

PACKAGE LEAFLET: INFORMATION FOR THE USER

MICARDIS PLUS 40/12.5 mg Tablets

MICARDIS PLUS 80/12.5 mg Tablets

Telmisartan/hydrochlorothiazide

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 PLUS is and what it is used for
2. What you need to know before you take MICARDIS PLUS
3. How to take MICARDIS PLUS
4. Possible side effects
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1. What MICARDIS PLUS is and what it 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.

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 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.
- 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.

2. What you need to know before you take MICARDIS PLUS

Do not take MICARDIS PLUS

- if you are allergic to telmisartan or any other ingredients of this medicine (listed in section 6).
- if you are allergic to hydrochlorothiazide or to any other sulfonamide-derived medicines.
- if you are pregnant.
- 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 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 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 PLUS.

Warnings and precautions

Talk to your doctor before taking MICARDIS PLUS 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.
- 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. See also information under the heading “Do not take MICARDIS PLUS”.

- if you are taking digoxin.

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.

MICARDIS PLUS may be less effective in lowering the blood pressure in black patients.

Children and adolescents

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

Other medicines and MICARDIS PLUS:

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 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. quinidine, disopyramide, amiodarone, sotalol), medicines used for mental disorders (e.g. thioridazine, chlorpromazine, levomepromazine) and other medicines such as certain antibiotics (e.g. sparfloxacin, pentamidine) or certain medicines to treat allergic reactions (e.g. terfenadine).
- 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 nonsteroidal anti-inflammatory drugs [NSAIDs]), medicines to treat cancer, gout or arthritis.
- If you are taking an ACE-inhibitor or aliskiren.
- Digoxin.
- Some antipsychotics (e.g. thioridazine, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, sultopride, amisulpride, tiapride, pimozide, haloperidol, droperidol).
- Prokinetic medicinal products, such as cisapride.

MICARDIS PLUS 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). Furthermore, low blood pressure may be aggravated by alcohol, barbiturates, narcotics or antidepressants. You may notice this as dizziness when standing up. 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).

MICARDIS PLUS with food and alcohol

You can take MICARDIS PLUS with or without food.

Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

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 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 contraindicated in all trimesters of pregnancy, and must not be taken when pregnant is diagnosed, 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.

Driving and using machines

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

MICARDIS PLUS contains milk sugar (lactose) and sorbitol.

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

3. How to take MICARDIS PLUS

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 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.

If you take more MICARDIS PLUS than you should

If you accidentally take too many tablets you may experience symptoms such as low blood pressure and rapid heartbeat. Slow heartbeat, dizziness, vomiting, reduced kidney function including kidney failure, have also been reported. Due to the hydrochlorothiazide component, markedly low blood pressure and low blood levels of potassium can also happen, which may result in nausea, sleepiness

and muscle cramps and/or irregular heartbeat associated with the concomitant use of drugs such as digitalis or certain anti-arrhythmic treatments. Contact your doctor, pharmacist, or your nearest hospital emergency department immediately.

If you forget to take MICARDIS PLUS

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), blistering and peeling of the top layer of skin (toxic epidermal necrolysis); these side effects are rare (may affect up to 1 in 1,000 people) or of unknown frequency (toxic epidermal necrolysis) 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. Increased incidence of sepsis has been observed with telmisartan only, however can not be ruled out for MICARDIS PLUS.

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

Possible side effects of MICARDIS PLUS:

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

Dizziness

Uncommon side effects (may affect up 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.

There are other adverse reactions reported with one of the individual components (Telmisartan or Hydrochlorothiazide) may be potential adverse reactions with MICARDIS PLUS, even if not observed in clinical trials with this product. Refer more details in full prescribing information.

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 PLUS

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.

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 PLUS contains

- The active substance are telmisartan and hydrochlorothiazide. Each tablet contains 40mg or 80 mg telmisartan and 12.5 mg hydrochlorothiazide
- The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone K25, red iron oxide (E172), sodium hydroxide, sodium starch glycollate, and sorbitol (E420).

What MICARDIS PLUS looks like and contents of the pack

40/12.5mg: Oblong, white-red, Biconvex two-layer tablets. The white face is marked with "H4" and the Boehringer Ingelheim company symbol.

80/12.5mg: Oblong, white-red, Biconvex two-layer tablets. The white face is marked with "H8" and the Boehringer Ingelheim company symbol.

MICARDIS PLUS 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/12.5 mg - SIN12394P

80 mg/12.5 mg - SIN12395P

Marketing Authorization Holder and Manufacturer

The marketing authorization holder for MICARDIS PLUS is:

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

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Singapore 199555

The manufacturer for MICARDIS PLUS is:

Boehringer Ingelheim Pharma GmbH & Co.KG
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Or

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