Boehringer Ingelheim

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

CO-MICARDIS® 40/12,5 mg
CO-MICARDIS® 80/12,5 mg

Tablets

Telmisartan/Hydrochlorothiazide

Contains sugar (112 mg lactose monohydrate per tablet) and sorbitol

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CO-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.

What is in this leaflet

1. What CO-MICARDIS is and what it is used for
2. What you need to know before you take CO-MICARDIS
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1. What CO-MICARDIS is and what it is used for

CO-MICARDIS tablets are used for the treatment of mild to moderate high blood pressure (also known as essential hypertension) in adults. Your doctor will usually prescribe CO-MICARDIS once your blood pressure has been stabilised with the two individual active components given separately.

2. What you need to know before you take CO-MICARDIS

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

Do not take CO-MICARDIS if you:

- are pregnant or breastfeeding
- are allergic to telmisartan, hydrochlorothiazide, or to other similar sulphonamide-derived medicines, or any of the inactive ingredients of the tablets (mentioned in section 6)
- suffer from either of the rare hereditary conditions called fructose intolerance or galactose 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 Addison's disease (i.e. your adrenal glands don't work properly)
- suffer from porphyria
- suffer from severe liver disease or liver cirrhosis
- suffer from moderate to severe kidney disease
- suffer from biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- have narrowing of blood vessels to your heart
- have narrowing of blood vessels to your kidneys
- are currently taking lithium or potassium sparing water tablets containing spironolactone, triamterene or amiloride
- know that you have low levels of potassium or sodium in your blood
- know that you have high levels of calcium in your blood
- know that you have high levels of uric acid in your blood or are experiencing symptoms of gout
- are currently taking aliskiren-containing products
- have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Take special care with CO-MICARDIS and tell your doctor if you:

- suffer from kidney disease or have had a kidney transplant
- suffer from liver problems
- have heart problems
- 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 strong 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
- already take a medicine called an angiotensin converting enzyme inhibitor (ACE-I) or the direct renin-inhibitor aliskiren
- have diabetes; your doctor should perform tests before you start treatment with CO-MICARDIS to ensure that you do not have coexisting coronary artery disease (CAD).
- have high cholesterol or blood fat levels
- have gout
- have systemic lupus erythematosus (also called "lupus" or "SLE").
- 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 CO-MICARDIS, seek medical attention immediately.
- 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 CO-MICARDIS.
- If you are going to have surgery or receive an anaesthetic, you should make sure your doctor knows you are taking CO-MICARDIS.
- 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 CO-MICARDIS. This can lead to permanent vision loss, if not treated.
- Signs such as excessive thirst, a dry mouth, unusual tiredness or weakness, drowsiness, muscle pain or cramps, nausea and vomiting, or an abnormally fast heart rate could indicate blood electrolyte imbalances due to an excessive effect of the hydrochlorothiazide ingredient of CO-MICARDIS. If you experience any of these symptoms you should tell your doctor.
- Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic.
- You should 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.

Children and adolescents
The use of CO-MICARDIS in children and adolescents up to 18 years is not recommended.

Other medicines and CO-MICARDIS
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

CO-MICARDIS tablets can interact with some other medicines such as digoxin, lithium, some medicines used to treat depression, epilepsy or mental illnesses, alcohol, barbiturates, narcotics, antidiabetic medicines (oral agents and insulin), cholestyramine and colestipol resins, non-steroidal anti-inflammatory medicines including aspirin, noradrenaline, muscle relaxants, allopurinol, calcium supplements, vitamin D, beta-blockers, diazoxide, atropine, biperiden, amantadine, certain cancer medicines, ACE inhibitors, methyldopa, ciclosporin and contrast media containing iodine which are used for radiographic procedures.

When certain diuretics (water tablets), laxatives, corticosteroids, ACTH, amphotericin, carbenoxolone, penicillin, salicylic acid, heparin sodium, potassium supplements and salt substitutes that contain potassium are taken with CO-MICARDIS, your potassium levels could be affected and your doctor may recommend that your blood potassium levels be monitored at regular intervals.

CO-MICARDIS with food and drink
You can take CO-MICARDIS with a drink of water, with or without food. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

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

Do not take CO-MICARDIS and tell your doctor if you are pregnant, are considering becoming pregnant or are breastfeeding. A switch to a suitable alternative treatment should be carried out in advance of planned pregnancy.
If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines
When driving vehicles or operating machinery, it should be taken into account that dizziness, fainting or a spinning sensation (vertigo) may occasionally occur when taking blood pressure lowering medication. If you feel dizzy or faint, do not drive or operate machinery.

CO-MICARDIS contains milk sugar (lactose) and sorbitol
If you are intolerant to some sugars, consult your doctor before taking CO-MICARDIS.

3. How to take CO-MICARDIS
Do not share medicines prescribed for you with any other person.

Take CO-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 the effect of CO-MICARDIS is too strong or too weak, tell your doctor or pharmacist.

CO-MICARDIS tablets are only for adults and should not be taken by children and adolescents up to 18 years.

CO-MICARDIS 40/12,5 mg or 80/12,5 mg tablets are usually used once your blood pressure is controlled using the two medicines (i.e. telmisartan and hydrochlorothiazide) separately. The combination tablet is then used instead of the individual medicines.

The usual dose of CO-MICARDIS is one tablet per day. Try to take the tablet at the same time each day.
You can take CO-MICARDIS with or without food. The tablets should be swallowed with a drink of water.
Swallow the tablet whole - do not break, cut or crush it.
Remove your CO-MICARDIS tablet from the blister only immediately prior to intake.

