

Valsartan and Hydrochlorothiazide 80 mg/12.5 mg film-coated tablets

Valsartan and Hydrochlorothiazide 160 mg/12.5 mg film-coated tablets

Valsartan and Hydrochlorothiazide 160 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 Valsartan and Hydrochlorothiazide is and what it is used for
2. What you need to know before you take Valsartan and Hydrochlorothiazide
3. How to take Valsartan and Hydrochlorothiazide
4. Possible side effects
5. How to store Valsartan and Hydrochlorothiazide
6. Contents of the pack and other information

1. What Valsartan and Hydrochlorothiazide is and what it is used for

Valsartan and Hydrochlorothiazide 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.

Valsartan and Hydrochlorothiazide 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 Valsartan and Hydrochlorothiazide

Do not take Valsartan and Hydrochlorothiazide:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or 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 Valsartan and Hydrochlorothiazide 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.

Warnings and precautions

Talk to your doctor or pharmacist before using Valsartan and Hydrochlorothiazide

- if you 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 (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Valsartan and Hydrochlorothiazide.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Valsartan/ Hydrochlorothiazide seek medical attention immediately.
- 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 Valsartan and Hydrochlorothiazide 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 Valsartan/Hydrochlorothiazide, stop taking Valsartan/Hydrochlorothiazide 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 fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Valsartan/Hydrochlorothiazide. 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:
 - an “ACE-inhibitor” (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading “Do not take Valsartan and Hydrochlorothiazide”

Children and adolescents

The use of Valsartan and Hydrochlorothiazide 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. Valsartan and Hydrochlorothiazide 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).

Other medicines and Valsartan and Hydrochlorothiazide

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 Valsartan and Hydrochlorothiazide 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 (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Valsartan/ Hydrochlorothiazide.
- 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).

Valsartan and Hydrochlorothiazide with food, drink and alcohol

You can take Valsartan and Hydrochlorothiazide 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

- **You must tell your doctor if you think that you are (or might become) pregnant**
Your doctor will normally advise you to stop taking Valsartan and Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan and Hydrochlorothiazide. Valsartan and Hydrochlorothiazide 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**
Valsartan and Hydrochlorothiazide 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 Valsartan and Hydrochlorothiazide affects you. Like many other medicines used to treat high blood pressure, this medicine may occasionally cause dizziness and affect the ability to concentrate.

Valsartan and Hydrochlorothiazide contains lactose

You have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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