Micardis® Plus

Telmisartan/Hydrochlorothiazide (40/12.5mg, 80/12.5mg)

What is in this leaflet

1. What MICARDIS PLUS is used for

Micardis Plus is used to treat high blood pressure (essential hypertension) in patients whose blood pressure is not controlled enough when either telmisartan or hydrochlorothiazide is used alone.

2. How MICARDIS PLUS works

Micardis Plus is a combination of two active substances, telmisartan and hydrochlorothiazide in one tablet. Both of these substances help to control high blood pressure.

- Telmisartan belongs to a group of medicines called angiotensin II receptor blockers. 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.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics, which cause your urine output to increase, leading to a lowering of your blood pressure.

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.

3. Before you use MICARDIS PLUS

- *When you must not use it*
  - if you are allergic (hypersensitive) to telmisartan or any other ingredients of this medicine (listed in section 8).
  - if you are allergic (hypersensitive) to hydrochlorothiazide or to any other sulfonamide-derived medicines.
  - if you are more than 3 months pregnant. (It is also better to avoid Micardis Plus in early pregnancy – see pregnancy section.)
  - if you have severe liver problems such as cholestasis or biliary obstruction (problems with drainage of the bile from the gall bladder) or any other severe liver disease.
  - if you have severe kidney disease.
  - if your doctor determines that you have low potassium levels or high calcium levels in your blood that do not get better with treatment.

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

- *Before you start to use it*

  Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:
  - 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, diarrhoea, vomiting, or haemodialysis.
  - Kidney disease or kidney transplant.
  - Renal artery stenosis (narrowing of the blood vessels to one or both kidneys).
  - Liver disease.
  - Heart trouble.
  - Diabetes.
  - Gout.
  - Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals).
  - Systemic lupus erythematosus (also called “lupus” or “SLE”) a disease where the body’s immune system attacks the body.

- The active ingredient hydrochlorothiazide can cause an unusual reaction, resulting in a decrease in vision and eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Micardis Plus. This can lead to permanent vision impairment, if not treated.

- Inform your healthcare providers before taking Micardis Plus if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Micardis Plus.

Talk to your doctor before taking Micardis Plus:

- 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.
- if you are taking digoxin.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking MICARDIS PLUS, seek medical treatment immediately.

Treatment with hydrochlorothiazide may cause electrolyte imbalance in your body. Typical symptoms of fluid or

electrolyte imbalance include dry mouth, weakness, lethargy, drowsiness, restlessness, muscle pain or cramps, nausea (feeling sick), vomiting, tired muscles, and an abnormally fast heart rate (faster than 100 beats per minute). If you experience any of these, you should tell your doctor.

You should also tell your doctor, if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal.

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

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

- *Taking other medicines*

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including medicines obtained without a prescription. Your doctor may need to change the dose of these other medicines 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 Plus:

- Lithium containing medicines to treat some types of depression.
- Medicines associated with low blood potassium (hypokalaemia) such as other diuretics, ('water tablets'), laxatives (e.g. castor oil), corticosteroids (e.g. prednisone), ACTH (a hormone), amphotericin (an antifungal medicine), carbenoxolone (used to treat mouth ulcers), penicillin G sodium (an antibiotic), and salicylic acid and derivatives.
- Medicines that may increase blood potassium levels such as potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, ACE inhibitors, and other medicinal products such as heparin sodium (an anticoagulant).
- Medicines that are affected by changes of the blood potassium level such as heart medicines (e.g. digoxin) or medicines to control the rhythm of your heart (e.g. digitalis glycosides),
- Medicines for the treatment of diabetes (insulins or oral agents such as metformin).
- Cholestyramine and colestipol, medicines for lowering blood fat levels.
- Medicines to increase blood pressure, such as noradrenaline.
- Muscle relaxing medicines, such as tubocurarine.
- Calcium supplements and/or vitamin D supplements.
- Anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia) such as atropine and biperiden.
- Amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses).
- Other medicines used to treat high blood pressure, corticosteroids, painkillers (such as non-steroidal anti-inflammatory drugs [NSAIDs]), medicines to treat cancer, gout or arthritis.
- If you are taking an ACE-inhibitor or aliskiren.
- Digoxin.

Micardis Plus may increase the blood pressure lowering effect of other medicines and low blood pressure may be aggravated by alcohol, barbiturates, or narcotics. You should consult with your doctor if you need to adjust the dose of your other medicine while taking Micardis Plus.
The effect of Micardis Plus may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen).

4. How to use MICARDIS PLUS

- *How much to use*

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

The usual dose of Micardis Plus is one tablet a day. Try to take a tablet at the same time each day. You can take Micardis Plus with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take Micardis Plus every day until your doctor tells you otherwise.

