

# **MICARDIS 40mg Tablets**

# **MICARDIS 80mg Tablets**

Telmisartan

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

## **What is in this leaflet**

1. What MICARDIS is and what it is used for
2. What you need to know before you take MICARDIS
3. How to take MICARDIS
4. Possible side effects
5. How to store MICARDIS
6. Contents of the pack and other information

## **1. What MICARDIS is and what it is used for**

MICARDIS is used to treat essential hypertension (high blood pressure) in adults.

MICARDIS contains telmisartan belongs to a class of medicines called angiotensin II receptor antagonists. Angiotensin-II is a substance produced in your body which causes your blood vessels to narrow thus increasing your blood pressure. Telmisartan blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

High blood pressure, if not treated, can damage blood vessels in several organs, which could lead sometimes to heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus it is important to regularly measure blood pressure to verify if it is within the normal range.

MICARDIS is also used to reduce cardiovascular events (i.e. heart attack or stroke) in adults 55 years or older who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have had a stroke or have high risk diabetes. Your doctor can tell you if you are at high risk for such events.

## **2. What you need to know before you take MICARDIS**

### **Do not take MICARDIS**

- if you are allergic to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is also better to avoid MICARDIS in early pregnancy – see pregnancy section.)
- if you are breast-feeding.

- if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the liver and gall bladder) or any other severe liver disease.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above applies to you, tell your doctor or pharmacist before taking MICARDIS.

### **Warnings and precautions**

Talk to your doctor before taking MICARDIS if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant.
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
- Low blood pressure (hypotension), likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhea or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.

Talk to your doctor before taking MICARDIS:

- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading “Do not take MICARDIS”.

- if you are taking digoxin.

In case of surgery or anaesthetics, you should tell your doctor that you are taking MICARDIS.

As with all other angiotensin II receptor antagonists, MICARDIS may be less effective in lowering the blood pressure in black patients.

### **Children and adolescents**

The use of MICARDIS in children and adolescents up to the age of 18 years is not recommended.

### **Other medicines and MICARDIS:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose of these other medications or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below taken at the same time with MICARDIS:

- Lithium containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain ‘water tablets’), ACE inhibitors, angiotensin II receptor antagonists, NSAIDs (non steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen), and heparin.
- Diuretics (‘water tablets’), especially if taken in high doses together with MICARDIS may lead to excessive loss of body water and low blood pressure (hypotension).
- If you are taking an ACE-inhibitor or aliskiren.
- Digoxin.

The effect of MICARDIS may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

MICARDIS may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine). You should consult with your doctor if you need to adjust the dose of your other medicine while taking MICARDIS.

## **Pregnancy and breast-feeding**

### **Pregnancy**

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking MICARDIS before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of MICARDIS.

MICARDIS is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

### **Breast-feeding**

Tell your doctor if you are breast-feeding or about to start breast-feeding. MICARDIS is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

## **Driving and using machines**

Some people feel dizzy or tired when taking MICARDIS. If you feel dizzy or tired, do not drive or operate machinery.

## **MICARDIS contains sorbitol.**

If you are intolerant to some sugars, consult your doctor before taking MICARDIS.

## **3. How to take MICARDIS**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet a day. Try to take the tablet at the same time each day.

You can take MICARDIS with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. Micardis tablets should not be divided into halves as the tablets have no score line and no studies have been performed on halved tablets. It is important that you take MICARDIS every day until your doctor tells you otherwise.

If you have the impression that the effect of MICARDIS is too strong or too weak, talk to your doctor or pharmacist.

For treatment of high blood pressure, the usual dose of MICARDIS for most patients is one 40 mg tablet once a day to control blood pressure over the 24 hour period. However, sometimes your doctor may recommend a higher dose of 80 mg. Alternatively, MICARDIS may be used in combination with diuretics ('water tablets') such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with MICARDIS.

For reduction of cardiovascular events, the usual dose of MICARDIS is one 80 mg tablet once a day. At the beginning of the preventive therapy with MICARDIS 80 mg, blood pressure should be frequently monitored. If your liver is not working properly, the usual dose should not exceed 40 mg once daily.

