NOVARTIS

CO-MIGROBEN®

80/12.5, 160/12.5 mg tablets

(valsartan/hydrochlorothiazide)

Patient Information Leaflet

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PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CO-MIGROBEN TABLET (film-coated tablet)

CO-MIGROBEN 160 TABLET (film-coated tablet)

READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TAKING CO-MIGROBEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CO-MIGROBEN 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 this leaflet contains:

1. What CO-MIGROBEN is and what it is used for
2. What you need to know before you take or use CO-MIGROBEN
3. How to take or use CO-MIGROBEN
4. Possible side effects
5. How to store CO-MIGROBEN
6. Contents of the pack and other information

1. What CO-MIGROBEN is and what it is used for

What CO-MIGROBEN IS

Your medicine is called CO-MIGROBEN and is available as a film-coated tablet. CO-MIGROBEN contains 2 medicines, valsartan (80 mg, 160 mg or 320 mg) and hydrochlorothiazide (12,5 or 25 mg).

WHAT CO-MIGROBEN IS USED FOR:

CO-MIGROBEN contains valsartan which is an angiotensin-II receptor antagonist and hydrochlorothiazide which is a diuretic, both these medicines together help control high blood pressure.

CO-MIGROBEN is used to treat mild to moderate high blood pressure.

2. What you need to know before you take or use CO-MIGROBEN

BEFORE YOU TAKE CO-MIGROBEN:

Follow your doctor's instructions carefully. They may differ from the general instructions in this leaflet.

Do not take CO-MIGROBEN:

- If you have had any unusual or allergic reaction to valsartan or to hydrochlorothiazide or related sulfonamides or to any other component of CO-MIGROBEN listed at the beginning of this leaflet. If you are not sure which medicines to avoid, ask your doctor or pharmacist;
- If you have a history of any type of angioedema (is the rapid swelling (oedema) of the skin, face, tongue, lips and throat);
- If you ever had a swelling mainly of the face and throat while taking other medicines (including an ACE-inhibitor). If you get those symptoms, stop taking CO-MIGROBEN and contact your doctor straight away. You should never take CO-MIGROBEN again;
- If you are suffering from heart failure or have experienced a heart attack;
- If you have too low a level of potassium or sodium in your blood, or if you have too high a level of calcium in your blood despite treatment;
- If you have gout;
- If you are pregnant, planning to become pregnant or breastfeeding your baby;

- If you suffer from severe kidney disease;
- If you suffer from liver disorders or from a severe liver disease with destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the builds up bile in the liver (cholestasis);
- If you have porphyria, (porphyrias are a group of inherited or acquired disorders of certain enzymes or chemicals in the blood product manufacturing system);
- If you have aortic stenosis (valvular heart disease caused by the incomplete opening of the aortic valve) or hypertrophic obstructive cardiomyopathy (is a disease of the myocardium (the muscle of the heart) in which a portion of the myocardium is hypertrophied (thickened));
- If you use lithium;
- If you use potassium sparing diuretics (any medicine that elevates the rate of urination and thus provides a means of forced diuresis) such as spironolactone, triamterene, amiloride;
- If you are treated with an ACE-inhibitor or another class of medicine e.g. aliskiren;
- If you have Addison's disease (a rare endocrine system of glands that secrete hormones that regulate the body) disorder wherein the adrenal glands (triangular shaped glands on top of the kidneys) produce insufficient steroid hormones (glucocorticoids and often mineralocorticoids);
- If you have acute angle-closure glaucoma, or if you are experiencing a decrease in vision or eye pain;
- If you suffer from severe kidney disease with being unable to produce urine (anuria);
- If you have serious kidney impairment and are elderly, do not take CO-MIGROBEN with fluoroquinolones.

Take special care with CO-MIGROBEN

- If you have liver or kidney disease;
- If you have diabetes (high blood sugar);
- If you have fever, rash, and joint pain, which may be signs of lupus erythematosus (or a history of this disease);

- If you have low levels of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions);
- If you have low levels of potassium in your blood;
- If you have high levels of cholesterol in your blood;
- If you are suffering from vomiting or diarrhoea, or taking high doses of a diuretic (water pill);
- If you are treated with an ACE-inhibitor or aliskiren;
- If you have non-melanoma skin cancer (appearance of a lump or discoloured patch on the skin that continues to persist after a few weeks);
- If you are using fluoroquinolones (a type of antibiotic) as this may precipitate acute kidney injury.

If any of the following apply to you, **tell your doctor before you take CO-MIGROBEN.**

Taking CO-MIGROBEN with food and drink:

CO-MIGROBEN can be taken with or without food. Do not crush or chew the tablets, it should be swallowed whole with a glass of water.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Pregnant women:

Do not take CO-MIGROBEN if you are pregnant. Use of CO-MIGROBEN may cause serious harm to the unborn child. It is therefore important to check with your doctor immediately if you think you are pregnant or are planning to become pregnant.

