PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MICARDIS® 40 mg & 80 mg tablets
Telmisartan

Read all of this leaflet carefully before you start taking MICARDIS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- MICARDIS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MICARDIS TABLETS CONTAIN

The active ingredient is telmisartan 40 mg or 80 mg per tablet.
The other ingredients are magnesium stearate, meglumine, povidone, sodium hydroxide and sorbitol.
Sugar free.

2. WHAT MICARDIS IS USED FOR

MICARDIS tablets are used for the treatment of high blood pressure. This is also known as essential hypertension.

MICARDIS tablets can also be used to reduce cardiovascular events and death in patients 55 years or older who are at high risk of cardiovascular disease; the benefit of treatment is evident after at least 6 months of continued treatment.

3. BEFORE YOU TAKE MICARDIS TABLETS

Do not take MICARDIS if you are pregnant, are considering becoming pregnant or are breast-feeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.

Do not take MICARDIS if you:

- are allergic to telmisartan or any of the other ingredients in the tablets
- suffer from the rare hereditary condition called fructose intolerance
- have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin converting enzyme inhibitors (ACE-I) or angiotensin receptor blockers (ARBs) – you should never take these medicines again
- suffer from severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- suffer from obstruction of blood vessels to your heart or kidneys

- suffer from severe kidney function impairment
- suffer from porphyria
- are currently taking lithium
- are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride
- are currently taking aliskiren-containing products.
- Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Take special care with MICARDIS and tell your doctor if you:
- suffer from kidney disease or have had a kidney transplant
- suffer from liver problems
- have heart problems
- have diabetes
- if your body could be lacking in salt due to a low salt diet, or if you have recently lost a lot of body fluids due to taking diuretic medicines (water tablets), vomiting or diarrhoea
- have high potassium levels in your blood or use salt substitutes containing potassium
- have been told previously that you have raised aldosterone levels
- are already taking a medicine called an angiotensin converting enzyme inhibitor (ACE-I).

Pregnancy and breastfeeding:
Do not take MICARDIS if you are pregnant, are considering becoming pregnant or are breastfeeding.

If you are a woman of childbearing age, you must use effective contraception.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:
When driving vehicles or operating machinery, it should be taken into account that dizziness or drowsiness may occur when taking blood pressure lowering medication including MICARDIS.

Important information about some of the ingredients of MICARDIS:
Sorbitol is not suitable for patients with hereditary fructose intolerance.

Taking other medicines with MICARDIS:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

MICARDIS can interfere with some other medicines such as digoxin, lithium, ACE-inhibitors and non-steroidal anti-inflammatory medicines (NSAIDs) like aspirin.

4. HOW TO TAKE MICARDIS
- Do not share medicines prescribed for you with any other person.
- Always take MICARDIS tablets exactly as your doctor has instructed you. Do not take

more or less tablets and do not take them more often than recommended. You should check with your doctor or pharmacist if you are unsure.
- If you have the impression that MICARDIS is too strong or too weak, talk to your doctor or pharmacist. Do not stop taking MICARDIS without first talking to your doctor.
- MICARDIS tablets are only for adults and should not be taken by children and adolescents up to 18 years.

For high blood pressure:
MICARDIS is usually taken in a dose of one 40 mg or 80 mg tablet once daily (preferably at about the same time each day) and swallowed with a drink of water.
Your doctor may prescribe MICARDIS in combination with other blood pressure lowering medicines.

To reduce cardiovascular events and death in patients 55 years or older who are at high risk of cardiovascular disease:
MICARDIS is usually taken in a dose of one 80 mg tablet once daily (preferably at about the same time each day) and swallowed with a drink of water.

When initiating treatment, your doctor may wish to monitor your blood pressure and, if appropriate, adjust your blood pressure lowering medicines.

If you take more MICARDIS than you should:
In the event of overdosage or accidental intake, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take MICARDIS:
If you miss a dose of this medicine, take it as soon as you remember on the same day. If you do not take your tablet on that same day, take your normal dose on the next day. Do not double the dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS
MICARDIS tablets can have side effects.

If any of the following happens, stop taking MICARDIS and tell your doctor immediately or go to the casualty department at your nearest hospital:
Less frequent:
- anaphylactic reaction (sudden allergic reaction including signs like rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or trouble breathing)
- eczema, facial swelling, severe allergic reactions of the skin (with possible fatal outcome)

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MICARDIS. You may need medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Frequent:
- changes in the heart-rate, low blood pressure, shortness of breath
- faintness, dizziness for example when standing up quickly

- you pass less urine than is normal for you and you notice that your feet are swollen
- elevated blood potassium levels
- urinary tract infections (including inflammation of the bladder), upper respiratory tract infections (e.g. sore throat or sinusitis)
- anaemia and other changes to the blood chemistry
- back pain, muscle tenderness, cramps in the legs, chest pain, weakness

Less frequent:
- blood poisoning
- low blood sugar in diabetic patients
- liver or kidney problems
- influenza-like symptoms

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent:
- feeling sad (depression), difficulty sleeping
- abdominal pain, loose/runny stools, indigestion, flatulence, vomiting
- cough

Less frequent:
- increased sweating, skin rashes and itching
- abnormal vision
- joint pain, leg pain
- sore tendons
- stomach upset, dry mouth
- anxiety
- hives (itchy rash)
- hypersensitivity (allergy)

Not all side effects reported for MICARDIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MICARDIS, please consult your doctor, pharmacist, or other healthcare professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MICARDIS
Store MICARDIS tablets in a dry, cool place (at or below 30 °C). The tablets should be kept in the original blister foil until required for administration in order to protect them from moisture.
Store all medicines out of reach of children.

Do not take this medicine after the expiry date stated on the blister strips and carton. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MICARDIS
Carton containing 28 tablets packed in aluminium blister strips of 7 tablets per strip.

8. IDENTIFICATION OF MICARDIS
MICARDIS 40 mg: White or off-white, oblong tablets; one face marked with 51H and the

other with the Boehringer Company symbol.
MICARDIS 80 mg: White or off-white, oblong tablets; one face marked with 52H and the other with the Boehringer Company symbol.

9. REGISTRATION NUMBERS

MICARDIS 40 mg tablets: 33/7.1.3/0020
MICARDIS 80 mg tablets: 33/7.1.3/0021

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Ingelheim Pharmaceuticals (Pty) Ltd
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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Date of registration: 20 August 1999
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