

Package leaflet: Information for the user

Co-Vatan 80 mg/12.5 mg Film-Coated Tablets

Co-Vatan 160 mg/12.5 mg Film-Coated Tablets

Co-Vatan 160 mg/25 mg Film-Coated Tablets

Co-Vatan 320 mg/12.5 mg Film-Coated Tablets

Co-Vatan 320 mg/25 mg Film-Coated Tablets

Valsartan/hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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



1 What Co-Vatan is and what it is used for

Co-Vatan 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-Vatan 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 What you need to know before you take Co-Vatan

Do not take Co-Vatan

- if you are allergic to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or to any of the other ingredients of this medicine (listed in section 6),
- if you are **more than 3 months pregnant** (it is also better to avoid Co-Vatan 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 **diuretic**.

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

Warnings and precautions

Talk to your doctor before taking Co-Vatan

- 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-Vatan 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 which makes swallowing and breathing difficult
- if you are taking ACE inhibitors, tell your doctor, if these occur when you are taking Co-Vatan, stop taking Co-Vatan 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-Vatan. 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
- if you are taking any of the following medicines used to treat high blood pressure:
 - "ACE inhibitors" such as enalapril, lisinopril, etc.
 - diuretic

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

You must tell your doctor if you think you are (or might become) pregnant. Co-Vatan 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).

Children and adolescents

The use of Co-Vatan in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and Co-Vatan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effect of the treatment can be influenced if Co-Vatan 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, carbenoxalone, amphotericin or penicillin G
- some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS

infection (HIV virus). These medicines may increase the effect of Co-Vatan.

- 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, anti-epileptics
- 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 insulin)
- other medicines to lower your blood pressure including methylgluta, ACE inhibitors (such as enalapril, lisinopril, etc.) or diuretic
- 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 more than 3 grams of acetylsalicylic acid per day
- 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 to speed heart or prevent certain illnesses caused by virus)
- 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 paralyzing effect used for example during surgery)
- iodine contrast media (agents used for imaging examinations).

Co-Vatan with food, drink and alcohol

You can take Co-Vatan 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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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-Vatan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Co-Vatan. Co-Vatan 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-Vatan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breastfeed, 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-Vatan affects you. Like many other medicines used to treat high blood pressure, Co-Vatan may occasionally cause dizziness and affect the ability to concentrate.

3 How to take Co-Vatan

Always take this medicine exactly as your doctor has told you. This will help you to get the best results and lower the risk of side effects. 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-Vatan to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

- The recommended dose of Co-Vatan 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-Vatan with or without food
- Swallow the tablet with a glass of water.

If you take more Co-Vatan 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-Vatan

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-Vatan

Stopping your treatment with Co-Vatan 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 medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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-Vatan and contact your doctor straight away (see also section 2 "Warnings and precautions").

Other side effects include:

Uncommon, affects 1 to 10 per 1,000 users

- cough
 - low blood pressure
 - lightheadedness
 - dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark coloured urine, dry skin)
 - muscle pain
 - tiredness
 - ringing or numbness
 - blurred vision
 - noises (e.g. hissing, buzzing) in ears.
- Very rare, affects less than 1 per 10,000 users
- dizziness
 - diarrhoea
 - joint pain.

Frequency, not known, according to the available data

- 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 infection, 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 valproton or hydrochlorothiazide alone.

Valproton

Uncommon, affects 1 to 10 per 1,000 users

- spinning sensation
- abdominal pain

Frequency, not known, according to the available data

- blistering skin (sign of dermatitis bullois)
- 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, purplish-red spots, fever, itching (symptom 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 mostly 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, affects more than 1 per 10 users

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

Common, affects 1 to 10 per 100 users

- 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, affects 1 to 10 per 10,000 users

- 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
- ringing or numbness
- vision disorder.

Very rare, affects less than 1 per 10,000 users

- 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)
 - focal rash, joint pain, muscle disorder, fever (lupus erythematosus)
 - severe upper stomach pain (pancreatitis)
 - difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress including pneumonia and pulmonary oedema)
 - fever, sore throat, more frequent infections (leucopenia)
 - 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 (hypochloreaemic alkalosis).
- Frequency, not known, according to the available data
- weakness, bruising and frequent infections (oplastic anaemia)
 - 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 HPRA Pharmacovigilance, Earlsfort Terrace, 181, Dublin 2, Tel: +353 1 67646971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medic@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Co-VaTan

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Do not use any Co-VaTan pack that is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

- The active substances are valproton and hydrochlorothiazide.

Each tablet contains 80 mg of valproton and 12.5 mg of hydrochlorothiazide

Each tablet contains 160 mg of valproton and 12.5 mg of hydrochlorothiazide

Each tablet contains 160 mg of valproton and 25 mg of hydrochlorothiazide

Each tablet contains 320 mg of valproton and 12.5 mg of hydrochlorothiazide.

Each tablet contains 320 mg of valproton and 25 mg of hydrochlorothiazide.