If your liver is not working properly, the usual dose should not exceed 40 mg/12.5 mg once a day.

- *When to use it*

Use as directed by your doctor or pharmacist.

- *How long to use it*

Continue taking Micardis Plus for as long as your doctor recommends.

- *If you forget to use it*

If you forget to take a dose, take it as soon as you remember and 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 use too much (overdose)*

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

5. While you are using it

- *Things you must do*

Take your medicine exactly as your doctor has told you.
Tell all the doctors, dentists and pharmacists treating you that you are taking Micardis Plus.
Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.
Do not take any new medicines without consulting your doctor.
Do not give Micardis Plus to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Pregnancy and lactation

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 Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Micardis Plus.

Micardis Plus 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 Plus is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Children and adolescents

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

Driving and using machines

Some people feel like dizzy, fainting (syncope) or spinning (vertigo) when taking Micardis Plus. If you experience these symptoms, do not drive or operate machinery.

Micardis Plus contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, consult your doctor before taking Micardis Plus.

***Micardis Plus* contains sorbitol**

This medicine contains 169 mg sorbitol in the dose strength 40/12.5 mg and 338 mg sorbitol in the dose strength 80/12.5 mg.

Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

6. Side effects

Like all medicines, Micardis Plus 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 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.

Possible side effects of Micardis Plus:

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

Dizziness

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

Decreased blood potassium levels, anxiety, fainting (syncope), sensation of tingling, pins and needles (paraesthesia), feeling of spinning (vertigo), fast heart beat (tachycardia), heart rhythm disorders, low blood pressure, a sudden fall in blood pressure when you stand up, shortness of breath (dyspnoea), diarrhoea, dry mouth, flatulence, back pain, muscle spasm, muscle pain, erectile dysfunction (inability to get or keep an erection), chest pain, increased blood uric acid levels.

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

Inflammation of the lung (bronchitis), activation or worsening of systemic lupus erythematosus (a disease where the body's immune system attacks the body, which causes joint pain, skin rashes and fever); sore throat, inflamed sinuses, feeling sad (depression), difficulty falling asleep (insomnia), impaired vision, difficulty breathing, abdominal pain, constipation, bloating (dyspepsia), feeling sick (vomiting), inflammation of the stomach (gastritis), abnormal liver function (Japanese patients are more likely to experience this side effect), redness of the skin (erythema), allergic reactions such as itching or rash, increased sweating, hives (urticaria), joint pain (arthralgia) and pain in extremities, muscle cramps, flu-like-illness, pain, increased levels of uric acid, low levels of sodium, increased levels of creatinine, hepatic enzymes or creatine phosphokinase in the blood.

Adverse reactions reported with one of the individual components may be potential adverse reactions with Micardis Plus, even if not observed in clinical trials with this product.

Hydrochlorothiazide:

Side effects of frequency 'very rare':

- Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).

Side effects of frequency 'not known':

- Skin and lip cancer (non-melanoma skin cancer);
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden nearsightedness or blurred vision;
- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects:

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)].

7. Storage and Disposal of MICARDIS PLUS

- *Storage*

  Keep out of the reach and sight of children.

  Store below 30°C.

Store in the original package in order to protect from moisture.

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

- *Disposal*
  Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- *What it looks like*
  Micardis Plus 40 mg/12.5 mg tablets are red and white, oblong-shaped two-layer tablets engraved with the company logo and the code 'H4'.

  Micardis Plus 80 mg/12.5 mg tablets are red and white, oblong-shaped two-layer tablets engraved with the company logo and the code 'H8'.

- *Ingredients*
  - Active ingredient(s):

    Micardis Plus 40 mg/12.5 mg tablets - Each tablet contains 40 mg telmisartan and 12.5 mg hydrochlorothiazide

    Micardis Plus 80 mg/12.5 mg tablets - Each tablet contains 80 mg telmisartan and 12.5 mg hydrochlorothiazide

  - Inactive ingredients:
    The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone, red iron oxide (E172), sodium hydroxide, sodium starch glycollate (type A), sorbitol (E420)

- *MAL number(s):*
  Micardis Plus 40 mg/12.5 mg - MAL20034439AZ

  Micardis Plus 80 mg/12.5 mg - MAL20034440AZ

9. Manufacturer
Boehringer Ingelheim Hellas Single Member S.A.
Koropi Attiki, 19441, Greece.

10. Product Registration Holder
Boehringer Ingelheim (Malaysia) Sdn. Bhd.
Level 23A, Mercu Aspire,
No. 3, Jalan Bangsar,
KL Eco City,
59200 Kuala Lumpur, Malaysia.

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