

PART III: CONSUMER INFORMATION

**Pr APO-VALSARTAN
valsartan Tablets**

Read this carefully before you start taking APO-VALSARTAN and each time you get a refill. This leaflet is a summary and will not tell you everything about APO-VALSARTAN. Talk to your doctor, nurse or pharmacist about your medical condition and treatment and ask if there is any new information about APO-VALSARTAN.

ABOUT THIS MEDICATION

What the medication is used for:

High blood pressure (hypertension):

APO-VALSARTAN lowers high blood pressure.

Following a heart attack (myocardial infarction):

APO-VALSARTAN is used to treat people after a heart attack when an angiotensin-converting enzyme (ACE) inhibitor, considered part of standard therapy for this condition, is not appropriate.

Chronic heart failure:

APO-VALSARTAN is used in patients with chronic heart failure, when they are unable to tolerate the standard treatment with medications called ACE inhibitors. There is no evidence that APO-VALSARTAN provides added benefit when it is used with ACE inhibitors.

What it does:

APO-VALSARTAN is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking APO-VALSARTAN regularly even if you feel fine.

When it should not be used:

Do not take APO-VALSARTAN if you:

- Are allergic to **valsartan** or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ARB. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.

- Are taking a medicine that contains aliskiren (such as Rasilez) **and** you have diabetes or kidney disease.
- Are pregnant or intend to become pregnant. Taking APO-VALSARTAN during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that APO-VALSARTAN passes into breast milk.

What the medicinal ingredient is:

Valsartan

What the important nonmedicinal ingredients are:

APO-VALSARTAN also contains the following non-medicinal ingredients:

40 mg tablets: Croscarmellose Sodium, Colloidal Silicon Dioxide, Dibasic Calcium Phosphate, Magnesium Stearate, Powdered Cellulose, Ferric Oxide Orange Shade, Ferric Oxide Yellow Shade, Hydroxypropyl Methyl Cellulose, Hydroxypropyl Cellulose, polyethylene glycol and Titanium Dioxide.

80 mg tablets: Croscarmellose Sodium, Colloidal Silicon Dioxide, Dibasic Calcium Phosphate, Magnesium Stearate, Powdered Cellulose, Ferric Oxide Yellow Shade, Ferric Oxide Orange Shade, Hydroxypropyl Methyl Cellulose, Hydroxypropyl Cellulose, polyethylene glycol, and Titanium Dioxide.

160 mg tablets: Colloidal Silicon Dioxide, Croscarmellose Sodium, Dibasic Calcium Phosphate, Magnesium Stearate and Powdered Cellulose, Black Iron Oxide, Ferric Oxide Orange Shade, Ferric Oxide Yellow Shade, Hydroxypropyl Methyl Cellulose, Hydroxypropyl Cellulose, polyethylene glycol and Titanium Dioxide.

320 mg tablets: Croscarmellose Sodium, Colloidal Silicon Dioxide, Dibasic Calcium Phosphate, Magnesium Stearate and Powdered Cellulose, Black Iron Oxide, Ferric Oxide Yellow Shade, Ferric Oxide Orange Shade, Hydroxypropyl Methyl Cellulose, Hydroxypropyl Cellulose, polyethylene glycol and Titanium Dioxide.

If you are on a special diet, or if you are allergic to any substance, ask your doctor or pharmacist whether any of these ingredients may cause a problem

What dosage forms it comes in:

APO-VALSARTAN is available in four tablet strengths containing valsartan 40 mg, 80 mg, 160 mg and 320 mg.

IMPORTANT: PLEASE READ

APO-VALSARTAN tablets 40 mg is a divisible film-coated tablet. The 20 mg dose may be obtained by dividing a 40 mg tablet in half at the break line

- APO-VALSARTAN 40 mg tablet is Yellow, modified capsule shaped, film-coated, tablets, engraved "APO" on one side and "VA" scored "40" on the other side and contains 40 mg of valsartan.

- APO-VALSARTAN 80 mg tablet is Pale red, round; biconvex film coated tablets, engraved "APO" on one side and "VA" over "80" on the other side and contains 80 mg of valsartan.

- APO-VALSARTAN 160 mg tablet is Yellow, modified, capsule shaped, film-coated, tablets, engraved "APO" on one side and "VA160" on the other side and contains 160 mg of valsartan.

- APO-VALSARTAN 320 mg tablet is Dark grey-violet, oval shaped, film-coated tablets, engraved "APO" on one side and "VA320" on the other side and contains 320 mg of valsartan.

