

CO-DIOVAN[®] FILM-COATED TABLET

Valsartan/Hydrochlorothiazide(80/12.5 mg, 160/12.5 mg, 160/25mg, 320/12.5 mg, 320/25mg)

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What Co-Diovan is used for

Co-Diovan contains an angiotensin-II receptor antagonist and a diuretic, which help control high blood pressure. Co-Diovan is used to treat high blood pressure. High blood pressure increases the workload of the heart and arteries (blood vessels). If it continues for a long time, it can damage the blood vessels of the brain, heart, 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.

How Co-Diovan works

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. Valsartan in Co-Diovan blocks the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered. Diuretics reduce the amount of salt and water in the body by increasing the flow of urine. With longer use this helps to reduce and control blood pressure. If you have any questions about how Co-Diovan works or why this medicine has been prescribed for you, ask your doctor.

Before you use Co-Diovan

You may take Co-Diovan only after a medical examination. Co-Diovan may not be suitable for all patients. Follow your doctor's instructions carefully. They may differ from the general information contained in this leaflet.

When you must not use it

- If you have had any unusual or allergic reaction to valsartan or to hydrochlorothiazide or sulfonamides or to any other component of this product listed at the end of this

leaflet. If you are not sure which medicines to avoid, ask your doctor or pharmacist;

- If you suffer from severe kidney disease with being unable to produce urine (anuria)
- 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 your doctor has told you that you have low levels of potassium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm).
- If your doctor has told you that you have low levels of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- If your doctor has told you that you have high levels of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- If your doctor has told you that you have high levels of uric acid in the blood.
- If you are pregnant or planning to become pregnant.
- If you have high level of sugar in the blood and you are suffering from type 2 diabetes (also called non-insulin dependent diabetes mellitus) while you are taking a blood pressure lowering medicine called aliskiren

If either of these applies to you, tell your doctor without taking Co-Diovan

Pregnant and breast-feeding

Do not take Co-Diovan if you are pregnant or planning to become pregnant. Use of similar medicines may cause serious harm to the 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-Diovan during pregnancy.

Breast-feeding

It is also advisable not to take Co-Diovan during breast-feeding. The diuretic component of Co-Diovan passes into the breast milk and may also reduce your milk supply. If you are breast-feeding, avoid using Co-Diovan unless recommended by your doctor.

Before you start to use it

Take special care with Co-Diovan

- If you suffer from kidney disorders;
- If you have previously experienced angioedema (swelling of the face, lips, throat and/or tongue) with valsartan or other medicines like ACE inhibitors;
- If you suffer from high blood pressure with renal artery stenosis which is the narrowing of the blood vessels of the kidneys;
- If you suffer from diabetes (high blood sugar in your blood);
- If you have fever, rash, and joint pain, which may be signs of lupus erythematosus (or a history of this disease);
- If you are suffering from allergy or asthma;
- If your doctor has told you that you have high levels of cholesterol or triglycerides in your blood;
- If you are suffering from vomiting or diarrhoea, or taking high doses of a diuretic (water pill);
- If you are breast feeding;
- 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 are treated with an ACE-inhibitor or aliskiren for high blood pressure.

If any of these apply to you, tell your doctor before taking Co-Diovan. If you get any of the described symptoms, tell your doctor straight away.

Older people (age 65 and over)

You can also use Co-Diovan if you are 65 years of age or older.

Children and adolescents

There is no experience with Co-Diovan in children.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. Remember also those not prescribed by a doctor. It may be necessary to change the dose or, in some cases, for you to stop taking one of the medicines. This applies to both prescription and non-prescription (over-the-counter) medicines, especially:

- Other medicines used to lower blood pressure, especially ACE-inhibitors or aliskiren;
- Potassium-sparing medicines, potassium supplements, or salt substitutes containing potassium; Your doctor may check the amount of potassium in your blood periodically;
- Some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of Co-Diovan;
- Lithium, antidepressants, antipsychotics, medicines used to treat some psychological conditions;
- Medicines used to relieve pain or inflammation, especially non-steroidal anti-inflammatory agents (NSAIDs), including Selective Cyclooxygenase-2 Inhibitors (Cox-2 inhibitors); your doctor may also check your kidney function;
- Cortisone-like medicines, steroids, carbenoxolone (a medicine used to treat ulceration and inflammation), antibiotics such as penicillin G, amphotericin, antiarrhythmics (medicines used to treat heart problems) These medicines may decrease the blood potassium level if used together with Co-Diovan;
- Digoxin or other digitalis glycosides (medicines used to treat heart problems);
- Muscle relaxant medicines; (medicines used during operations)
- 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);
- Certain cancer medicines;
- 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 and in autoimmune disorders);
- Insulin or antidiabetic medicines taken by mouth (medicines used to treat high levels of sugar in your blood);
- Cholestyramine, colestipol or other resins (medicines used mainly to treat high levels of fats in the blood);
- Vitamin D and calcium salts;
- Diazoxide (a medicine used to treat high blood pressure or low sugar level in the body);
- Antiepileptics, such as carbamazepine (medicines used to treat convulsions);
- Barbiturates, narcotics (medicines with sleep-inducing properties) and alcohol;
- Pressor amines, such as noradrenaline (substances that raise blood pressure).