Breast-feeding mothers:

You should not breast feed while taking CO-MIGROBEN.

Driving and using machinery:

CO-MIGROBEN may cause dizziness and affect the ability to concentrate. So before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of CO-MIGROBEN.

Taking other medicines with CO-MIGROBEN (i.e., interactions)

Always tell your healthcare professional if you are taking any other medicine.

If you are taking medicines on a regular basis (including complementary or traditional medicines), concomitant use of the medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

Remember also those not prescribed by a doctor (including complementary or traditional medicines). It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This applies to both prescription and non-prescription medicines, especially:

- other medicines used to lower blood pressure, especially ACE-inhibitors or aliskiren;
- potassium-sparing medicines (water tablets), such as spironolactone, triameterone, amiloride, potassium supplements, or salt substitutes containing potassium;
- cortisone-like medicines, steroids;
- carbenoxolone (a medicine used to treat ulceration and inflammation);
- antibiotics such as penicillin G, amphothericine, antidysrrhythmics (medicines used to treat heart problems);
- allopurinol (medicine used to treat gout);

- amantadine (medicine to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses);
- anticholinergic agents (medicines used to treat symptoms of stomach cramps, bladder spasm, asthma, motion sickness, and muscular spasms);
- ciclosporin (a medicine used in transplantation and in autoimmune disorders);
- lithium, a medicine used to treat some psychological conditions;
- antiepileptics, such as carbamazepine (used to treat convulsions);
- medicines used to relieve pain or inflammation, especially non-steroidal anti-inflammatory drugs (including aspirin);
- digoxin (a heart medicine);
- insulin or antidiabetic medicines taken by mouth;
- cholestyramine and colestipol, resins used mainly to treat high levels of lipids in the blood;
- vitamin D and calcium salts;
- cytotoxic medicines, methyldopa, ciclosporin, barbituates and narcotics;
- using medicines known as fluoroquinolones and CO-MIGROBEN together, and have moderate to severe renal impairment and are an elderly patient. Use of these medicines together may precipitate acute kidney injury.

Avoid alcohol until you have talked to your doctor. Alcohol may make blood pressure fall more and/or increase the possibility of dizziness or fainting.

Older people (age 65 and over):

You can also use CO-MIGROBEN if you are 65 years of age or older.

Children and adolescents (below the age of 18 years):

There is no experience with CO-MIGROBEN in children and adolescents.

3. HOW TO TAKE CO-MIGROBEN:

Do not share medicines prescribed for you with others.

Do not exceed the recommended dosage.

CO-MIGROBEN is for oral use only.

How much CO-MIGROBEN to take

Your doctor will tell you exactly how many tablets of CO-MIGROBEN to take.

To treat high blood pressure the usual dosage is one CO-MIGROBEN 80/12,5 mg or CO-MIGROBEN 160/12,5 mg once a day.

Your doctor will tell you exactly how long you will need to take the tablets.

How long to take CO-MIGROBEN

Your doctor will tell you exactly how long you will need to take the tablets.

If you take more CO-MIGROBEN than you should:

If you experience severe dizziness and/or fainting, unusual tiredness, weakness or muscle cramps, or irregular heartbeats, tell your doctor as quickly as possible.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison control centre.

If you forget to take CO-MIGROBEN:

It is advisable to take your medicine at the same time each day, preferably in the morning. However, if you forget to take a dose of CO-MIGROBEN, carry on with the next one at the usual time. Do not take a double dose to make up for the forgotten tablet.

Effects when treatment with CO-MIGROBEN is stopped:

Stopping your treatment with CO-MIGROBEN may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. POSSIBLE SIDE EFFECTS

CO-MIGROBEN can have side effects.

Not all side-effects reported for CO-MIGROBEN are included in this leaflet. Should your general health worsen while taking CO-MIGROBEN, please consult your doctor, pharmacist or other health care professional for advice.

Tell your doctor immediately or go to the nearest casualty department at your nearest hospital if you notice any of the following:

- Breathlessness (possible symptoms of non-cardiogenic pulmonary oedema)
- Sudden loss of consciousness (possible symptoms of syncope)
- Severely decreased urine output (possible symptoms of impaired renal function)
- Fever, sore throat or mouth ulcers due to infections (possible symptoms of neutropenia)
- Muscle weakness, muscle spasms, abnormal heart rhythm (possible symptoms of low level of potassium in blood)
- Tiredness, confusion, muscle twitching, convulsions (possible symptoms of hyponatremia)
- Allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (angioedema)
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

These are all serious side effects. If you get any of these, tell your doctor straight away. You may need urgent medical attention

Some side effects are Less Frequent:

- Non-melanoma skin cancer (appearance of a lump or discoloured patch on the skin that continues to persist after a few weeks
- Thirst, low urine output, dark urine, dry flushed skin, irritability (possible symptoms of dehydration)
- Tingling or numbness (possible symptoms of paraesthesia)
- Vision disorders
- Tiredness
- Cough
- Muscle pain
- Noises in ears
- Dizziness, light headedness (possible symptoms of hypotension)

