NOVARTIS

CO-COPALIA 5 mg/160 mg/12.5 mg
CO-COPALIA 10 mg/160 mg/12.5 mg
CO-COPALIA 5 mg/160 mg/25 mg
CO-COPALIA10 mg/160 mg/25 mg
CO-COPALIA 10 mg/320 mg/25 mg

Film-coated tablets

(amlodipine/valsartan/hydrochlorothiazide)

Patient Information Leaflet

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

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CO-COPALIA 10 mg/160 mg/25 mg film-coated tablets

CO-COPALIA 10 mg/320 mg/25 mg film-coated tablets

amlodipine/valsartan/hydrochlorothiazide

Sugar free

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- CO-COPALIA 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-COPALIA is and what it is used for
2. What you need to know before you take CO-COPALIA
3. How to take CO-COPALIA
4. Possible side effects
5. How to store CO-COPALIA

6. Contents of the pack and other information

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

Your medicine is called CO-COPALIA and is available as a film-coated tablet.

CO-COPALIA contains three medicines: Amlodipine, a medicine that belongs to the class of calcium antagonists, valsartan, which belongs to the class of so-called angiotensin-II receptor antagonists and hydrochlorothiazide, a diuretic which belongs to the sulfonamides. All three medicines help in different ways to control high blood pressure.

CO-COPALIA is used to treat high blood pressure in patients whose blood pressure is adequately controlled on the combination of the three medicines contained in CO-COPALIA, on individual doses

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

Do not take CO-COPALIA

- If you are allergic (hypersensitive) to amlodipine, valsartan, hydrochlorothiazide, or sulfonamides or any of the other ingredients of CO-COPALIA.
- If you are pregnant or planning to become pregnant or breastfeeding your baby.
- If you have serious liver or kidney disease or impairment.
- If you have inability to produce urine.
- If you have only one kidney or you suffer from or a narrowing or blockage of the arteries that supply blood to your kidney.
- If you have porphyria, a rare disease of a deficiency of certain enzymes. The disease can be recognised by nerve pain and skin problems.
- If you have a too low a level of potassium or sodium in your blood, or if you have a too high level of calcium in your blood despite treatment.
- If you have uric acid crystals in the joints (gout).

- If you have imbalances in your blood chemistry, such as low sodium and potassium levels, or high calcium or urea levels.
- If you are taking any medicine that contain lithium.
- If you are taking other medicines or substances, which increase the potassium levels in your blood (such as certain types of diuretics, such as spironolactone, triamterene, amiloride and potassium supplements). These medicines are usually used to treat high blood pressure or swelling.
- If you suffer from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy.
- If you have previously suffered from the rapid swelling of the skin or mucous membranes of the face (angioedema) while taking this type of medicines, called angiotensin receptor blockers (ARBs). This reaction can also occur without any apparent reason or can be hereditary.
- If you have Addison's disease, a rare, chronic disease of the adrenal glands.
- If you have serious kidney impairment and are elderly, do not take CO-COPALIA with fluoroquinolones.

If any of these apply to you, tell your doctor before taking CO-COPALIA.

- If you are taking a blood pressure lowering medicine called aliskiren.
- If you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Take special care with CO-COPALIA:

- Your doctor may wish to have your blood tested before and at regular intervals during your treatment to check the values of potassium, magnesium, calcium, sodium, sugar, cholesterol, uric acid and the amounts of red and white cells as well as platelets.
- If you are already taking a diuretic (a medicine to increase the amount of urine you produce).

- If you have fever, facial rash, and joint pain, which may be signs of lupus erythematosus (or a history of this disease).
- If you have diabetes (high blood sugar).
- If you have been told you have high levels of calcium (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- If you have high levels of cholesterol or triglycerides in your blood.
- If you have been told you have low levels of potassium or magnesium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm)
- If you suffer from a liver disorder.
- If you are suffering from several episodes of vomiting or diarrhoea.
- One of the ingredients of CO-COPALIA is hydrochlorothiazide, a thiazide diuretic. This ingredient may change a person's glucose tolerance (this is used to determine your resistance to glucose and is used to test for diabetes) and raise the levels of cholesterol, triglycerides (fatty acid in the blood), and uric acid (a component in your blood formed from the breakdown of proteins).

If any of these apply to you, tell your doctor before taking CO-COPALIA.

- If you experience dizziness and/or faintness during treatment with CO-COPALIA.
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Long-term treatment with hydrochlorothiazide may increase the risk of non-melanoma skin cancer, probably by increasing the sensitivity of the skin to UV radiation. Protect your skin from excessive sun exposure while taking CO-COPALIA. Regularly check your skin for any new lesions and promptly report any suspicious skin lesions to your doctor.
- Use of fluoroquinolones and ACE inhibitors/Renin-Angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients.
- if you have kidney problems, have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.