How to use Co-Diovan

Follow your doctor's instructions carefully. Do not exceed the recommended dose. Patients who have 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 take your medicine exactly as the doctor or pharmacist tells you and to keep your appointments with the doctor even if you are feeling well. Co-Diovan is for oral use only.

How much to use

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 is one Co-Diovan (80/12.5 mg) or Co-Diovan (160/12.5 mg) or Co-Diovan (160/25 mg) or Co-Diovan (320/12.5 mg) or Co-Diovan (320/25 mg) tablet once a day. Do not change the dose or stop treatment without talking to your doctor.

When to take Co-Diovan

Taking Co-Diovan at the same time each day will help you remember when to take your medicine. You can take Co-Diovan with or without food.

Swallow your tablet with a glass of water.

How long to use Co-Diovan

Continue to take Co-Diovan as your doctor tells you. If you have questions about how long to take Co-Diovan, talk to your doctor or your pharmacist.

If you forget to use Co-Diovan

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 this medicine, take it as soon as possible. If it is almost time for the next dose, skip the missed dose and carry on with the next one at the usual time. Do not double dose.

If you use more Co-Diovan than you should (overdose)

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

While you are using Co-Diovan

Things you must do

- If you ever had a swelling mainly of the face and throat after taking this medicine, stop taking Co-Diovan and contact your doctor straight away. You should never take Co-Diovan again.
- It is important for your doctor to check your progress at regular visits to make sure that this medicine is working properly.
- 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 weeks of taking Co-Diovan. This can lead to permanent vision impairment, if not treated. If this happens to you, stop Co-Diovan and visit your doctor immediately.
- You might have regular blood tests before and during treatment with Co-Diovan. These will monitor the amount of electrolytes (such as potassium, sodium, calcium or magnesium) in your blood and may also monitor your kidney function, especially if you are over 65 years old, have certain heart, liver and kidney diseases, or are taking potassium supplements. Your doctor will advise you about this.

Things you must not do

Stopping your treatment with Co-Diovan may cause your disease to get worse. Do not stop taking your medicine unless instructed by your doctor.

Things to be careful of**Driving and using machines**

Like many other medicines used to treat high blood pressure, Co-Diovan may cause effects such as dizziness or fainting in some patients. So before you drive a vehicle, use machinery, or do other things that need concentration, make sure you know how you react to the effects of Co-Diovan.

Side effects

As with all medicines, patients taking Co-Diovan can experience side effects although not everybody gets them.

Some side effects could be serious

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

- Breathlessness (possible symptoms of non cardiogenic pulmonary edema)
- Sudden loss of consciousness (possible symptoms of syncope)
- Severely decreased urine output (possible symptoms of impaired kidney 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)

If you get any of these, tell your doctor immediately.

Some side effects are uncommon (these side effects may affect between 1 and 10 in every 1,000 patients)

- 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)

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

- Uric acid, creatinine, urea nitrogen in the blood increase. (abnormal kidney function test results)
- Bilirubin in the blood increase. (abnormal liver function test result)

The following effects have also been observed with Co-Diovan:

- Abdominal pain, upper abdominal pain
- anxiety, insomnia
- back pain, muscle strain, muscle spasms, ligament sprain, joint pain and stiffness (arthritis), weakness (asthenia)
- cough with phlegm together with chest pain and fever (bronchitis or bronchitis acute)
- chest pain
- fainting on standing up
- stomach discomfort after meal (dyspepsia)
- dry mouth
- nose bleeds (epistaxis)
- inability to achieve or maintain an erection (erectile dysfunction)
- inflammation of the stomach and intestines (gastroenteritis)
- headache
- excessive sweating (hyperhidrosis),
- decreased skin sensitivity (hypoesthesia)
- flu (influenza)
- blocked nose (nasal congestion), common cold (nasopharyngitis),
- neck pain
- swelling (edema), swollen hands, ankles or feet (edema peripheral),
- ear infection (otitis media),
- pain in extremity
- palpitations, fast heart beat (tachycardia)
- sore throat (pharyngolaryngeal pain),
- excessive frequent urination (pollakiuria)
- fever (pyrexia)
- feeling of pressure pain in the cheeks and forehead (sinusitis), sinus congestion,
- drowsiness (somnia),
- upper respiratory tract infections, urinary tract infections, viral infections
- spinning sensation (vertigo)

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

The following, other possibly serious, additional undesirable effects have been reported with other products containing either valsartan or hydrochlorothiazide alone.

