

Valsartan 320mg Film-coated Tablets

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.
- The full name of this medicine is Valsartan 320mg Film-coated Tablets but within the leaflet it will be referred to as Valsartan tablets.

What is in this leaflet:

- 1 What Valsartan tablets are and what they are used for**
- 2 What you need to know before you take Valsartan tablets**
- 3 How to take Valsartan tablets**
- 4 Possible side effects**
- 5 How to store Valsartan tablets**
- 6 Contents of the pack and other information**

1 What Valsartan tablets are and what they are used for

Valsartan tablets belong 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 tablets work by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Valsartan tablets can be used to treat high blood pressure in adults and in children and adolescents 6 to 18 years of age. High blood pressure increases the workload on 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 Before you take Valsartan tablets

Do not take Valsartan tablets if you:

- are **allergic** to valsartan, soya oil, peanut oil or any of the other ingredients of this medicine (listed in section 6).
- have **severe liver disease**
- are **more than 3 months pregnant** (it is also better to avoid Valsartan tablets in early pregnancy – see pregnancy section).
- have **diabetes** or **impaired kidney function** and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of these apply to you, do not take Valsartan tablets

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan tablets

- if you have **liver disease**
- if you have **severe kidney disease** or if you are undergoing **dialysis**
- if you are suffering from a **narrowing of the kidney artery**
- if you have recently **undergone kidney transplantation** (received a new kidney)
- if you are treated after a **heart attack or for heart failure**, your doctor may check your kidney function
- if you have **severe heart disease** other than heart failure or heart attack
- 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 tablets, stop taking Valsartan tablets immediately and never take it again. See also section 4, "Possible side effects".

- if you are taking medicines that **increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals
- if you are **below 18 years of age** and you take Valsartan tablets in combination with other medicines that inhibit the renin angiotensin aldosterone system (medicines that lower blood pressure), your doctor may check your kidney function and the amount of potassium in your blood at regular intervals
- if you suffer from **aldosteronism**. 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 tablets is not recommended
- if you have **lost a lot of fluid** (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics)
- you must tell your doctor if you think you **are (or might become) pregnant**. Valsartan tablets are 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).
- 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 are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol).

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 tablets"

Other medicines and Valsartan tablets

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 tablets are 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 applies to both prescription and non-prescription medicines, especially:

- **other medicines that lower blood pressure**, especially **water tablets** (diuretics)
- **medicines that increase the amount of potassium** in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin
- **certain type of pain killers** called non-steroidal anti-inflammatory medicines (**NSAIDs**)
- 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 tablets.
- **lithium**, a medicine used to treat some types of psychiatric illness.

Your doctor may need to change your dose and/or to take other precautions:

- If you are taking an **ACE-inhibitor** or **aliskiren** (see also information under the headings "Do not take Valsartan" and "Warnings and precautions")

Valsartan tablets with food and drink

You can take Valsartan tablets with or without food.

Pregnancy and breast-feeding

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 tablets before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan tablets. Valsartan tablets are 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 tablets 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 tablets affect you. Like many other medicines used to treat high blood pressure, Valsartan tablets may in rare cases cause dizziness and affect the ability to concentrate.

Valsartan tablets contain lactose and soya oil and Sunset Yellow

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product. Valsartan tablets contain soya oil. If you are allergic to peanut or soya, do not take this medicinal product. Valsartan tablets contain Sunset yellow FCF (E110) which may cause allergic reactions.

3 How to take Valsartan tablets

Always take this medicine exactly as your doctor or pharmacist has told you in order to get the best results and reduce 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 the doctor even if you are feeling well.

Adult patients with high blood pressure

The usual dose is 80mg daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). He may also combine Valsartan tablets with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure

In patients who weigh less than 35kg the usual dose is 40mg of valsartan once daily. In patients who weigh 35kg or more the usual starting dose is 80mg of valsartan once daily. In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

You can take Valsartan tablets with or without food. Swallow Valsartan tablets with a glass of water. Take Valsartan tablets at about the same time each day.

If you take more Valsartan tablets 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 tablets

Do not take a double dose to make up for a forgotten dose. 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.

If you stop taking Valsartan tablets

Stopping your treatment with Valsartan tablets may cause your disease 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 symptoms need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction), such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching.

If you get any of these, see a doctor immediately.

Other side effects include:

Common (may affect up to 1 in 10 people):

- dizziness
- low blood pressure with or without symptoms such as dizziness and fainting when standing up
- decreased kidney function (signs of renal impairment).

Uncommon (may affect up to 1 in 100 people):

- angioedema (see section "Some symptoms need immediate medical attention")
- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- severely decreased kidney function (signs of acute renal failure)
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

Not known: frequency cannot be estimated from the available data.

- blistering skin (sign of dermatitis bullous)
- allergic reaction with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness)
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis)
- unusual bleeding or bruising (signs of thrombocytopenia)
- muscle pain (myalgia)
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases)
- increase of level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)
- rash, itching.

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

Side effects in children and adolescents are similar to those seen in adults.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Valsartan tablets

- 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, blister and bottle as EXP. The expiry date refers to the last day of that month.
- Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- Do not store above 30°C.

6 Contents of the pack and other information

What Valsartan tablets contain

- The active substance is valsartan. Each film-coated tablet contains 320mg of valsartan.
- The other ingredients are: tablet core: lactose monohydrate, cellulose microcrystalline, croscarmellose sodium, povidone K29-K32, talc, magnesium stearate, colloidal anhydrous silica; tablet coat: polyvinyl alcohol, macrogol 3350, talc, lecithin (contains soya oil) (E322), titanium dioxide (E171), iron oxide black (E172), sunset yellow FCF aluminium lake (E110).

What Valsartan tablets look like and contents of the pack

Valsartan 320mg film-coated tablets: Brown, oval, biconvex, film-coated tablets, 19 x 8.2mm, with a scoreline on one side and sidescores and marked with a "V" on the other.

The tablet can be divided into equal doses.

Pack sizes

PVC/PE/PVDC/aluminium blister: 28 tablets

Marketing Authorisation Holder

Actavis Group PTC ehf.
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Balkanpharma – Dupnitsa AD
3 Samokovsko Schosse Str.
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