- if you have or have had heart failure or coronary artery disease, particularly if you are prescribed the maximum dose of CO-COPALIA (10 mg/320 mg/25 mg)
- if you have experienced a heart attack
- if your doctor has told you that you have a narrowing of the valves in your heart (called “aortic or mitral stenosis”) or that the thickness of your heart muscle is abnormally increased (called “obstructive hypertrophic cardiomyopathy”).
- if you suffer from aldosteronism. This is a disease in which the adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of CO-COPALIA is not recommended.
- if you suffer from a disease called systemic lupus erythematosus (also called “lupus” or “SLE”).
- if you have a low level of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- if you experience skin reactions such as rash after sun exposure
- if you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to a week of taking CO-COPALIA. This can lead to permanent vision impairment, if not treated.
    - 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 (see **Do not take CO-COPALIA**)

If you get any of these symptoms, tell your doctor as soon as possible.

- Angioedema, swelling of the face, lips, mouth or tongue, which may cause difficulty in swallowing or breathing.
- 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 (nonmelanoma skin cancer). Protect your skin from sun exposure and UV rays while taking CO-COPALIA.

Children and adolescents (below 18 years):

The use of CO-COPALIA in children and adolescents is not recommended.

Other medicines and CO-COPALIA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or a pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This includes in particular:

- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium.
- some medicines used to treat infections such as amphotericin, penicillin G;
- medicines used for oesophageal ulceration and inflammation (carbenoxolone);
- medicines used to lower blood pressure;
- lithium, a medicine used to treat some psychological conditions;
- medicines used to relieve pain or inflammation, especially nonsteroidal anti-inflammatory agents;
- cortisone-like medicines, steroids;
- digoxin (a heart medicine);
- muscle relaxant medicines used during operations;
- allopurinol (anti-gout treatment);
- amantadine (anti-Parkinson therapy, also used for influenza treatment);
- cytotoxic medicines (cancer therapy e.g. cyclophosphamide, methotrexate);
- anticholinergic agents (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);
- ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g: rheumathoid arthritis or atopic dermatitis);
- insulin or antidiabetic medicines (oral agents such as metformin or insulins);
- cholestyramine and colestipol (resins used mainly to treat high levels of lipids in the blood);

- vitamin D and calcium salts;
- carbamazepine (anticonvulsant and mood stabilising medicine used primarily in the treatment of epilepsy and bipolar disorder);
- use of fluoroquinolones and ACE inhibitors/Angiotensin receptor blockers may precipitate acute kidney injury;
- rifampicin (used, for example, to treat tuberculosis;
- St. John's wort (*Hypericum perforatum*);
- Methyldopa (other medicine also used to treat high blood pressure);
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- medicines to increase blood pressure such as adrenaline or noradrenaline. alcohol, sleeping pills and anaesthetics (medicines allowing patients to undergo surgery and other procedures);
- simvastatin (a medicine used to control high cholesterol levels);
- diltiazem (heart medicine);
- medicines that may increase blood sugar levels (diazoxide);
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics.

CO-COPALIA with food, drink and alcohol:

You can take CO-COPALIA with or without food.

Grapefruit and grapefruit juice should not be consumed by people who are prescribed **CO-COPALIA**. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of **CO-COPALIA**.

Talk to your doctor before drinking alcohol. Alcohol may make your blood pressure fall too much and/or increase the possibility of dizziness or fainting.

Pregnancy, breast-feeding and fertility

Do not take CO-COPALIA if you are pregnant or planning to become pregnant. Use during pregnancy may cause serious damage to your unborn child. It is therefore important to check with your doctor immediately if you think you may have become pregnant or are planning to become pregnant.

Your doctor will discuss with you the potential risk of taking CO-COPALIA during pregnancy.
Tell your doctor if you are breast-feeding. Treatment with CO-COPALIA is not recommended during breast-feeding (see "Do not take CO-COPALIA").
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.

Driving and using machines

CO-COPALIA may [cause dizziness] make you feel dizzy, drowsy, nauseous or have a headache, 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-COPALIA.
It is not always possible to predict to what extent CO-COPALIA may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CO-COPALIA affects them.

3. How to take CO-COPALIA:

Do not share medicines prescribed for you with any other person.
Always take CO-COPALIA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Do not exceed the recommended dose. Follow your doctor's instructions carefully. CO-COPALIA is for oral use only.

How much CO-COPALIA to take:

Your doctor will tell you exactly how many tablets of CO-COPALIA you should take.