Tell your doctor if you notice any of the following:

- Decreased level of hemoglobin and decrease of the percentage of blood cells in the blood (which can, in severe cases lead to anaemia), unusual bleeding or bruising (thrombocytopenia),
- Weakness, bruising and frequent infections (possible signs of pancytopenia, bone marrow depression),
- Pale skin, tiredness, breathlessness and dark urine (possible signs of haemolytic anaemia),
- High levels of sugar in the blood (hyperglycaemia, glycosuria),
- Facial rash, joint pain, muscle disorder, fever (possible signs of Systemic Lupus Erythematosus),
- Headache, insomnia, fainting on standing up, drowsiness (somnolence), spinning sensation (vertigo), sleep disorder, depression,
- Chest pain, fast heart beat (tachycardia), irregular heartbeat (possible signs of dysrrhythmia),
- Cough with phlegm together with chest pain and fever (bronchitis or bronchitis acute), nose bleeds (epistaxis), flu (influenza), blocked nose (nasal congestion), nasopharyngitis, otitis

media, palpitations, sore throat (pharyngolaryngal pain), pollakiuria, fever (pyrexia), feeling of pressure pain in the cheeks and forehead (sinusitis), sinus congestion,

- Diarrhoea, stomach discomfort after meal (dyspepsia), dry mouth, gastroenteritis, nausea, severe upper stomach pain (possible signs of pancreatitis), decreased appetite,
- Yellow eyes and skin (cholestasis or jaundice),
- Excessive sweating (hyperhidrosis), decreased skin sensitivity (hypoesthesia), swelling (oedema), swollen hands, ankles or feet (edema peripheral), pain in extremity, purplish-red spots with fever and itching (vasculitis), purple skin patches (possible signs of thrombocytopenia, purpura), itchy rash or other forms of rash (uticuria),
- Red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of Toxic Epidermal Necrolysis, erythema multiforme),
- Joint pain, abdominal pain, abdominal pain upper, anxiety, weakness (asthenia), back pain, ligament sprain, muscle spasms, muscle strain, neck pain,
- Confusion, tiredness, muscle twitching and spasm, rapid breathing (possible signs of hypochloraemic alkalosis),
- High levels of lipids in your blood (hyperlipidaemia), low levels of magnesium in your blood (hypomagnesaemia) , high levels of uric acid in your blood (hyperuricaemia),
- Inability to achieve or maintain an erection (erectile dysfunction),
- Upper respiratory tract infections, urinary tract infections, viral infections,
- Fever, sore throat, more frequent infections (possible signs of agranulocytosis).

If any of these affects you severely, tell your doctor.

Also reported (frequency unknown: frequency cannot be estimated from the available data)

- Abnormal kidney function test results (possible symptoms of serum uric acid or creatinine or blood urea nitrogen increased)
- Abnormal liver function test results (possible symptoms of serum bilirubin increased).

If you notice any other 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 Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CO-MIGROBEN.

5. How to store CO-MIGROBEN

Store at or below 30°C. Protect from moisture.

Store your tablets in the original package.

Do not take CO-MIGROBEN after the expiry date shown on the pack.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets). Do not use any CO-MIGROBEN pack that is damaged or shows signs of tampering.

Store all medicines out of the reach of children.

6. Content of the Pack and Other information

What CO-MIGROBEN contains:

Each tablet contains the active substances valsartan (80 mg, 160 mg or 320 mg) and hydrochlorothiazide (12,5 or 25 mg).

The other ingredients are microcrystalline cellulose, hydroxypropyl methylcellulose, silicon dioxide, crospovidone, polyethylene glycol, talc, magnesium stearate, titanium dioxide (E171). In addition, the 80/12,5 mg tablets contain red iron oxide (E172) and yellow iron oxide (E172). The 160/12,5 mg tablets

contain only red iron oxide (E172) additionally. The 160/25 mg tablets contain in addition red iron oxide (E172), yellow iron oxide (E172) and black iron oxide (E172).

PRESENTATION OF CO-MIGROBEN:

28 tablets in polyvinyl chloride/polyvinyldichloride (PVC/PVDC) / aluminium foil blisters or polyamide/aluminium/polyvinylchloride (PA/Al/PVC) / aluminium foil blisters. The outer container is a printed cardboard box.

IDENTIFICATION OF CO-MIGROBEN:

CO-MIGROBEN 80/12,5 TABLET:

Light orange, ovaloid, convex tablet. One side bears the imprint “HGH”, the other “CG”.

CO-MIGROBEN 160/12,5 TABLET:

Dark red, ovaloid, convex film-coated tablets. One side bears the imprint “HHH”, the other “CG” on the reverse side.

Holder of the certificate of registration:

Novartis South Africa (Pty) Ltd.
Magwa Crescent West
Waterfall City
Jukskei View
Johannesburg
2090
+27 11 347 6600

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