

Package leaflet: Information for the user

Valsartan/Hydrochlorothiazide 320 mg/12.5 mg film-coated tablets Valsartan/Hydrochlorothiazide 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.

What is in this leaflet:

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

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

Valsartan/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/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/Hydrochlorothiazide

Do not take Valsartan/Hydrochlorothiazide:

- if you are allergic to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide), soya, peanut 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 Valsartan/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 urinate.
- 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 any of the above apply to you, do not take this medicine and speak to your doctor.

Warnings and precautions Valsartan/Hydrochlorothiazide

Talk to your doctor or pharmacist before taking Valsartan/Hydrochlorothiazide:

- 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/Hydrochlorothiazide is not recommended.
- if you have liver or kidney disease.
- if you have ever experienced swelling of the tongue and face caused by allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when 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 fats 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 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.

The use of Valsartan/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/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/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/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 that may induce “torsades de pointes” (irregular heart beat) such as antiarrhythmics (medicines used to treat heart problems) and some antipsychotics
- medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or potassium-containing salt substitutes, potassium-sparing medicines and heparin
- medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, some 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 Valsartan/Hydrochlorothiazide.
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics (such as carbamazepine)
- 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, such as beta-blockers or methyl dopa
- medicines that tighten your blood vessels or stimulate your heart, 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 spasm, Parkinson’s disease and as an aid to anaesthesia) such as atropine or biperiden
- amantadine (a medicine used to treat Parkinson’s disease and prevent influenza)
- cholestyramine and colestipol (medicines used to treat high levels of lipids in the blood)
- 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/Hydrochlorothiazide with food, drink and alcohol

You can take Valsartan/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, breast-feeding and fertility

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 Valsartan/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/Hydrochlorothiazide. Valsartan/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/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/Hydrochlorothiazide affects you. Like many other medicines used to treat high blood pressure, Valsartan/Hydrochlorothiazide may occasionally cause dizziness and affect the ability to concentrate.

Valsartan/Hydrochlorothiazide contains lactose and soya oil

This medicine contains lactose, if you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Valsartan/Hydrochlorothiazide contains soya oil. If you are allergic to peanut or soya, do not take this medicinal product.

3. How to take Valsartan/Hydrochlorothiazide

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 Valsartan/Hydrochlorothiazide to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

- The recommended dose of Valsartan/Hydrochlorothiazide 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 Valsartan/Hydrochlorothiazide with or without food.
- Swallow the tablet with a glass of water.

If you take more Valsartan/Hydrochlorothiazide 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 Valsartan/Hydrochlorothiazide

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 Valsartan/Hydrochlorothiazide

Stopping your treatment with Valsartan/Hydrochlorothiazide 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 (allergic reaction), such as:

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

Other side effects include:

Uncommon (may affect up to 1 in 100 people)

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

Very rare (may affect up to 1 in 10,000 people)

- dizziness
- diarrhoea
- joint pain

Not known (frequency cannot be estimated from the available data)

- breathing difficulty
- severely decreased urine output
- low level of sodium in the blood (sometimes with nausea, tiredness, confusion, malaise, 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 (may affect up to 1 in 100 people)

- spinning sensation
- abdominal pain

Not known (frequency cannot be estimated from the available data)

- 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 (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 (may affect more than 1 in 10 people)

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

Common (may affect up to 1 in 10 people)

- 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 (may affect up to 1 in 1,000 people)

- 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

Very rare (may affect up to 1 in 10,000 people)

- 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 (frequency cannot be estimated from the available data)

- weakness, bruising and frequent infections (aplastic 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)

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store Valsartan/Hydrochlorothiazide

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 carton, tablet container or blister. The expiry date refers to the last day of that month.

PVC/PE/PVDC-Al blisters: Do not store above 25°C.

Polyethylene tablet containers: This medicinal product does not require any special storage conditions
Shelf life after first opening of the tablet container is 100 days.

Do not throw away any medicines via wastewater or household waste. 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

What Valsartan/Hydrochlorothiazide contains

- The active substances are valsartan and hydrochlorothiazide.
Each film-coated tablet contains 320 mg of valsartan and 12.5 mg of hydrochlorothiazide.
Each film-coated tablet contains 320 mg of valsartan and 25 mg of hydrochlorothiazide.
- The other ingredients are: *tablet core*: Microcrystalline Cellulose, Lactose Monohydrate, Croscarmellose Sodium, Povidone K29-K32, Talc, Magnesium Stearate, Colloidal Anhydrous Silica; *film-coat*:
[320/12.5 mg tablets] Polyvinyl Alcohol, Talc, Titanium Dioxide (E171), Macrogol 3350, Iron Oxide Yellow (E172), Lecithin (contains soya oil) (E322), Iron Oxide Red (E172).
[320/25 mg tablets] Polyvinyl Alcohol, Talc, Titanium Dioxide (E171), Macrogol 3350, Iron Oxide Yellow (E172), Lecithin (contains soya oil) (E322), Iron Oxide Red (E172).

What Valsartan/Hydrochlorothiazide looks like and contents of the pack

Valsartan/Hydrochlorothiazide 320 mg/12.5 mg film-coated tablets: Pink, oval, biconvex film-coated tablets, 18.9 x 7.5 mm, marked 'V' on one side and 'H' on the other.

Valsartan/Hydrochlorothiazide 320 mg/25 mg film-coated tablets: Yellow, oval, biconvex film-coated tablets, 18.9 x 7.5 mm, score on one face and side-scores, marked 'V' on one side and 'H' on the other.

The tablet can be divided into equal halves.

Pack sizes

Blister: 7, 10, 14, 20, 28, 30, 56, 90, 98 or 100 film-coated tablets

Tablet container: 100 film-coated tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Actavis Group PTC ehf

Reykjavíkurvegi 76-78

220 Hafnarfjörður

Iceland

Manufacturer

Actavis Ltd

BLB016, Bulebel Industrial Estate

Zejtun

ZTN3000

Malta

Balkanpharma – Dupnitsa AD

3 Samokovska Schosse Str

Dupnitsa 2600

Bulgaria

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

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| Austria | Valsartan/HCT Actavis 320 mg /12,5 mg, 320 mg /25 mg Filmtabletten |
| Bulgaria | Valtensin plus |
| Cyprus | Valsartan/HCT Sigillata |

| | |
|-------------|---|
| Finland | Valsartan/Hydroklortiazid Actavis 320 mg / 12,5 mg ja 320 mg / 25 mg kalvopäällysteiset tabletit |
| Germany | Valsartan – Actavis comp 320 mg/12,5 mg & 320 mg/25 mg Filmtabletten |
| Hungary | Valsartan HCT Actavis 320 mg/12,5 mg & 320 mg/25 mg filmtabletta |
| Ireland | Valsartan/Hydrochlorothiazide |
| Italy | VALSARTAN E IDROCLOROTIAZIDE ACTAVIS |
| Lithuania | Valsartan HCT Actavis |
| Malta | Valsartan/HCT Sigillata |
| Netherlands | Valsartan/Hydrochloorthiazide Actavis |
| Norway | Valsartan/Hydrochlorthiazid Actavis |
| Portugal | Valsartan + Hidroclorotiazida Actavis |
| Spain | Valsartán/Hidroclorotiazida Actavis 320 mg/12,5 mg & 320 mg/ 25 mg comprimidos recubiertos con película EFG |

This leaflet was last revised in April 2013.