

IMPORTANT PLEASE READ

PART III: CONSUMER INFORMATION

^{Pr}APO-VERAP SR
verapamil hydrochloride sustained-release tablet

Apotex Standard

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

ABOUT THIS MEDICATION

What the medication is used for:

- APO-VERAP SR is used to treat hypertension (high blood pressure).

What it does:

APO-VERAP 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:

APO-VERAP SR should not be used if:

- you are allergic to any component of APO-VERAP 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:

APO-VERAP SR contains verapamil hydrochloride.

What the non-medicinal ingredients are:

carnauba wax, colloidal silicon dioxide, hydroxyethyl cellulose, magnesium stearate, polyethylene glycol, sodium alginate, and titanium dioxide. The 180 mg tablet also contains the non-medicinal ingredient ferric oxide red. The 240 mg tablet also contains the non-medicinal ingredients

ferric oxide yellow and brilliant blue FCF AL Lake.. *For a full listing of non-medicinal ingredients see PART I of the Product Monograph.*

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

BEFORE you use APO-VERAP 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 APO-VERAP 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, sulfinpyrazone, 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.

IMPORTANT PLEASE READ

PROPER USE OF THIS MEDICATION

Usual dose:

Always take your tablets exactly as your doctor has told you. The usual starting adult dose for APO-VERAP 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 APO-VERAP 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 APO-VERAP 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 think you have taken too much APO-VERAP 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.

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 APO-VERAP 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 APO-VERAP SR, contact your doctor or pharmacist.

HOW TO STORE IT

Keep APO-VERAP SR and all other medicines out of reach of children.

APO-VERAP SR tablets should be stored at 15°C to 30°C. Protect from light.

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

It is important to keep the APO-VERAP SR tablets in the original package.

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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 health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting DISpedia, Apotex's Drug Information Service at:

1-800-667-4708

This leaflet can also be found at:
<http://www.apotex.ca/products>.

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