

Information for patients

Read this leaflet carefully before taking this medicine. This medicine has been prescribed for you personally. Do not pass it on to anyone else. It may harm them even if their symptoms are the same as yours. Keep this leaflet. You may want to read it again later.

Co-Diovan®

What Co-Diovan is and what it is used for

Co-Diovan contains two complementary active substances that act on the system that regulates blood pressure in the body: valsartan, which primarily serves to widen the blood vessels, decreasing the blood pressure, and hydrochlorothiazide, which reduces the amount of sodium chloride and water in the body by increasing urine output.

Co-Diovan is used to treat mild and moderate high blood pressure in patients whose high blood pressure requires a combination drug. Your doctor can check and demonstrate the effect of this medicine by measuring blood pressure. Co-Diovan must only be used if prescribed by your doctor.

Additional information to be aware of Why high blood pressure (hypertension) should be treated

If high blood pressure is not treated, vital organs such as the heart, kidneys and brain may be damaged. You may feel well and have no symptoms, but untreated hypertension may cause long-term effects such as stroke, heart attack, heart failure, kidney function disorders or blindness.

Do not take Co-Diovan

Do not take Co-Diovan if you have ever have an allergic (hypersensitivity) reaction to valsartan, hydrochlorothiazide or any other ingredient of this medicine. Do not take Co-Diovan if you are pregnant, plan to become pregnant or are breast-feeding, if you have biliary cirrhosis (destruction of the small bile ducts in the liver) leading to a decrease in the flow of bile (cholestasis), if you have diabetes (type 1 or 2) or reduced kidney function and are taking aliskiren to lower your blood pressure, or if you produce a severely decreased amount of urine (anu-

ria). If you have hereditary angioedema. Do not take Co-Diovan if you have ever experienced swelling of your face, lips, tongue or throat (difficulty swallowing or breathing) when taking a medicine to lower blood pressure.

Warnings and precautions

As with any other blood pressure-lowering medicine, Co-Diovan can also affect your attention and concentration levels. Therefore, caution is required when driving or using tools or machines.

Caution is required:

- If you have a kidney or liver disorder, allergies or asthma.
- If you experience reactions such as swelling of the face, arms and legs, eyes, lips or tongue (signs of angioedema) after taking Co-Diovan. In such cases you must be monitored and may need to be treated accordingly.

Potentially low levels of salt/fluids due to excessive vomiting, diarrhoea or diuretics (medicines that increase urine output) should be corrected before starting treatment with Diovan. Your doctor may also check your kidney function. Caution is required if you are being treated with an ACE inhibitor or aliskiren (medicines to treat high blood pressure). If you experience vision loss or eye pain, this may be due to a build-up of fluid in the blood vessels of the eye (choroidal effusion) or increased pressure in the eye. This can occur within a few hours or weeks of taking Co-Diovan and may lead

to permanent vision loss if treatment is not started in time. If you have a penicillin or sulphonamide allergy, the risk of experiencing choroidal effusion may be increased.

If you have heart failure or have had a heart attack, caution is also required. Follow your doctor's instructions on the starting dose carefully. Your doctor may also check your kidney function.

Tell your doctor before starting treatment with Co-Diovan if you:

- Have a mild to moderate kidney or liver disorder
- Have an acute rash (lupus erythematosus)
- Have hyperuricaemia, gout or diabetes
- Have or have ever had low blood potassium or sodium levels or high blood calcium levels
- If you have ever had skin cancer or if you notice an unexpected skin change during treatment. Treatment with hydrochlorothiazide (one of the active substances of Co-Diovan), particularly for a prolonged period and at a high dosage, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer), possibly due to increased skin sensitivity to UV radiation. Protect your skin from sunlight and UV rays during treatment with Co-Diovan. Regularly have your skin checked for new changes and tell your doctor immediately if you notice any suspicious changes to your skin.

Interactions with other medicines

When Co-Diovan is used with other medicines, interactions may occur (strengthening or weakening of the effect of Co-Diovan or of the other medicine or increased side effects). These include: medicines containing potassium, salt substitutes containing potassium or other medicines that may increase the amount of potassium in the blood (e.g. heparin for thinning the blood; your doctor may periodically check the amount of potassium in your blood), medicines used to treat inflammation or pain (non-steroidal anti-inflammatory drugs (NSAIDs), including COX-2 inhibitors), lithium (a medicine used to treat certain mental illnesses), diuretics (medicines that increase urine output), ACE inhibitors or aliskiren, cortisone-like medicines (steroids), antiarrhythmics (used to treat heart rhythm disorders), certain medicines used to treat infections (amphotericin B, penicillin G, rifamycin group), other blood pressure-lowering medicines, digoxin or other digitalis glycosides (heart medicines), insulin or antidiabetic medicines taken by mouth, allopurinol (medicine used to treat gout), amantadine (used to treat Parkinson's disease and for certain viral diseases), certain cancer medicines, anticholinergic agents (used to treat various disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscle spasms, Parkinson's disease and as an aid to anaesthesia), colestyramine, colestipol and other resins (used to treat high levels of blood

fats), medicines that relax the muscles (muscle relaxants), vitamin D and calcium salts, ciclosporin (used to prevent organ rejection after transplantation or in other diseases such as rheumatoid arthritis or neurodermatitis), ritonavir (an antiretroviral medicine used to treat HIV/AIDS infection), medicines used to treat epilepsy such as carbamazepine, diazoxide (high blood pressure or low blood sugar), lithium, antidepressants, antipsychotics (used to treat certain mental illnesses), pressor amines (substances that raise blood pressure such as noradrenaline), barbiturates, narcotics (medicines with sleep-inducing properties) and alcohol. Tell your doctor if you are using any other medicines. Your doctor will decide which medicines you can use at the same time as Co-Diovan and may adjust the dose of a medicine.

