants, medicines used to treat depression (e.g., tranquilizers, tricyclic antidepressants, and imipramine).
- antidiabetics, medicines used to treat diabetes (e.g., glibenclamide and metformin).
- anti-gout agents, medicines used to treat chronic gout (e.g., colchicine and sulfapyrazone).
- antihypertensive agents, medicines used to treat high blood pressure:
 - alpha blockers (e.g., terazosin and prazosin);
 - beta blockers (e.g., propranolol, metoprolol, atenolol, and timolol);
 - vasodilators;
 - angiotensin-converting enzyme (ACE) inhibitors; and
 - diuretics (e.g., hydrochlorothiazide).
- anti-infectives, medicines used to prevent or treat infections (e.g., clarithromycin, erythromycin,

rifampicin, and telithromycin).

- antineoplastics, medicines used to treat cancer (e.g., doxorubicin).
- anxiolytics, medicines typically used to treat anxiety, insomnia, and seizures (e.g., benzodiazepines, buspirone, and midazolam).
- aspirin (acetylsalicylic acid), a non-steroidal anti-inflammatory agents (NSAIDs) used to reduce pain and swelling.
- barbiturates, medicines used to relax the body and help with sleeping (e.g., phenobarbital)
- cardiac glycosides, medicines used to treat heart failure and certain heartbeats problems (e.g., digitoxin and digoxin).
- cimetidine, a medicine used to treat heartburn and certain types of stomach ulcers.
- grapefruit juice.
- HIV antiviral agents, medicines used to treat HIV infection (e.g., ritonavir).
- immunosuppressive agents, medicines used to treat autoimmune diseases (e.g., cyclosporine, everolimus, sirolimus, and tacrolimus).
- lipid metabolism regulators, medicines used to lower the amount of cholesterol in the blood and prevent coronary heart disease (e.g., atorvastatin, simvastatin, and lovastatin).
- lithium, a medicine used to treat bipolar disorder.
- neuromuscular blocking agents, medicines used to cause muscle relaxation (e.g., atracurium).
- St. John's wort, a herbal medicines commonly used to treat depression and mood disorders.
- theophylline, a medicine used to relieve symptoms of asthma.

How to take ISOPTIN® SR:

- Take ISOPTIN® SR exactly as directed by your healthcare professional.
- The ISOPTIN® SR tablets should be taken with food 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. However, only the 240 mg tablets may be cut in half without damaging the modified release formulation. Do not cut the 180 mg tablets.

Usual dose:

Your healthcare professional will decide how much ISOPTIN® SR you should take each day. This may depend on your condition and if you take other medications.

The usual starting adult dose for ISOPTIN® SR is 180 mg to 240 mg per day, taken at the same time every day. The maximum dose 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.

Overdose:

If you think you, or a person you are caring for, have taken too much ISOPTIN® SR, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget or miss a dose of ISOPTIN® SR, take it as soon as you remember. If it is almost time for your next dose, then do not take the missed dose at all. Do not take a double dose to make up for a missed dose. If you are unsure what to do, ask your healthcare professional.

What are possible side effects from using ISOPTIN® SR?

These are not all the possible side effects you may have when taking ISOPTIN® SR. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of ISOPTIN® SR may include constipation and headaches. Check with your healthcare professional if you are concerned by any of the above side effects.

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			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, or fatigue (may occur when you go from lying or sitting to standing up).		√	
Edema: unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages.		√	
Heart failure (heart does not pump blood as well as it should): shortness of breath, difficult breathing, fatigue, weakness, swelling in ankles, legs and feet, cough, fluid retention, lack of appetite, nausea, rapid or irregular heartbeat, or reduced ability to exercise.			√
Heart block (a type of irregular heartbeat and rhythm): feeling lightheaded, fainting, dizziness, shortness of breath, difficult breathing, nausea, or fatigue.			√
Bradycardia (abnormally slow heartbeat)		√	
UNCOMMON			
Skin disorders: rash, painful red lumps, itchiness, sweating, redness, pain in joints, or pain in			√

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	
muscles.			
Muscle problems: joint pain, muscle cramps, or muscle weakness.		√	
UNKNOWN FREQUENCY			
Liver problems: feeling of discomfort, fever, right upper abdominal pain, jaundice (yellowing of the skin or whites of eyes), dark urine, or light coloured stools.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell 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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store the ISOPTIN® SR tablets at 15°C 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.

Keep out of reach and sight of children.

If you want more information about ISOPTIN® SR:

- 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://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.mylan.ca, or by calling 1-844-596-9526.

This information is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

This leaflet was prepared by BGP Pharma ULC.

Last Revised: December 7, 2021