- decrease of level of hemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- unusual bleeding or bruising (thrombocytopenia), rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (other hypersensitivity/allergic reactions including serum sickness)
- abnormal heart rhythm (increase of serum potassium or arrhythmia)
- purplish-red spots, fever, itching (vasculitis)
- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (angioedema)
- blistering skin (sign of dermatitis bullous), rash, itching (pruritus)
- severely decreased urine output (kidney failure)
- facial rash, joint pain, muscle disorder, fever (possible signs of Systemic Lupus Erythematosus)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of Toxic Epidermal Necrolysis, erythema multiforme)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (possible signs of hypochloreaemic alkalosis)
- gastrointestinal disturbances, such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching (possible signs of hypercalcemia)
- severe or persistent vomiting or diarrhea
- fever, sore throat, more frequent infections (possible signs of agranulocytosis)
- fever, sore throat or mouth ulcers due to infections (possible signs of leucopenia)
- pale skin, tiredness, breathlessness, dark urine (possible signs of hemolytic anemia)
- decrease in vision or pain in your eyes due to high pressure (possible

- signs of acute angle-closure glaucoma)
- high levels of lipids and uric acid in your blood (hyperlipidemia, hyperuricaemia)
- low levels of magnesium in your blood (hypomagnesaemia)
- decreased appetite
- high levels of sugar in your blood or in your urine (hyperglycemia, glycosuria)
- increased sensitivity of the skin to sun (photosensitivity)
- abdominal discomfort, constipation
- yellow eyes and skin (cholestasis or jaundice)
- headache
- depression

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

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and disposal of Co-Diovan

Storage

- Keep out of the reach and sight of children.
- Do not store above 30°C
- Store your tablets in the original package.
- Do not take Co-Diovan after the expiry date shown on the pack.

Disposal

- Any unused product or waste material should be disposed of in accordance with local requirements.

Product Description

What it looks like

Co-Diovan is supplied as film-coated-tablets in five strengths:

- Co-Diovan film-coated tablets (80/12.5 mg) containing 80 mg valsartan and 12.5 mg hydrochlorothiazide. They are ovaloid, non-divisible, film-coated tablets. The tablets are coloured light orange and imprinted with HGH on one side and CG on the other side.

- Co-Diovan film-coated tablets (160/12.5 mg) containing 160 mg valsartan and 12.5 mg hydrochlorothiazide. They are ovaloid, non-divisible, film-coated tablets. The tablets are coloured dark red and imprinted with HHH on one side and CG on the other side.

- Co-Diovan film-coated tablets (160/25 mg) containing 160 mg valsartan and 25 mg hydrochlorothiazide. They are ovaloid, non-divisible, film-coated tablets. The tablets are coloured brown-orange and imprinted with HXH on one side and NVR on the other side.

- Co-Diovan film-coated tablets (320/12.5 mg) containing 320 mg valsartan and 12.5 mg hydrochlorothiazide. They are ovaloid, non-divisible, film-coated tablets. The tablets are coloured pink and imprinted with HIL on one side and NVR on the other side.

- Co-Diovan film-coated tablets (320/25 mg) containing 320 mg valsartan and 25 mg hydrochlorothiazide. They are ovaloid, non-divisible, film-coated tablets. The tablets are coloured yellow and imprinted with CTI on one side and NVR on the other side.

Ingredients

- Active ingredients
 - The active substances of Co-Diovan are valsartan (80 mg, 160 mg or 320 mg) and hydrochlorothiazide (12.5 mg or 25 mg)
- Inactive ingredients
 - 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). The 320/12.5 mg tablets contain in addition black iron oxide (E172) and red iron oxide (E172). The 320/25 mg tablets contain in

addition only yellow iron oxide (E172).

MAL Number

Co-Diovan 80/12.5mg Film-Coated Tablets:

MAL09062164ARS

Co-Diovan 160/12.5mg Film-Coated Tablets:

MAL09062165ARS

Co-Diovan 160/25mg Film-Coated Tablets:

MAL09062166ARS

Co-Diovan 320/12.5mg Film-Coated Tablets: MAL09051533AR

Co-Diovan 320/25mg Film-Coated Tablets: MAL09051534AR

Manufacturer

320/12.5mg , 320/25mg:

Novartis Pharma Stein AG, Schaffhauserstrasse, CH-4332 Stein, Switzerland

80/12.5mg, 160/12.5mg, 160/25mg:

Novartis Farma S.P.A., Via Provinciale Schito 131, 80058 Torre Annunziata, Italy

Product Registration Holder

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