

PACKAGE LEAFLET

Package leaflet: Information for the patient

Valsartan/Hydrochlorothiazide Rivopharm 80 mg/12.5 mg film-coated tablets
Valsartan/Hydrochlorothiazide Rivopharm 160 mg/12.5 mg film-coated tablets
Valsartan/Hydrochlorothiazide Rivopharm 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Valsartan/Hydrochlorothiazide Rivopharm 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 Rivopharm 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 Rivopharm

Do not take Valsartan/Hydrochlorothiazide Rivopharm:

- if you are allergic to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) soya oil, peanut oil 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 Rivopharm 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 you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing 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, pharmacist or nurse before taking Valsartan/Hydrochlorothiazide Rivopharm, especially:

- 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 Rivopharm 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 Rivopharm, stop taking Valsartan/Hydrochlorothiazide Rivopharm immediately and never take it again. See also section 4.
- 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 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 Rivopharm. 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 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/Hydrochlorothiazide Rivopharm.
- 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.

- 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 Rivopharm, seek medical attention immediately.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Valsartan/Hydrochlorothiazide Rivopharm. Your doctor will decide on further treatment. Do not stop taking Valsartan/Hydrochlorothiazide Rivopharm on your own.

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/Hydrochlorothiazide Rivopharm”

Children and adolescents

The use of Valsartan/Hydrochlorothiazide Rivopharm in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and Valsartan/Hydrochlorothiazide Rivopharm

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 Rivopharm 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 illness
- 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 (hypokalaemia), such as diuretics (water tablets), corticosteroids (e.g prednisone), some laxatives (e.g castor oil), ACTH (a hormone), carbenoxolone (used to treat mouth ulcers), amphotericin (an antifungal medicine), penicillin G (an antibiotic), salicylic acid and derivatives.
- 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 Rivopharm.
- 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 methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings “Do not take Valsartan/Hydrochlorothiazide Rivopharm” and “Warnings and precautions”)
- 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 and arthritis medicines, 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), such as atropine or biperiden
- amantadine (a medicine used to prevent influenza and treat Parkinson's disease)
- cholestyramine and colestipol (medicines used to treat high levels of fats 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/Hydrochlorothiazide Rivopharm with food and alcohol

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

Valsartan/Hydrochlorothiazide Rivopharm 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 Rivopharm contains soya oil

If you are allergic to peanut or soya, do not take this medicinal product.

Valsartan/Hydrochlorothiazide Rivopharm contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

Valsartan/Hydrochlorothiazide Rivopharm 160/12.5 mg contains Sunset yellow FCF (E110)

This may cause allergic reactions.

3. How to take Valsartan/Hydrochlorothiazide Rivopharm

Always take this medicine exactly as your doctor or pharmacist 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 Rivopharm 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 Rivopharm 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 Rivopharm with or without food.
- Swallow the tablet with a glass of water.

If you take more Valsartan/Hydrochlorothiazide Rivopharm than you should

If you experience severe dizziness and/or fainting, lay 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 Rivopharm

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 Rivopharm

Stopping your treatment with Valsartan/Hydrochlorothiazide Rivopharm 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, pharmacist or nurse.

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 Valsartan/Hydrochlorothiazide Rivopharm and contact your doctor straight away (see also section 2).

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 colored 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
- diarrhea
- 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, convulsions)
- 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

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

- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea

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

- blistering skin (sign of dermatitis bullous)
- 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
- faintness, fainting on standing up
- impotence

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 (yellow skin or 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 associated with joint pain, muscle disorder, fever (cutaneous lupus erythematosus)
- severe upper stomach pain (pancreatitis); lack or low levels of different blood cells
- difficulty breathing with fever, coughing, wheezing, lung infection, 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)
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

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

- weakness, bruising and frequent infections (aplastic anemia)
- 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 fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme)
- skin and lip cancer (non-melanoma skin cancer)
- muscle spasm
- fever (pyrexia)

- weakness (asthenia)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valsartan/Hydrochlorothiazide Rivopharm

Keep this medicine out of the sight and reach of children.

Blister packs:

Do not store above 30°C.

Tablet containers:

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton, blister and tablet container as EXP. The expiry date refers to the last day of that month.

Tablet containers:

After first opening of the bottle: use within 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 Rivopharm contains

- The active substances are valsartan and hydrochlorothiazide.
Each film-coated tablet contains 80 mg valsartan and 12.5 mg hydrochlorothiazide
Each film-coated tablet contains 160 mg valsartan and 12.5 mg hydrochlorothiazide
Each film-coated tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide
- The other ingredients are: *tablet core*: Microcrystalline Cellulose, Lactose Monohydrate, Croscarmellose Sodium, Povidone K29-K32, Talc, Magnesium Stearate, Colloidal Anhydrous Silica; *film-coat*:
[80/12.5 mg tablets] Polyvinyl Alcohol, Talc, Titanium Dioxide (E171), Macrogol 3350, Lecithin (contains soya oil) (E322), Iron Oxide Red (E172), Iron Oxide Yellow (E172), Iron Oxide Black (E172).
[160/12.5 mg tablets] Polyvinyl Alcohol, Talc, Macrogol 3350, Titanium Dioxide (E171), Iron Oxide Red (E172), Sunset Yellow FCF Aluminium Lake (E110), Lecithin (contains soya oil) (E322).
[160/25 mg tablets] Polyvinyl Alcohol, Talc, Titanium Dioxide (E171), Macrogol 3350, Iron Oxide Yellow (E172), Lecithin (contains soya oil) (E322), Iron Oxide Red (E172), Iron Oxide Black (E172).

What Valsartan/Hydrochlorothiazide Rivopharm looks like and contents of the pack

Valsartan/Hydrochlorothiazide Rivopharm 80 mg/12.5 mg film-coated tablets: Pink, oval, biconvex film-coated tablets, 11 x 5.8 mm, marked 'V' on one side and 'H' on the other.

Valsartan/Hydrochlorothiazide Rivopharm 160 mg/12.5 mg film-coated tablets: Red, oval, biconvex film-coated tablets, 15 x 6 mm, marked 'V' on one side and 'H' on the other.

Valsartan/Hydrochlorothiazide Rivopharm 160 mg/25 mg film-coated tablets: Orange, oval, biconvex film-coated tablets, 15 x 6 mm, marked 'V' on one side and 'H' on the other.

Contents of the pack:

Blister:

7, 14, 28, 30, 56, 98 and 280 tablets

Tablets container:

7, 14, 28, 30, 56, 98, 100 and 280 tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer:

Actavis Ltd.

BLB016 Bulebel Industrial Estate, Zejtun ZTN3000

Malta

Balkanpharma Dupnitsa AD

3, Samokovsko Shosse Str.

2600 Dupnitsa

Bulgaria

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

Sweden: Valsartan/Hydrochlorothiazide Rivopharm

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