

PART III: CONSUMER INFORMATION**Pr TELMISARTAN**
telmisartan

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

ABOUT THIS MEDICATIONWhat the medication is used for:

- To treat high blood pressure

What it does:

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 TELMISARTAN regularly even if you feel fine.

When it should not be used:

Do not take TELMISARTAN if you:

- Are lactose intolerant.
- 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 TELMISARTAN during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that TELMISARTAN passes into breast milk.
- Are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease.

What the medicinal ingredient is:

Telmisartan

What the nonmedicinal ingredients are:

Crospovidone, lactose anhydrous, lactose monohydrate, magnesium stearate, meglumine, povidone and sodium hydroxide.

What dosage forms it comes in:

Tablets containing telmisartan: 40 mg and 80 mg

WARNINGS AND PRECAUTIONS**Serious Warnings and Precautions - Pregnancy**

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

Before you use 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, used to lower high blood pressure. The combination with TELMISARTAN is not recommended.
- If you have lactose intolerance
- 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.

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

- Blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products, or angiotensin-converting-enzyme inhibitors (ACEI).
- Lithium, used to treat mood disorder.
- 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 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 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 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.

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	
Uncommon	Shortness of breath	√	
	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		√
Rare	Urinary Tract Infections (Cystitis): Frequent or painful urination, feeling unwell		√
	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)		√
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 TELMISARTAN, contact your doctor, nurse or pharmacist.

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	√	

HOW TO STORE IT

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

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 document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sanis Health Inc. at: 1-866-236-4076, or by email: quality@sanis.com.

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Last revised: October 19, 2018