- The other ingredients are:

Tablet core:
microcrystalline cellulose, croscarmellose, magnesium stearate, colloidal anhydrous silica

Coating:
hypromellose, macrogol 8000, i.e.c. titanium dioxide [E171], red iron oxide [E172], yellow iron oxide [E172], black iron oxide [E172].

Tablet core:
microcrystalline cellulose, croscarmellose, magnesium stearate, colloidal anhydrous silica

Coating:
hypromellose, macrogol 4000, i.e.c. titanium dioxide [E171], red iron oxide [E172], black iron oxide [E172].

Tablet core:
microcrystalline cellulose, croscarmellose, magnesium stearate, colloidal anhydrous silica

Coating:
hypromellose, macrogol 4000, i.e.c. titanium dioxide [E171], yellow iron oxide [E172].

Coating:
hypromellose, macrogol 4000, i.e.c. titanium dioxide [E171], red iron oxide [E172], black iron oxide [E172].

What Co-VaTan looks like and contents of the pack

Co-VaTan 80 mg/12.5 mg film-coated tablets
Film-coated tablet, light orange, ovaloid, slightly convex faces, imprinted (debossed) with "HGT" on one side and "CG" on the reverse side

Co-VaTan 160 mg/25 mg film-coated tablets
Film-coated tablet, brown orange, ovaloid, slightly convex faces, imprinted (debossed) with "HMT" on one side and "NVR" on the reverse side

Co-VaTan 160 mg/12.5 mg film-coated tablets
Film-coated tablet, dark red, ovaloid, slightly convex faces, imprinted (debossed) with "HHT" on one side and "CG" on the reverse side.

Co-VaTan 320 mg/25 mg film-coated tablets
Yellow, ovaloid shaped, bevelled edge, film coated tablet, imprinted (debossed) with "NVR" on one side and "CTI" on the reverse side

Pack sizes: one pack contains 7, 10, 14, 15, 20, 28, 30, 50, 50x1, 56, 60, 84, 90, 98, 100 or 280 film-coated tablets.

All pack sizes may be marketed.

Marketing Authorization Holder and Marketing Authorisation Holder

Manufacturers
Sollus Pharma GmbH, Olivo-von-Guericke-Allee 1, 39179 Bortheim, Germany.
Lek S.A., Ul. Dąbrowskiego 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.
Lek Pharmaceuticals d.d., Trzinčevi 2 D, 9220 Lendava, Slovenia.
Novartis Farma S.p.A., Via Pionini 131, 80058 Torre Annunziata, Italy.
Novartis Pharma GmbH, Roonstrasse 25, 90429 Nuremberg, Germany.
S.C. Sandoz S.R.L., Str. Livezeni nr. 7A, 540472 Targu-Mures, Romania.

This medicinal product is authorised in the Member States of the EEA under the following names:

Sweden:
Co-VaTan 80mg/12.5 mg
film-coated tablet
Co-VaTan 160mg/12.5 mg
film-coated tablet
Co-VaTan 160mg/25 mg
film-coated tablet
Co-VaTan 320mg/12.5 mg
film-coated tablet
Co-VaTan 320mg/25 mg
film-coated tablet

Austria:
Valproton/HCT Hexal 80 mg/12.5 mg - Filmtabletten
Valproton/HCT Hexal 160 mg/12.5 mg - Filmtabletten
Valproton/HCT Hexal 160 mg/25 mg - Filmtabletten
Valproton/HCT Hexal 320 mg/12.5 mg - Filmtabletten
Valproton/HCT Hexal 320 mg/25 mg - Filmtabletten

Germany:
Valproton HEXAL comp.
80mg/12.5mg Filmtabletten
Valproton HEXAL comp.
160mg/12.5mg Filmtabletten
Valproton HEXAL comp.
160mg/25mg Filmtabletten
Valproton HEXAL comp.
320mg/12.5mg Filmtabletten
Valproton HEXAL comp.
320mg/25mg Filmtabletten

Spain:
Valproton Hidroclorizato Bexel 80/12.5 mg comprimidos recubiertos con película EFG
Valproton Hidroclorizato Bexel 160/12.5 mg comprimidos recubiertos con película EFG
Valproton Hidroclorizato Bexel 160/25 mg comprimidos recubiertos con película EFG
Valproton Hidroclorizato Bexel 320/12.5 mg comprimidos recubiertos con película EFG
Valproton Hidroclorizato Bexel 320/25 mg comprimidos recubiertos con película EFG

Ireland:
Co-VaTan 80 mg/12.5 mg Film-coated tablets
Co-VaTan 160 mg/12.5 mg Film-coated tablets
Co-VaTan 160 mg/25 mg Film-coated tablets
Co-VaTan 320 mg/12.5 mg Film-coated tablets
Co-VaTan 320 mg/25 mg Film-coated tablets

Luxemburg:
Valproton HEXAL comp.
80mg/12.5mg Filmtabletten
Valproton HEXAL comp.
160mg/12.5mg Filmtabletten
Valproton HEXAL comp.
160mg/25mg Filmtabletten
Valproton HEXAL comp.
320mg/12.5mg Filmtabletten
Valproton HEXAL comp.
320mg/25mg Filmtabletten

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