

**PART III: CONSUMER INFORMATION**

**PrMICARDIS®  
(Telmisartan tablets)**

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

Your doctor has prescribed MICARDIS to treat your mild to moderate high blood pressure and to reduce the risk of non-fatal heart attack or non-fatal stroke.

**What it does:**

Angiotensin II is a naturally occurring hormone in the human body that causes the blood vessels to constrict, thus making the blood pressure higher. MICARDIS lowers blood pressure by specifically blocking the action of angiotensin II, and thus relaxing the blood vessels. As a result blood pressure is lowered.

**When it should not be used:**

- Patients who are hypersensitive to this drug or to any non-medicinal ingredient in the formulation (see the section "What the nonmedicinal ingredients are") should not take MICARDIS.
- Patients who are in their second/third trimester of pregnancy should not take MICARDIS.
- Patients who are breastfeeding should not take MICARDIS.
- Patients who are fructose intolerant.

**What the medicinal ingredient is:**

Telmisartan

**What the nonmedicinal ingredients are:**

Magnesium stearate, meglumine, povidone, sodium hydroxide and sorbitol

If you are on a special diet, or if you are allergic to any substance, ask your doctor or pharmacist whether any of these ingredients may cause a problem for you.

**What dosage forms it comes in:**

Tablets in 40 mg and 80 mg strengths

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions**

**MICARDIS should not be used during pregnancy. If you discover that you are pregnant while taking MICARDIS, stop the medication and please contact your physician.**

Before you use MICARDIS talk to your doctor or pharmacist:

- If you have any allergies to this drug or to any ingredient in the formulation or component of the container
- If you have narrowing of a heart valve
- If you recently suffered from excess diarrhea or vomiting
- If you have any other health problems, including kidney or liver disease
- If you are taking any other medication, including diuretics, herbal preparations or any other medications you can buy without a prescription.
- If you are taking any other medication that may affect potassium levels.
- If you have hereditary fructose intolerance
- If you have been told by your doctor that you have an intolerance to some sugars

Please remember:

- To tell any other doctor, dentist or pharmacist with whom you consult that you are using MICARDIS.
- Dizziness or drowsiness may occasionally occur when taking any medicine to lower blood pressure. Therefore, before you perform tasks which may require special attention (driving a car or operating dangerous machinery), wait until you know how you respond to your medicine.
- If you have any other questions about MICARDIS, contact your doctor or pharmacist.

Effects on Pregnancy and Breastfeeding:

- Taking MICARDIS during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking MICARDIS, contact immediately your doctor. It is possible that MICARDIS passes into breast milk. MICARDIS should not be used in patients who are breastfeeding.

**MICARDIS has been prescribed to treat your condition. Do not give it to other people**

**INTERACTIONS WITH THIS MEDICATION**

As with most medicines, interaction with other drugs is possible. Therefore, do not take any other medication without your doctor's or pharmacist's advice.

Drugs that may interact with MICARDIS include: Warfarin, Digoxin, Lithium, Ramipril and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as acetylsalicylic acid (ASA).

**PROPER USE OF THIS MEDICATION**

**Usual dose:**

The recommended dose of MICARDIS is 80 mg once daily. It

may be taken with or without food, but it should be taken the same way each day. You should follow any other direction that your doctor has given you for the treatment and/or monitoring of your condition.

**Overdose:**

If you experience dizziness and/or fainting or racing heart rate, contact your doctor immediately or go to the nearest emergency room so that medical attention may be given promptly.

In case of accidental drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

Try to take your dose at the same time each day, preferably in the morning. However, 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**

Like any drug product, MICARDIS may cause some unwanted effects along with good effects. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

If you develop an allergic reaction involving swelling of the face, lips and/or tongue, stop taking MICARDIS and contact your physician immediately.

Side effects such as muscle pain, muscle weakness, muscle inflammation and a muscle-wasting disease, in rare cases leading to kidney failure, have been reported with the use of angiotensin II receptor blockers, the class of drugs to which MICARDIS belongs. You should contact your physician promptly if you experience muscle pain that you cannot explain, muscle tenderness or weakness, generalised weakness, or when you notice dark/brown urine.

The following side effects are very common (frequency  $\geq 1/10$ ) or common (frequency  $\geq 1/100, < 1/10$ ): chest pain, influenza-like symptoms, symptoms of infection (e.g. urinary tract infection including cystitis), insomnia, abdominal pain, diarrhoea, dyspepsia, arthralgia, muscle spasms (cramps in legs) or pain in extremity (leg pain), myalgia, back pain, anxiety, depression, upper respiratory tract infections, dyspnea, eczema and rash.

Sepsis, which is often called "blood poisoning", has occurred in some patients. It is a severe infection with whole-body inflammatory response which can lead to death.

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 call your doctor or pharmacist
		Only if severe	In all cases	
<b>Very Common</b>	Headache	✓		
<b>Common</b>	Constipation	✓		
	Diarrhoea	✓		
	Dizziness	✓		
	Eczema	✓		
	Fatigue	✓		
	Nausea	✓		
	Pain		✓	
	Rash	✓		
	Upper respiratory tract infections		✓	
<b>Rare</b>	Increased levels of potassium in the blood		✓	
	Kidney disease/failure		✓	
	Liver disorder		✓	
	Syncope/faintness		✓	
<b>Not known</b>	Allergic Reaction: swelling of the face, lips and/or tongue accompanied by difficulty breathing		✓	✓
	Dark brown urine			✓
	Muscle pain		✓	
	Muscle wasting disease			✓
	Muscle weakness		✓	
	Weakness	✓		

*This is not a complete list of side effects. For any unexpected effects while taking MICARDIS, contact your doctor 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 of children and pets.

**REPORTING SUSPECTED SIDE EFFECTS**

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345

By toll-free fax 866-678-6789

By email: [CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@hc-sc.gc.ca)

By regular mail:

Canada Vigilance National Office  
 Marketed Health Products Safety and Effectiveness  
 Information Bureau  
 Marketed Health Products Directorate  
 Health Products and Food Branch  
 Health Canada  
 Tunney's Pasture, AL 0701C  
 Ottawa ON K1A 0K9

*NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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-ingelheim.ca>

or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at:

1-800-263-5103 ext. 4633 (Medical Information)

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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