

PART III: CONSUMER INFORMATION

**Pr APO-TELMISARTAN
Telmisartan Tablets, USP**

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

ABOUT THIS MEDICATION

What the medication is used for:

- To treat high blood pressure
- To reduce the risk of non-fatal heart attack or non-fatal stroke

What it does:

APO-TELMISARTAN 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-TELMISARTAN regularly even if you feel fine.

When it should not be used:

Do not take APO-TELMISARTAN if you:

- Are allergic to telmisartan or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction with swelling of the face, lips, tongue, throat, or sudden difficulty breathing or swallowing to any ARB. Be sure to tell your doctor, nurse, or pharmacist that this happened to you.
- Are pregnant or intend to become pregnant. Taking APO-TELMISARTAN during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that telmisartan passes into breast milk.
- Are allergic to some sugars (fructose, mannitol and/or meglumine intolerant).
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

What the medicinal ingredient is:

Telmisartan

What the non-medicinal ingredients are:

Magnesium Stearate, Mannitol, Meglumine, Potassium Hydroxide and Povidone

What dosage forms it comes in:

Tablets: 40 mg and 80 mg

WARNINGS AND PRECAUTIONS

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

Before you use APO-TELMISARTAN talk to your doctor or pharmacist if you:

- Have experienced an allergic reaction to any drug used to lower blood pressure.
- Have narrowing of a heart valve, diabetes, liver or kidney disease, heart or blood vessel disease.
- Are dehydrated or if you suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with APO-TELMISARTAN is not recommended.
- Are taking an angiotensin-converting-enzyme inhibitor (ACEI).
- 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 on dialysis.
- Are less than 18 years old.
- Have been told by your doctor that you have an intolerance to some sugars.

Before you perform tasks which require special attention (driving a car or operating dangerous machinery), wait until you know how you respond to APO-TELMISARTAN. Dizziness, lightheadedness, 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-TELMISARTAN:

- Blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), or angiotensin-converting-enzyme inhibitors (ACEI).

- Lithium, used to treat mood disorder.

IMPORTANT: PLEASE READ

- Nonsteroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling. Examples include acetylsalicylic acid (ASA), celecoxib, naproxen and ibuprofen.
- Digoxin to treat many heart conditions.
- Warfarin, used to prevent blood clots (blood thinner).

PROPER USE OF THIS MEDICATION

Take APO-TELMISARTAN exactly as prescribed. It is recommended to take your dose at about the same time everyday with or without food, but it should be taken the same way each day.
Do not stop taking your medication before informing your doctor, nurse, or pharmacist.

Usual adult dose:

The recommended dose of APO-TELMISARTAN (Telmisartan) is 80 mg once daily. Your doctor may prescribe 40 mg once daily if you have liver disease.

Overdose:

If you think you have taken too much APO-TELMISARTAN 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:

- back or leg pain, muscle cramps, joint pain, muscle spasms
- headache, anxiety
- diarrhea, constipation, nausea, vomiting, upset stomach, abdominal pain, flatulence
- dry mouth
- rash, eczema, skin eruptions
- drowsiness, insomnia, fatigue
- visual disturbances
- upper respiratory infection

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

APO-TELMISARTAN 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, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Very Common	Chest pain		✓	
Common	Low Blood Pressure: dizziness, fainting, lightheadedness	✓		
	Shortness of breath	✓		
Uncommon	Depression: Low mood, loss of interest in activities, change in appetite and sleep patterns	✓		
	Kidney Disorder: Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
	Increased levels of potassium in the blood: Irregular heartbeats, muscle weakness and generally feeling unwell		✓	
	Urinary Tract Infections (Cystitis): Frequent or painful urination, feeling unwell		✓	
Rare	Liver disorder: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	Low blood sugar: Shaky, irregular heartbeat, sweating, hunger, dizziness (in diabetic patients)		✓	

IMPORTANT: PLEASE READ

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
Unknown	Allergic Reaction: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing (potentially with fatal outcome)			✓
	Sepsis (blood poisoning): Chills, confusion, fever or low body temperature, shakiness, irregular heartbeat (including fatal outcome)			✓
	Rhabdomyolysis : Muscle pain that you cannot explain, muscle tenderness or weakness or dark brown urine		✓	

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

HOW TO STORE IT

APO-TELMISARTAN tablets should be stored at room temperature (15°C to 30°C). Tablets should not be removed from blisters and bottles until immediately prior to administration. Protect from light.

Keep out of reach and sight of children and pets.

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 online 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, or
 - 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

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>.

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

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