Your doctor may prescribe CO-MICARDIS in combination with other blood pressure lowering medicines.

Your doctor will tell you how long your treatment with CO-MICARDIS will last. Do not stop treatment early because it may interfere with the management of your blood pressure.

If you take more CO-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 CO-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.

4. Possible side effects
CO-MICARDIS tablets can have side effects.

Not all side effects reported for CO-MICARDIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CO-MICARDIS, please consult your healthcare provider for advice.

If any of the following happens, stop taking CO-MICARDIS and tell your doctor immediately or go to the casualty department at your nearest hospital:
Less frequent side effects:
- 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 CO-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:
Less frequent side effects:
- worsening or activation of systemic lupus erythematosus
- changes in the heart-rate, low blood pressure, shortness of breath
- you pass less urine than is normal for you and you notice that your feet are swollen
- urinary tract infections (including inflammation of the bladder), upper respiratory tract infections (e.g. sore throat or sinusitis)
- blood poisoning
- liver or kidney problems

Tell your doctor if you notice any of the following:
Frequent side effects:
Dizziness.

Less frequent side effects:
Increased liver enzymes, changes in blood chemistry, changes in blood potassium or uric acid levels, lowered blood level of sodium, vertigo, lowered blood pressure especially when standing up quickly, fainting, abnormal vision or transient blurred vision, bronchitis, anxiety, depression, skin rashes, vomiting, diarrhoea, influenza-like symptoms, sore throat, sinusitis, abdominal pain, back pain, joint pain, muscle

cramps, muscle pain, cramps in legs, leg pain, pain, impotence, tingling feeling in the limbs, constipation, upset stomach, flatulence, indigestion, trouble sleeping, increased sweating, dry mouth.

Side effects previously reported with one of the individual components may be potential side effects for CO-MICARDIS tablets.

In patients taking telmisartan alone the following side effects have been reported:
Less frequent: Severe allergic reaction, blood poisoning, changes in heart rate, kidney problems, anaemia and other changes to the blood chemistry, reduced blood sodium levels, increased blood potassium levels and uric acid levels, increased liver enzymes, low blood sugar in diabetic patients, anxiety, depression, insomnia, fainting, visual impairment, vertigo, low blood pressure, breathlessness, urinary tract infections (including inflammation of the bladder), upper respiratory tract infections, chest pain, flu-like illness, allergy, skin rashes, eczema, itching, increased sweating, back pain, cramps in legs, muscle pain, sore joints, leg pain sore tendons, weakness, liver problems, diarrhoea, dry mouth, flatulence, stomach pain, indigestion, vomiting, stomach discomfort.

In patients taking hydrochlorothiazide alone the following side effects have been reported:
Frequent: electrolyte imbalance, decreased appetite, changes in blood fat levels, e.g. cholesterol, feeling lightheaded or dizzy after standing up, nausea, vomiting, diarrhoea, skin rashes, impotence, dehydration.

Less frequent: allergic reactions, including allergic skin reactions or reactivation of lupus erythematosus, pancreas problems, jaundice (yellow skin), changes to blood cell counts (e.g. reduced amount of platelets and white blood cells), loss of diabetic control, changes in blood sugar levels, sugar in the urine, increased calcium levels, depression, dizziness, trouble sleeping, tingling feeling in the limbs, headache, visual impairment, irregular heartbeat, skin discolouration caused by inflamed blood vessels, shortness of breath, trouble breathing or fluid in the lungs, constipation, stomach upset, abdominal pain, increased sensitivity of the skin to the sun, suddenly passing less urine than normal.

The following side effects have been reported but frequencies are not known: kidney problems, anaemia, blurred or yellow vision, decrease in vision and eye pain (possible signs of acute-angle closure glaucoma or fluid build-up in the eye (choroidal effusion)), leg cramps, fever, weakness, skin and lip cancer (non-melanoma skin cancer).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

Side effects can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingelheim.com.

5. How to store CO-MICARDIS

Store all medicines out of reach of children.

Store CO-MICARDIS tablets in a 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.

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

6. Contents of the pack and other information

What CO-MICARDIS contains

CO-MICARDIS tablets contain two active substances called telmisartan and hydrochlorothiazide.

Each CO-MICARDIS 40/12,5 mg double layered tablet contains 40 mg telmisartan and 12,5 mg hydrochlorothiazide.

Each CO-MICARDIS 80/12,5 mg double layered tablet contains 80 mg telmisartan and 12,5 mg hydrochlorothiazide.

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone, red iron oxide, sodium hydroxide, sodium starch glycolate and sorbitol.

What CO-MICARDIS looks like and contents of the pack

CO-MICARDIS 40/12,5 mg: Oblong, biconvex double layer tablets; first layer white to off-white, second layer red. Very small red particles from the second layer may be visible in the first layer. Boehringer Ingelheim Company symbol and “H4” engraved in the white layer. Diameter: 6,8 x 14,0 mm.

CO-MICARDIS 80/12,5 mg: Oblong, biconvex double layer tablets; first layer white to off-white, second layer red. Very small red particles from the second layer may be visible in the first layer. Boehringer Ingelheim Company symbol and “H8” engraved in the white layer. Diameter: 7,9 x 16,2 mm.
Carton containing 28 tablets packed in aluminium blister strips of 7 tablets per strip.

Holder of Certificate of Registration

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