

## PART III: CONSUMER INFORMATION

PrMicardis®  
(Telmisartan) Tablets

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

### 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:

MICARDIS 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 MICARDIS regularly even if you feel fine.

#### When it should not be used:

Do not take MICARDIS 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 MICARDIS during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. It is possible that MICARDIS 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:

Magnesium stearate, meglumine, povidone, sodium hydroxide and sorbitol

#### What dosage forms it comes in:

Tablets: 40 mg and 80 mg

### WARNINGS AND PRECAUTIONS

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

Before you use MICARDIS 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 MICARDIS 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 MICARDIS. 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 MICARDIS:

- 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 MICARDIS 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 MICARDIS 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 MICARDIS 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.

MICARDIS 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	

**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	
<b>Very Common</b> Chest pain		√	
<b>Common</b> <b>Low Blood Pressure:</b> dizziness, fainting, lightheadedness <b>Shortness of breath</b>	√		
	√		
<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		√	

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Symptom / effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
<b>Low blood sugar:</b> Shaky, irregular heartbeat, sweating, hunger, dizziness (in diabetic patients)		√	
<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		√	

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

**HOW TO STORE IT**

MICARDIS tablets should be stored at room temperature (15°C - 30°C). Tablets should not be removed from blisters 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](http://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, Ontario  
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](http://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**

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.boehringer-ingenelheim.ca> or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103 ext. 84633

Please check our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

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