

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

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**TELMISARTAN**

#### **Telmisartan Tablets**

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 this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **TELMISARTAN**.

#### **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 healthcare professional as soon as possible.**

#### **What is TELMISARTAN used for?**

- To treat high blood pressure in adults

#### **How does TELMISARTAN work?**

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. Do not stop taking your medicine without talking to your healthcare professional.

#### **What are the ingredients in TELMISARTAN?**

Medicinal ingredient: Telmisartan

Non-medicinal ingredients: Hydroxypropyl methylcellulose, magnesium stearate, mannitol, meglumine, povidone, sodium hydroxide and sorbitol.

#### **TELMISARTAN comes in following dosage forms:**

Tablets: 40 mg and 80 mg

#### **Do not use TELMISARTAN if:**

- you are allergic to telmisartan or to any non-medicinal ingredient in the formulation.
- you 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.

- you are pregnant or intend to become pregnant. Taking TELMISARTAN during pregnancy can cause injury and even death to your baby.
- you are breastfeeding. It is possible that TELMISARTAN passes into breast milk.
- you are allergic to some sugars (fructose and/or sorbitol intolerant).
- you are already taking a blood pressure-lowering medicine that contains aliskiren and you have diabetes or kidney disease.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take TELMISARTAN. Talk about any health conditions or problems you may have, including 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.
- 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.

**Other warnings you should know about:**

Before you perform tasks which require special attention (driving a car or operating dangerous machinery), wait until you know how you respond to TELMISARTAN. Vertigo, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

**Tell your healthcare professional about all the medicines you take, including any drugs, 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).

**How to take TELMISARTAN:**

- 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 healthcare professional
- TELMISARTAN are for once-daily oral administration and should be swallowed whole with liquid.

**Usual 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, or a person you are caring for, have taken too much TELMISARTAN, contact a healthcare professional, 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.

**What are possible side effects from using TELMISARTAN?**

These are not all the possible side effects you may have when taking TELMISARTAN. If you experience any side effects not listed here, tell your healthcare professional.

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

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

| Serious side effects and what to do about them   |                                      |              |   |
|--|--------------------------------------|--------------|---|
| Symptom / effect   | Talk to your healthcare professional |              | Stop taking drug and get immediate medical help |
|  | Only if severe                       | In all cases |   |
| <b>Very Common</b>   |                                      |              |   |
| Chest pain   |                                      | ✓            |   |
| <b>Common</b>  |                                      |              |   |
| <b>Low Blood Pressure:</b> dizziness, fainting, light-headedness   | ✓                                    |              |   |
| Shortness of breath  | ✓                                    |              |   |
| <b>UNCOMMON</b>  |                                      |              |   |
| <b>Depression:</b> Low mood, loss of interest in activities, change in appetite and sleep patterns   | ✓                                    |              |   |
| <b>Kidney disorder:</b> Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue   |                                      | ✓            |   |
| <b>Increased levels of potassium in the blood:</b> Irregular heartbeats, muscle weakness and generally feeling unwell                                    |                                      | ✓            |   |
| <b>Urinary Tract Infections (Cystitis):</b> Frequent or painful urination, feeling unwell.   |                                      | ✓            |   |
| <b>RARE</b>  |                                      |              |   |
| <b>Liver disorder:</b> Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite                                     |                                      | ✓            |   |
| <b>Low blood sugar:</b> Shaky, irregular heartbeat, sweating, hunger, dizziness (in diabetic patients)   |                                      | ✓            |   |
| <b>Hyponatraemia (decreased blood sodium):</b> nausea, vomiting, abdominal cramps, agitation, confusion and hallucinations                               |                                      | ✓            |   |
| <b>Decreased Platelets:</b> bruising, bleeding, fatigue and weakness   |                                      | ✓            |   |
| <b>UNKNOWN</b>   |                                      |              |   |
| <b>Allergic Reaction:</b> Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing (potentially with fatal outcome) |                                      |              | ✓   |
| <b>Sepsis (blood poisoning):</b> Chills, confusion, fever or low body temperature, shakiness, irregular heartbeat (including fatal outcome)              |                                      |              | ✓   |
| <b>Rhabdomyolysis:</b> Muscle pain that you cannot explain, muscle tenderness or weakness or dark brown urine.   |                                      | ✓            |   |

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **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.*

### **Storage:**

For bottles: Store between 15°C and 30°C. Keep container tightly closed. Protect from moisture.

For blisters: Store between 15°C and 30°C. 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.

### **If you want more information about TELMISARTAN:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.sivem.ca](http://www.sivem.ca); or by calling 1-855-788-3153.

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