WARNINGS AND PRECAUTIONS

Serious warnings and precautions APO-VALSARTAN should not be used during pregnancy. If you discover that you are pregnant while taking APO-VALSARTAN stop the medication and please contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use APO-VALSARTAN talk to your doctor or pharmacist if you:

- Have experienced an allergic reaction to any drug, including drugs used to lower blood pressure, such as angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB).
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are on dialysis.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of "water pill" that makes your body keep potassium).
- Are on a low-salt diet.
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with APO-VALSARTAN is not recommended. Are taking

an angiotensin converting enzyme (ACE) inhibitor.

- Are less than 18 years old,

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to APO-VALSARTAN. Dizziness, light headedness or fainting can especially occur after the first dose and when the dose is increased.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with APO-VALSARTAN:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, - a potassium-sparing diuretic (a specific kind of "water pill") or other drugs that may increase potassium levels.
- Lithium, a medicine used to treat some types of psychiatric illness such as bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including diuretics ("water pills"), ACE inhibitors or aliskiren.
- Rifampin an antibiotic
- cyclosporine a drug used to protect against transplant rejection
- ritonavir a antiretroviral drug used to treat HIV/AIDS infection

PROPER USE OF THIS MEDICATION

Take APO-VALSARTAN exactly as prescribed. Swallow APO-VALSARTAN tablets with a glass of water. It is recommended to take your dose at about the same time everyday preferably in the morning. You can take APO-VALSARTAN with or without food, but it should be taken the same way each day. Do not exceed the recommended dose.

Usual Adult Dose:

High blood pressure (hypertension):

IMPORTANT: PLEASE READ

Recommended Initial dose: 80 mg once a day. Dose should be increased gradually.
Maximum dose: 320 mg a day

Following a heart attack (myocardial infarction):

Recommended starting dose: 20 mg twice a day
Dose can be increased gradually.
Target maintenance dose: 160 mg twice a day

Chronic heart failure:

Recommended starting dose: 40 mg twice a day.
Dose should be increased gradually.
Maximum dose: 160 mg twice a day

Overdose:

If you think you have taken too much APO-VALSARTAN contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Dizziness, light headedness,
- drowsiness,
- rash ,
- diarrhea, vomiting, nausea,
- headache,
- back or leg pain, muscle cramps,
- Muscle pain , muscle weakness,
- Unusual tiredness, weakness,
- Cough,
- Impotence,
- Nose bleed
- Blistering skin (sign of dermatitis bullous)

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

APO-VALSARTAN can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

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 medical help
		Only if severe	In all cases	
Common	Allergic Reactions : Skin rash, skin eruption or other effect on the skin or eyes			✓
	Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
Uncommon	Low blood pressure (hypotension) dizziness, fainting, light headedness May occur when you go from lying or sitting to standing up	✓		
	Angioedema/ Allergic reactions rash, hives, Swelling of the lips, face or neck, tongue or throat accompanied by difficulty in breathing, swallowing or speaking			✓
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities,		✓	

IMPORTANT: PLEASE READ

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 medical help
	Only if severe	In all cases	
fatigue			
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓	
Abdominal pain		✓	
Uncommon Cardiac failure: breathlessness, difficulty breathing when lying down, swelling of the feet or legs		✓	
Vasculitis: Inflammation of blood vessels purplish-red spots, fever, itching	✓		
Decreased Platelets: bruising, unusual bleeding, fatigue and weakness		✓	

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 medical help
	Only if severe	In all cases	
Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms, sore throat or mouth ulcers		✓	
Insomnia	✓		
Flu like symptoms, joint pain, pharyngitis, inflammation of sinuses, runny or stuffy nose, swollen hands, ankles or feet, upper respiratory tract infection, viral infection	✓		
Palpitations: irregular heartbeats		✓	
Unknown Change in libido	✓		
Blistering skin reactions with symptoms such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling and fever			✓

IMPORTANT: PLEASE READ

This is not a complete list of side effects. For any unexpected effects while taking APO-VALSARTAN, contact your doctor, nurse or pharmacist.

1-800-667-4708

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

HOW TO STORE IT

Do not use APO-VALSARTAN tablets past the expiry date shown on the pack.

Store your APO-VALSARTAN tablets in a dry place at room temperature (15°C -25°C)

Keep this medicine out of the reach and sight of children.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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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](#);
- 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](#).

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

Please consult your doctor or pharmacist with any questions or concerns you may have regarding your individual condition.

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: