PART III: CONSUMER INFORMATION

Pr TELMISARTAN tablets
(Telmisartan)

This leaflet is part III of a three-part "Product Monograph" published when TELMISARTAN tablets was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about TELMISARTAN tablets. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What 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 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 has happened to you.
- Patients who 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 allergic to some sugars (fructose and/or sorbitol 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:
Hydroxypropyl methylcellulose, magnesium stearate, mannitol, meglumine, povidone, sodium hydroxide and sorbitol.

What dosage forms it comes in:
Tablets in 40 mg and 80 mg strengths

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 possible.

Before you use TELMISARTAN tablets 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 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 may require special attention (driving a car or operating dangerous machinery), wait until you know how you respond to TELMISARTAN. 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 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.
- 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 tablets 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 a doctor, nurse of 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 or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Very Common			
Chest pain		√	

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			
Low Blood Pressure: dizziness, fainting, light-headedness	√		
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)		√	
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 tablets, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

For Bottles: Store between 15ºC and 30ºC.Keep container tightly closed. Protect from moisture.
For Blisters: Store between 15ºC and 30ºC. Protect from moisture.Tablets should not be removed from blisters until immediately prior to administration.

Keep out of reach and sight of children and pets.

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor Sivem Pharmaceuticals ULC at: 1-855-788-3153

Or at: www.sivem.ca

This leaflet was prepared by:
Sivem Pharmaceuticals ULC
4705 Dobrin Street
Saint-Laurent, Quebec, Canada
H4R 2P7

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