You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of CO-COPALIA is too strong or too weak, talk to your doctor or pharmacist.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

The recommended dose of CO-COPALIA is one film coated tablet per day.

Older people (over 65 years):

There are no special dose recommendations for patients aged 65 years or older.

When to take CO-COPALIA:

Taking CO-COPALIA at the same time each day will help you remember when to take your medicine.

How to take CO-COPALIA:

CO-COPALIA may be taken with or without food. Swallow the tablets with a glass of water.

If a tablet shows signs of cracking the tablet should not be taken.

How long to take CO-COPALIA:

Continue taking CO-COPALIA as your doctor tells you.

If you have questions about how long to take CO-COPALIA, talk to your doctor or your pharmacist.

If you take more CO-COPALIA than you should:

If you have accidentally taken too many tablets of CO-COPALIA, **consult your doctor** or pharmacist **immediately.** If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take CO-COPALIA:

It is advisable to take your medicine at the same time each day, preferably in the morning. If you forget to take CO-COPALIA, take it as soon as you remember and then take your next dose at its usual time. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for the forgotten tablet.

If you stop taking CO-COPALIA:

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

4. Possible side effects

CO-COPALIA can have side effects.

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

If any of the following happens, stop taking CO-COPALIA and tell your doctor immediately or go to the casualty department at your nearest hospital:

Swelling of the hands, feet, ankles, face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing;

- rash or itching;
- dizziness, light-headedness; sudden loss of consciousness;
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis
- rash, skin reddening, blistering of lips, eyes or mouth, skin peeling (signs of erythema multiforme);

- crushing chest inflammation of vessels with or without pain can interrupt your normal blood flow and can cause skin and muscle damage, including necrosis (sign of necrotizing vasculitis);
- Non-melanoma skin cancer (appearance of a lump or discoloured patch on the skin that continues to persist after a few weeks, and slowly progresses over months or sometimes years or cancerous lumps that are red/pink and firm and sometimes turn into ulcers, while cancerous patches are usually flat and scaly; often develops on areas of skin regularly exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CO-COPALIA. You may need urgent 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:

- Swelling of arms, hands, legs, ankles or feet;
- abdominal pain with nausea, vomiting, or fever (signs of pancreatitis);
- yellow skin and eyes, nausea, loss of appetite, light-coloured urine (signs of hepatitis);
- unusual bleeding or bruising (signs of thrombocytopenia);
- rash, purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis);
- swelling mainly of the face and throat (signs of angioedema);
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called leucopenia, agranulocytosis or neutropenia);
- pain (sign of myocardial infarction or increased angina), irregular heartbeat (sign of arrhythmia);
- weakness, bruising and frequent infections (signs of lack of blood cells also called pancytopenia);
- pale skin, tiredness, breathlessness, dark urine (signs of low level of red blood cells also called haemolytic anaemia);

- short and shallow breathing including fever coughing, difficulty breathing, wheezing and breathlessness (signs of respiratory distress, pneumonitis, pulmonary oedema);
- breathlessness (signs of pulmonary oedema and non-cardiogenic pulmonary oedema);
- rash, purplish-red spots, fever, itching (signs of vasculitis),
- skin rash with or without itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness),
- cough with phlegm, chest pain, fever (signs of bronchitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Flu-like symptoms; nasal congestion, sore throat and discomfort when swallowing;
- headache;
- tiredness;
- feeling sleepy;
- nausea;
- decreased appetite;
- inability to obtain an erection (impotence);
- fast heart beat (palpitations);
- faintness on standing up, which may be worsened by alcohol or sedatives;
- changes in blood chemistry;
- weakness,
- stomach discomfort after meal.

<u>The following side effects have been reported less frequently:</u>

- Stomach pain;
- dry mouth;

- drowsiness, vertigo (feeling dizzy);
- cough;
- diarrhoea;
- constipation;
- joint swelling, back pain;
- pain in joints;
- visual disturbance;
- anxiety;
- tinnitus (ringing in the ears);
- passing more urine than normal or feeling an increased urge to pass urine;
- sensation of heaviness;
- excessive sweating;
- muscle spasm;
- sensation of numbness or tingling in fingers and toes (signs of peripheral neuropathy);
- severely decreased urine output (sign of renal impairment),
- muscle weakness,
- abnormal heart rhythm (signs of hypokalaemia),

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 [~~or~~], pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (wh-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CO-COPALIA.

5. How to store CO-COPALIA

Store all medicines out of reach of children.

- Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Store at or below 30 °C.
- Store in the original package in order to protect from moisture.
- Do not use any CO-COPALIA if you notice the pack that is damaged or shows signs of tampering.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CO-COPALIA contains

CO-COPALIA 5 mg/160 mg/12.5 mg film-coated tablets

The active substances of CO-COPALIA are amlodipine (as amlodipine besylate), valsartan and hydrochlorothiazide. Each film-coated tablet contains 5 mg amlodipine (as amlodipine besylate), 160 mg valsartan and 12.5 mg hydrochlorothiazide.

The other ingredients are cellulose microcrystalline; crospovidone; silica, colloidal anhydrous; magnesium stearate; hypromellose, macrogol 4000, talc, titanium dioxide (E171).

CO-COPALIA 10 mg/160 mg/12.5 mg film-coated tablets

The active substances of CO-COPALIA are amlodipine (as amlodipine besylate), valsartan and hydrochlorothiazide. Each film-coated tablet contains 10 mg amlodipine (as amlodipine besylate), 160 mg valsartan, and 12.5 mg hydrochlorothiazide.

The other ingredients are cellulose microcrystalline; crospovidone; silica, colloidal anhydrous; magnesium stearate; hypromellose, macrogol 4000, talc, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172).

CO-COPALIA 5 mg/160 mg/25 mg film-coated tablets

The active substances of CO-COPALIA are amlodipine (as amlodipine besylate), valsartan and hydrochlorothiazide. Each film-coated tablet contains 5 mg amlodipine (as amlodipine besylate), 160 mg valsartan and 25 mg hydrochlorothiazide.

The other ingredients are cellulose microcrystalline; crospovidone; silica, colloidal anhydrous, magnesium stearate, hypromellose, macrogol 4000, talc, titanium dioxide (E171), yellow iron oxide (E172).

CO-COPALIA 10 mg/160 mg/25 mg film-coated tablets

The active substances of CO-COPALIA are amlodipine (as amlodipine besylate), valsartan and hydrochlorothiazide. Each film-coated tablet contains 10 mg amlodipine (as amlodipine besylate), 160 mg valsartan, and 25 mg hydrochlorothiazide.

The other ingredients are cellulose microcrystalline; crospovidone; silica, colloidal anhydrous, magnesium stearate, hypromellose, macrogol 4000, talc, yellow iron oxide (E172).

CO-COPALIA 10 mg/320 mg/25 mg film-coated tablets

The active substances of CO-COPALIA are amlodipine (as amlodipine besylate), valsartan and hydrochlorothiazide. Each film-coated tablet contains 10 mg amlodipine (as amlodipine besylate), 320 mg valsartan, and 25 mg hydrochlorothiazide.

The other ingredients are cellulose microcrystalline; crospovidone; silica, colloidal anhydrous, magnesium stearate, hypromellose, macrogol 4000, talc, yellow iron oxide (E172).

What CO-COPALIA looks like and contents of the pack

CO-COPALIA 5 mg/160 mg/12.5 mg film-coated tablets are white, oval tablets with “NVR” on one side and “VCL” on the other side.

CO-COPALIA 10 mg/160 mg/12.5 mg film-coated tablets are pale yellow, oval tablets with “NVR” on one side and “VDL” on the other side.

CO-COPALIA 5 mg/160 mg/25 mg film-coated tablets are yellow, oval tablets with “NVR” on one side and “VEL” on the other side.

CO-COPALIA 10 mg/160 mg/25 mg film-coated tablets are brown-yellow, oval tablets with “NVR” on one side and “VHL” on the other side.

CO-COPALIA 10 mg/320 mg/25 mg film-coated tablets are brown-yellow, oval tablets with “NVR” on one side and “VFL” on the other side.

CO-COPALIA is available in packs containing 7, 14, 28, 56 or 98 film-coated tablets in a colourless, transparent laminated plastic film made of PA/Al/PVC (polyamide/aluminium/polyvinylchloride) blisters with an aluminium foil backing. Not all pack sizes may be marketed.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

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Namibia		
Co-Copalia 5 mg/160 mg /12,5 mg	20/7.1.3/0131	NS2
Co-Copalia 5 mg/160 mg/25 mg	20/7.1.3/0128	NS2
Co-Copalia 10 mg/160 mg/12,5 mg	20/7.1.3/0132	NS2
Co-Copalia 10 mg/160 mg/25 mg	20/7.1.3/0129	NS2
Botswana		
Co-Copalia 5/160/12.5 mg:	BOT2203799A-D	S2
Co-Copalia 5/160/25 mg	BOT2203800A-D	S2
Co- Copalia 10/160/12.5 mg	BOT2203801A-D	S2
Co-Copalia 10/160/25 mg	BOT2203802A-D	S2

Manufacturer

Novartis Farma S.p.A.

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