

Very rare:

- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis)
- rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reactions)
- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis)
- facial rash, joint pain, muscle disorder, fever (lupus erythematosus)
- severe upper stomach pain (pancreatitis)
- difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema)
- fever, sore throat, more frequent infections (agranulocytosis)
- pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia)
- fever, sore throat or mouth ulcers due to infections (leucopenia)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis)

Not known:

- weakness, bruising and frequent infections (aplastic anemia)
- severely decreased urine output (possible signs of renal disorder or renal failure)
- decrease in vision or pain in your eyes due to high pressure (possible signs of acute angle-closure glaucoma)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme)
- muscle spasm
- fever (pyrexia)
- weakness (asthenia)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Co-Diovan

- KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 30°C. Store in the original package to protect from moisture.
- Do not use after the expiry date printed on the carton label or blister strip.
- If your doctor tells you to stop using the medicine, please take it back to the pharmacist for safe disposal. Only keep the medicine if your doctor tells you to.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Co-Diovan contains

- Each film coated tablet contains 160mg of the active ingredient valsartan and 12.5mg of the active ingredient hydrochlorothiazide.
- Co-Diovan also contains the following inactive ingredients: microcrystalline cellulose, colloidal anhydrous silica, crospovidone, magnesium stearate, hypromellose, macrogol 8000, talc, titanium dioxide (E171) and red iron oxide (E172).

What Co-Diovan looks like and contents of the pack

Co-Diovan tablets are oval, brown orange coloured, imprinted with 'HHH' on one side and 'CG' on the other side.

Co-Diovan tablets are available as calendar blister packs of 28 tablets.

Product Licence holder

Procured from within the EU and repackaged by the Product Licence holder: S&M Medical Ltd, Chemilines House, Alperton Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by Novartis Farma S.p.A., Via Provinciale Schito 131, 80058 Torre Annunziata, Naples, Italy.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

CO-DIOVAN 160/12.5mg TABLETS
(valsartan / hydrochlorothiazide)

Your medicine is known as Co-Diovan 160/12.5mg Tablets but will be referred to as Co-Diovan throughout the following patient information leaflet.

Please note that information regarding other strengths 80mg/12.5mg and 160mg/25mg of Co-Diovan Tablets is also present in the below leaflet.

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

- What Co-Diovan is and what it is used for
- Before you take Co-Diovan
- How to take Co-Diovan
- Possible side effects
- How to store Co-Diovan
- Further information

1. What Co-Diovan is and what it is used for

Co-Diovan film-coated tablets contain two active substances called valsartan and hydrochlorothiazide. Both of these substances help to control high blood pressure (hypertension).

- Valsartan** belongs to a class of medicines known as “angiotensin II receptor antagonists”, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.
- Hydrochlorothiazide** belongs to a group of medicines called thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

Co-Diovan is used to treat high blood pressure which is not adequately controlled by a single substance alone.

High blood pressure increases the workload of the heart and arteries. If not treated, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.

2. Before you take Co-Diovan

Do not take Co-Diovan:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or to any of the other ingredients of Co-Diovan.
- if you are **more than 3 months pregnant** (it is also better to avoid Co-Diovan in early pregnancy – see pregnancy section).

- if you have **severe** liver disease, destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the build up of bile in the liver (cholestasis).
- if you have **severe** kidney disease.
- if you are unable to produce urine (anuria).
- if you are treated with an artificial kidney.
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.
- if you have gout.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine called aliskiren.

If any of the above apply to you, do not take this medicine and speak to your doctor.

Take special care with Co-Diovan

- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you are suffering from heart failure or have experienced a heart attack. Follow your doctor's instruction for the starting dose carefully.
Your doctor may also check your kidney function.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- if you suffer from hyperaldosteronism.
This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of Co-Diovan is not recommended.
- if you have liver or kidney disease.
- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor.
If these symptoms occur when you are taking Co-Diovan, stop taking Co-Diovan immediately and never take it again. See also section 4, “Possible side effects”.

- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering agents of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- 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-Diovan. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this.

- it may cause increased sensitivity of the skin to sun.
- the use of Co-Diovan in children and adolescents below the age of 18 years is not recommended.
- you must tell your doctor if you think you are (or might become) pregnant. Co-Diovan is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).
- if you are taking any of the following medicines used to treat high blood pressure:
 - “ACE inhibitors” such as enalapril, lisinopril, etc
 - Aliskiren

If any of these apply to you, talk to your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

The effect of the treatment can be influenced if Co-Diovan is taken together with certain other 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 especially applies to the following medicines:

- lithium, a medicine used to treat some types of psychiatric diseases.
- medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G.
- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Co-Diovan.
- medicines that may induce “torsades de pointes” (irregular heart beat), such as antiarrhythmics (medicines used to treat heart problems) and some antipsychotics.
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone.
- therapeutic vitamin D and calcium supplements.
- medicines for the treatment of diabetes (oral agents such as metformin or insulins).
- other medicines to lower your blood pressure including methyl dopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren.
- medicines to increase blood pressure, such as noradrenaline or adrenaline.
- digoxin or other digitalis glycosides (medicines used to treat heart problems).
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers.
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide.
- pain killers such as non-steroidal anti-inflammatory agents (NSAIDs), including selective cyclooxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g.
- muscle relaxing medicines, such as tubocurarine.
- 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).
- amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses).
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood).
- ciclosporin, a medicine used for organ transplant to avoid organ rejection.
- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery).
- iodine contrast media (agents used for imaging examinations).

Taking Co-Diovan with food and drink

You can take Co-Diovan 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

Ask your doctor or pharmacist for advice before taking any medicine.

- **You must tell your doctor if you think that you are (or might become) pregnant**

Your doctor will normally advise you to stop taking Co-Diovan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Co-Diovan. Co-Diovan is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.

- **Tell your doctor if you are breast-feeding or about to start breast-feeding**

Co-Diovan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how Co-Diovan affects you. Like many other medicines used to treat high blood pressure, Co-Diovan may occasionally cause dizziness and affect the ability to concentrate.

3. How to take Co-Diovan

Always take Co-Diovan exactly as your doctor has told you. This will help you to get the best results and lower the risk of side effects.

You should check with your doctor or pharmacist if you are not sure.

People with high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with your doctor even if you are feeling well.

Your doctor will tell you exactly how many tablets of Co-Diovan to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

- The usual dose of Co-Diovan is one tablet per day.
- Do not change the dose or stop taking the tablets without consulting your doctor.
- The medicine should be taken at the same time each day, usually in the morning.
- You can take Co-Diovan with or without food.
- Swallow the tablet with a glass of water.

If you take more Co-Diovan than you should

If you experience severe dizziness and/or fainting, lie down and contact your doctor immediately.

If you have accidentally taken too many tablets, contact your doctor, pharmacist or hospital.

If you forget to take Co-Diovan

If you forget to take a dose, take it as soon as you remember. 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 a forgotten dose.

If you stop taking Co-Diovan

Stopping your treatment with Co-Diovan may cause your high blood pressure to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Co-Diovan can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data

Some side effects can be serious and need immediate medical attention:

You should see your doctor immediately if you experience symptoms of angioedema, such as:

- swollen face, tongue or pharynx
- difficulty in swallowing
- hives and difficulties in breathing

If you get any of these symptoms, stop taking Co-Diovan and contact your doctor straight away (see also section 2 “Take special care with Co-Diovan”).

Other side effects include:

Uncommon:

- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises (e.g. hissing, buzzing) in ears

Very rare:

- dizziness
- diarrhoea
- joint pain

Not known:

- breathing difficulty
- severely decreased urine output
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and / or convulsions in severe cases)
- low level of potassium in the blood (sometimes with muscle weakness, muscle spasms, abnormal heart rhythm)
- low level of white cells in the blood (with symptoms such as fever, skin infections, sore throat or mouth ulcers due to infections, weakness)
- the level of bilirubin increased in blood (which can, in severe cases, trigger yellow skin and eyes)
- the level of blood urea nitrogen and creatinine increased in blood (which can indicate abnormal kidney function)
- the level of uric acid in blood increased (which can, in severe cases, trigger gout)
- syncope (fainting)

The following side effects have been reported with products containing valsartan or hydrochlorothiazide alone:

Valsartan

Uncommon:

- spinning sensation
- abdominal pain

Not known:

- 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
- rash, purplished-red spots, fever, itching (symptoms of inflammation of blood vessels)
- low level of blood platelets (sometimes with unusual bleeding or bruising)
- high level of potassium in the blood (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness)
- swelling mainly of the face and throat; rash; itching
- elevation of liver function values
- the level of haemoglobin decreased and the percentage of red cells decreased in the blood (which both can, in severe cases, trigger an anaemia).
- kidney failure
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

Hydrochlorothiazide

Very common:

- low level of potassium in the blood
- increase of lipids in the blood

Common:

- low level of sodium in the blood
- low level of magnesium in the blood
- high level of uric acid in the blood
- itchy rash and other types of rash
- reduced appetite
- mild nausea and vomiting
- dizziness, fainting on standing up
- inability to achieve or maintain erection

Rare:

- swelling and blistering of the skin (due to increased sensitivity to sun)
- high level of calcium in the blood
- high level of sugar in the blood
- sugar in the urine
- worsening of diabetic metabolic state
- constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes
- irregular heart beat
- headache
- sleep disturbances
- sad mood (depression)
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin)
- dizziness
- tingling or numbness
- vision disorder