Tell your doctor or pharmacist if you:

- Have any other illnesses
- Have any allergies
- Are taking or have recently taken any other medicines or are externally applying any other medicines (including non-prescription medicines).

Pregnancy and breast-feeding

Do not take Co-Diovan if you are pregnant or planning to become pregnant.

Similar medicines have been associated with serious harm to unborn children, particularly when taken after the third month of pregnancy. No data are available on this for Co-Diovan. Therefore, it is important to consult your doctor immediately if you think you may be pregnant. Tell your doctor if you are planning to become pregnant. You must stop breast-feeding if treatment is required during breast-feeding.

How to use Co-Diovan

Your doctor will decide the right dosage for you. The usual dose is 1 film-coated tablet of Co-Diovan 80/12.5 (corresponds to 80 mg valsartan and 12.5 mg hydrochlorothiazide) once daily. If the reduction in blood pressure is not sufficient after 3-4 weeks, your doctor may first increase your dose to Co-Diovan 160/12.5 (corresponds to 160 mg valsartan and 12.5 mg hydrochlorothiazide) and then to Co-Diovan 160/25 (corresponds to 160 mg valsartan and 25 mg hydrochlorothiazide). The dose does not depend on your age. However, the efficacy and safety of treatment in children and adolescents under 18 years of age have not been studied. Therefore, the use of Co-Diovan in children and adolescents is not recommended. Co-Diovan should be taken with liquid. It can be taken with or without food. However, it is recommended to take Co-Diovan at the same time each day (e.g. in the morning).

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose. Do not stop your treatment unless your doctor tells you to. Do not change the prescribed dosage yourself. If you think the effect of your medicine is too weak or too strong, talk to your doctor or pharmacist.

Possible side effects

The following side effects may occur when taking Co-Diovan: Common side effects include headache, tiredness, light-headedness, decreased blood pressure when standing up, cough, nasal congestion, throat inflammation, infection of the upper airways, loss of appetite, diarrhoea, rash, back pain, joint pain, impotence. Uncommon side effects were viral infection, fever, weakness, dizziness, sleeplessness, anxiety, sensory disturbances, visual disturbances, middle ear inflammation, ringing in the ears, palpitations, rapid heartbeat, oedema, low blood pressure, excessive sweating, bronchitis, difficulty breathing, inflammation of the sinuses, sore throat, dry mouth, dehydration, abdominal pain, indigestion, nausea and vomiting, pain in the arms, legs, chest or neck, joint inflammation, sprains and strains, muscle spasm, frequent urination, urinary tract infection or decreased libido. Rare side effects were worsening of diabetic metabolic state, depression, consti-

pation, jaundice, sensitivity to light, conjunctival inflammation, visual impairment or pain in the eyes (high pressure in the eyes), heart rhythm disorders, muscle or nerve pain, severely decreased urine output (kidney disorder or kidney failure). Very rare side effects may include fainting, allergic hypersensitivity reactions with swelling of the face, redness or itching, reactivation of cutaneous lupus erythematosus, kidney function disorders, breathing difficulties, including lung inflammation and pulmonary oedema, nosebleed or severe upper abdominal pain (pancreatitis). Blistering of the skin, muscle spasms and weakness (asthenia) were also reported as well as skin and lip cancer (non-melanoma skin cancer: appearance of a lump or discoloured patch on the skin that does not disappear even after a few weeks and slowly grows over months or sometimes years or reddish/pink firm cancerous lumps that 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 body or back). If you notice any side effects which are not described here, tell your doctor or pharmacist. You should also show your doctor any unexpected changes to your skin that you notice during treatment with Co-Diovan without delay.

Further information

Keep out of the reach of children. Protect Co-Diovan from moisture and do not store above 30°C. Do not use after the expiry date (= EXP) printed on the pack. Your doctor or pharmacist will be able to give you more information. They have access to the full prescribing information.

What Co-Diovan contains

Co-Diovan 80/12.5 film-coated tablets contain the active substances valsartan (80 mg) and hydrochlorothiazide (12.5 mg).

Excipients :Colloidal silicon dioxide; crospovidone; hydroxypropyl methylcellulose; magnesium stearate; microcrystalline cellulose; polyethylene glycol; talc; titanium dioxide (E171); red iron oxide (E172); yellow iron oxide (E172). Co-Diovan 160/12.5 film-coated tablets contain the active substances valsartan (160 mg) and hydrochlorothiazide (12.5 mg).

Excipients: Colloidal silicon dioxide; crospovidone; hydroxypropyl-methylcellulose; magnesium stearate; microcrystalline cellulose; polyethylene glycol; talc; titanium dioxide (E171); red iron oxide (E172).

Co-Diovan 160/25 film-coated tablets contain the active substances valsartan (160 mg) and hydrochlorothiazide (25 mg)

Excipients: Colloidal silicon dioxide; crospovidone; hydroxypropyl methylcellulose; magnesium stearate; microcrystalline cellulose; polyethylene glycol; talc; titanium dioxide (E171), red iron oxide (E172), yellow iron oxide (E172), black iron oxide (E172).

Availability/pack sizes

Available only in pharmacies with a doctor's prescription.

Co-Diovan 80/12.5 film-coated tablets: 28 or 98

Co-Diovan 160/12.5 film-coated tablets: 28 or 98

Co-Diovan 160/25 film-coated tablets: 28 or 98

Not All pack sizes are marketed

Manufacturer

Novartis Farma S.p.A., Torre Annunziata, Italy for Novartis Pharma AG Lichtstrasse 35 Basel, Switzerland

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® = registered trademark Novartis Pharma AG, Basle, Switzerland

This is a medicament

– A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of reach of children

Council of Arab Health Ministers Union of Arab Pharmacist