## **Sign and symptoms of overdose**

The most prominent manifestations of telmisartan overdose were low blood pressure (hypotension) and fast heart beat (tachycardia), slow heart rate (bradycardia) also occurred.

## **If you take more MICARDIS than you should**

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

## **If you forget to take MICARDIS**

If you forget to take a dose, do not worry. Take it as soon as you remember then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Some side effects can be serious and need immediate medical attention:**

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis\* (often called "blood poisoning", is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side effects are rare (may affect up to 1 in 1,000 people) but are extremely serious and patients should stop taking the product and see their doctor immediately. If these effects are not treated they could be fatal.

\* The event may have happened by chance or could be related to a mechanism currently not known.

**Possible side effects of MICARDIS:**

Common side effects (may affect up to 1 in 10 people):

Low blood pressure (hypotension) in users treated for reduction of cardiovascular events.

Uncommon side effects (may affect up to 1 in 100 people):

Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, feeling sad (depression), fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, cough, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, drug rash, back pain, muscle cramps, muscle pain (myalgia), kidney impairment including acute kidney injury, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.

Rare side effects (may affect up to 1 in 1,000 people):

Sepsis\* (often called "blood poisoning", is a severe infection with whole-body inflammatory response which can lead to death), increase in certain white blood cells (eosinophilia), low platelet count (thrombocytopenia), severe allergic reaction (anaphylactic reaction), allergic reaction (e.g. rash, itching, difficulty breathing, wheezing, swelling of the face or low blood pressure), low blood sugar levels (in diabetic patients), symptoms that may indicate low sodium levels in the blood, such as headache, dizziness, confusion, forgetfulness, weakness, unsteadiness or difficulty concentrating feeling anxious, somnolence, impaired vision, fast heart beat (tachycardia), dry mouth, upset stomach, taste disturbance (dysgeusia), abnormal liver function (Japanese patients are more likely to experience this side effect), rapid swelling of the skin and mucosa which can also lead to death (angioedema also with fatal outcome), eczema (a skin disorder), redness of skin, hives (urticaria), severe drug rash, joint pain (arthralgia), pain in extremity, tendon pain, flu-like-illness, decreased haemoglobin (a blood protein), increased levels of uric acid, increased hepatic enzymes or creatine phosphokinase in the blood.

Reporting of side effects

If any of the side effects gets serious or, if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store MICARDIS**

Keep out of the reach and sight of children.

Store below 30°C.

Store in original package in order to protect from moisture.

MICARDIS is sensitive to moisture. Remove your MICARDIS tablet from the blister only directly prior to intake.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

**6. Contents of the pack and other information**

**What MICARDIS contains**

- The active substance is telmisartan. Each tablet contains 40mg or 80 mg telmisartan.
- The other ingredients are povidone K25, meglumine, sodium hydroxide, sorbitol (E420) and magnesium stearate.

**What MICARDIS looks like and contents of the pack**

40mg: White or off white, oblong tablets; one face marked with 51H, the other face with the Boehringer Ingelheim company symbol.

80mg: White or off white, oblong tablets; one face marked with “52H”, the other face with the Boehringer Ingelheim company symbol.

MICARDIS is available in blister packs containing 30 or 90 tablets per carton box.

- 3 strips of 10 tablets in aluminium/aluminium blisters
- 9 strips of 10 tablets in aluminium/aluminium blisters

Not all pack sizes may be marketed.

**Product Registration Number**

40 mg - SIN11072P

80 mg - SIN11073P

**Product Registrant and Manufacturer**

The product registrant for MICARDIS is:

Boehringer Ingelheim Singapore Pte Ltd  
300 Beach Road #37-00  
The Concourse  
Singapore 199555

The manufacturer for MICARDIS is:

Boehringer Ingelheim Pharma GmbH & Co.KG  
Ingelheim am Rhein, Germany.

Or

Boehringer Ingelheim Hellas Single Member S.A.  
5th km Paiania-Markopoulo  
Koropi Attiki 19441  
Greece

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