

PART III: CONSUMER INFORMATION

Pr MICARDIS® PLUS
(Telmisartan/Hydrochlorothiazide tablets)

This leaflet is part III of a three-part "Product Monograph" published when MICARDIS PLUS 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 PLUS. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

MICARDIS PLUS is prescribed to treat patients with high blood pressure where treatment with just one drug was not effective. The two drugs contained in this combination tablet treat high blood pressure in different ways, so it is expected that this combination may be more effective than either drug taken alone. In addition, it may be more convenient for you to take just one tablet than two tablets every day.

What it does:

MICARDIS PLUS contains a combination of two drugs. The drug telmisartan, acts to inhibit the naturally occurring substances in your body that induce constriction of blood vessels, which plays a part in development of high blood pressure. The drug hydrochlorothiazide, acts by a different mechanism, that being to induce diuresis or urination which leads to decreased amount of body water which is beneficial in patients with high blood pressure.

When it should not be used:

- MICARDIS PLUS should not be used in patients who are hypersensitive to any component of this product (see the section "What the nonmedicinal ingredients are").
- Patients who are in their second/third trimester of pregnancy should not take MICARDIS PLUS.
- Patients who are breastfeeding should not take MICARDIS PLUS.
- Patients who are fructose intolerant and lactose intolerant.
- Due to the hydrochlorothiazide component, MICARDIS PLUS should not be used in patients with an absent production of urine or hypersensitivity to other sulfonamide-related drugs.

What the medicinal ingredients are:

Telmisartan and hydrochlorothiazide

What the nonmedicinal ingredients are:

Iron oxide red (for the 80/12.mg tablet only), iron oxide yellow (for the 80/25 mg tablet only), lactose monohydrate, magnesium stearate, maize (corn) starch, meglumine, microcrystalline cellulose, povidone, sodium hydroxide, sodium starch glycolate, and sorbitol

If you are on a special diet or if you are allergic to anything, ask your doctor or pharmacist whether any of these ingredients may

cause a problem for you.

What dosage forms it comes in:

Tablets MICARDIS PLUS 80 mg/12.5 mg and 80/25 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

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

Before you use MICARDIS PLUS, you should tell your doctor the following:

- If you have any allergies to this drug or to any ingredient in the formulation or component of the container.
- If you have a history of allergy or bronchial asthma.
- If you have narrowing of a heart valve.
- If you recently suffered from excess sweating, diarrhea or vomiting.
- If you have any other health problems, including liver or kidney disease, gout, diabetes, lupus erythematosus, or if you are being treated with other diuretics (known as water pills).
- If you are taking any other medication, including both prescription and over-the-counter (non-prescription).
- Before surgery and general anesthesia, (even at the dentist's office), tell the doctor or dentist that you are taking MICARDIS PLUS as there may be a sudden fall in blood pressure associated with general anesthesia.
- If you have hereditary fructose intolerance.
- Lactose is a non-medicinal ingredient in MICARDIS PLUS. Do not take MICARDIS PLUS if a doctor has told you that you have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - glucose-galactose malabsorption

Please remember:

- 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 PLUS, contact your doctor or pharmacist.

Effects on Pregnancy and Breastfeeding:

- Taking MICARDIS PLUS 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 PLUS, contact immediately your doctor. It is possible that MICARDIS PLUS passes into breast milk. MICARDIS should not be used in patients who are breastfeeding.

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

INTERACTIONS WITH THIS MEDICATION

Foods - Use potassium-containing salt substitutes only after consulting with your doctor.

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 PLUS include:

Drugs that may interact with telmisartan:
 Diuretics (also known as water pills); Agents Increasing Serum Potassium; Digoxin; Lithium salts; Warfarin; Ramipril and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as acetylsalicylic acid (ASA).

Drugs that may interact with hydrochlorothiazide:
 Alcohol, Barbiturates and Narcotics; Anti-Diabetic Drugs (oral agents and insulin); Cholestyramine and Colestipol Resins (cholesterol lowering drugs); Corticosteroids, ACTH; Lithium salts; Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) including acetylsalicylic acid (ASA) and COX-2 Inhibitors); Adrenergic Pressor Amines (e.g. norepinephrine); Skeletal Muscle Relaxants, Nondepolarizing (e.g. tubocurarine); Other Antihypertensive Drugs.

PROPER USE OF THIS MEDICATION

Usual dose:
 Take MICARDIS PLUS exactly as instructed by your doctor. The usual dosing schedule is one tablet daily, taken at the same time each day, preferably in the morning. MICARDIS PLUS may be taken with or without food, but it should be taken the same way each day.

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

Missed Dose:
 If you have missed a dose, do not take a double dose. Just carry on with the next dose at the usual time.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like any drug product, MICARDIS PLUS may cause some undesirable 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 PLUS and contact

your doctor 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 a component of MICARDIS PLUS 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 for telmisartan 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.

IMPORTANT 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	
Very Common	Dizziness	✓		
	Diarrhea	✓		
	Headache	✓		
Common	Fatigue	✓		
	Upper respiratory tract infection		✓	
	Pain		✓	
Rare	Increased levels of potassium in the blood		✓	
	Kidney disease/failure		✓	
	Liver disorder		✓	
	Transient blurred Vision		✓	
	If diabetic, loss of control of diabetes		✓	
	Itchiness/skin blisters/rash/hives		✓	
	Syncope/ faintness		✓	

IMPORTANT SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Not known		Talk with your doctor or pharmacist	
		Frequency	Action
Allergic reaction involving swelling of the face, lips or tongue accompanied by difficulty breathing		✓	✓
	Unexplained muscle pain or weakness or dark/brown urine	✓	✓
	Muscle pain	✓	
	Muscle wasting disease/Muscle weakness	✓	✓
	Weakness	✓	
	Heart Rhythm/Heart Rate disturbances (e.g. heart racing or skipping a beat)	✓	

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

HOW TO STORE IT

Store MICARDIS PLUS at room temperature (15-30°C) in the package provided by your doctor or pharmacist and protect from excessive moisture. Do not remove tablets from blisters until immediately prior to administration.

Store MICARDIS PLUS out of the 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
 Online: www.healthcanada.gc.ca/medeffect
 By email: 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 (www.boehringer-ingelheim.ca).

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