APPROVED PATIENT INFORMATION: CO-MICARDIS

PATIENT INFORMATION LEAFLET_____

SCHEDULING STATUS S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ABCD

Co-Micardis® 40/12,5 mg tablets
Co-Micardis® 80/12,5 mg tablets
Co-Micardis® 80/25 mg tablets
Telmisartan/Hydrochlorothiazide

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 or pharmacist.
- 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.

1. WHAT CO-MICARDIS TABLETS CONTAIN

Active ingredients:
Each CO-MICARDIS 40/12,5 mg double layered tablet contains:
TELMISARTAN 40 mg
HYDROCHLOROTHIAZIDE 12,5 mg

Each CO-MICARDIS 80/12,5 mg double layered tablet contains:
TELMISARTAN 80 mg
HYDROCHLOROTHIAZIDE 12,5 mg

Each CO-MICARDIS 80/25 mg double layered tablet contains:
TELMISARTAN 80 mg
HYDROCHLOROTHIAZIDE 25 mg

The other ingredients are lactose monohydrate, magnesium stearate, maize starch, meglumine, microcrystalline cellulose, povidone, red iron oxide (or yellow iron oxide in the case of CO-MICARDIS 80/25 mg), sodium hydroxide, sodium starch glycolate and sorbitol. Contains sugar (lactose and sorbitol).

2. WHAT CO-MICARDIS IS USED FOR

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

3. 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
- 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 (ACE) inhibitors 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.

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 (ACE) inhibitor H 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").
- 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 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 Angiotensin-converting enzyme (ACE) inhibitors/Angiotensin receptor blockers (ARBs) together with a fluoroquinolone antibiotic.

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

Important information about some of the ingredients of CO-MICARDIS:
Sorbitol is not suitable for patients with hereditary fructose intolerance.
Lactose is not suitable for patients with galactose intolerance, e.g. galactosaemia.

Taking other medicines with 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, 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 and cyclosporin.

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.

4. 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, 80/12,5 mg or 80/25 mg tablets are usually used once your blood pressure is controlled using the two medicines (i.e. telmisartan and hydrochlorthiazide) separately. The combination tablet is then used instead of the individual medicines.
CO-MICARDIS is taken in a dose of one 40/12,5 mg, 80/12,5 mg or 80/25 mg tablet once daily (preferably at about the same time each day) and swallowed with a drink of water, with or without food.
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.

5. POSSIBLE SIDE EFFECTS

CO-MICARDIS tablets can have side effects.

The following side effect occurs frequently:
Dizziness.

The following side effects occur less frequently:
Itching and/or swelling, including serious allergic reaction with fatal outcome, worsening or activation of systemic lupus erythematosus, trouble breathing, breathlessness, changes in heart rate or irregular heartbeat, chest pain, liver problems, 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 additional 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, low blood sugar in diabetic patients, urinary tract infections (including inflammation of the bladder), upper respiratory tract infections, allergy, skin rashes, eczema, sore tendons, sore joints, weakness, stomach discomfort.

In patients taking hydrochlorothiazide alone the following additional side effects have been reported:

Frequent: electrolyte imbalance, dehydration.

Less frequent: allergic reactions, including allergic skin reactions or reactivation of lupus erythematosus, pancreas problems, jaundice (yellow skin), changes to blood cell counts, stomach upset.

The following side effects have been reported but frequencies are unknown: kidney problems, loss of diabetic control, changes in blood sugar levels, changes in blood fat levels, e.g. cholesterol, light-headedness, blurred or yellow vision, decrease in vision and eye pain (possible signs of acute-angle closure glaucoma), circulatory problems, fever, weakness, sore salivary glands, weight loss, loss of appetite, restlessness.

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-MICARDS, please consult your doctor, pharmacist, or other health care 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 CO-MICARDIS

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. ***Store all medicines out of reach of children*.**

Do not take this 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).

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

8. IDENTIFICATION OF CO-MICARDIS
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.

CO-MICARDIS 80/25 mg: Oblong biconvex double layered tablets, first layer white, second layer yellow. Very small yellow particles from the second layer may be visible in the first layer. The white layer is marked with "H9" and the Boehringer Ingelheim company symbol.

9. REGISTRATION NUMBERS
CO-MICARDIS 40/12,5 mg tablets: 35/7.1.3/0096
CO-MICARDIS 80/12,5 mg tablets: 35/7.1.3/0097
CO-MICARDIS 80/25 mg tablets: 42/7.1.3/0766

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Ingelheim Pharmaceuticals (Pty) Ltd
407 Pine Avenue
Randburg
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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET
Date of registration: 07 December 2001 (CO-MICARDIS 40/12,5 mg and 80/12,5 mg) and 25 November 2011 (CO-MICARDIS 80/25 mg)
Revised: 20 August 2019