What Valsartan is and what it is used for

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 pressure decreases.

Valsartan 40mg, 80mg and 160mg film-coated tablets can be used for three different conditions:

• to treat high blood pressure 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 these disorders in children and adolescents.

• to treat adults who have heart failure in adults. Valsartan is used when a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors (a medication to treat heart failure) cannot be used or it may be used in addition to ACE inhibitors when other medicines to treat heart failure cannot be used. These medicines include diuretics (which help the body to get rid of excess fluid) and medications that help to improve swelling due to fluid build up. It is caused when the heart muscle cannot pump blood strongly enough to supply the all the blood needed throughout the body.

• to treat adult patients after a recent heart attack (myocardial infarction). “Recent” here means between 12 hours and 10 days.

With Valsartan it may be possible to take other medicines such as:

• spironolactone, eplerenone or a beta blocker (for example atenolol, propranolol, metoprolol)

Contraindications

Do not take Valsartan if you:

• are allergic to valsartan, any of its excipients or any of the other ingredients of this medicinal product listed in section 6.

• have severe liver disease.

• have been treated with an ACE inhibitor (for example enalapril, lisinopril, ramipril), in a stroke, heart failure, or kidney failure.

• are taking or might take any other medicines.

• have recently undergone transplant surgery (received a new liver, kidney or heart).

Other medicines and Valsartan

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

Reduced dosage

If you are being treated with an ACE inhibitor together with certain other medicines to treat heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol).

In addition:

• if you have impaired kidney function (including dialysis patients). Your doctor may check your kidney function.

• if you are taking any of the following medicines used to treat high blood pressure:

• an ACE inhibitor (for example enalapril, lisinopril, ramipril), in a stroke, heart failure, or kidney failure. It is also better to avoid beta blockers (for example atenolol, propranolol)

• an aliskiren

• other medicines that lower blood pressure, especially water tablets (diuretics).

• allopurinol.

• medications that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medines and heparin.

• certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs) (for example ibuprofen, aspirin, diclofenac). These drugs may increase the effect of Valsartan.

• lithium, a medicine used to treat bipolar (bipolar) types of psychiatric illnesses.

Taking Valsartan with food and drink

You can take Valsartan with or without food.

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 they have the same illness as you.

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.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan

• 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 transplant surgery when taking another drug (including ACE inhibitors), tell your doctor if these symptoms occur when you are taking Valsartan, stop taking Valsartan immediately and never take it again. See also section 2 ‘WARNING about withdrawal symptoms’.

If you are pregnant

Valsartan is not recommended in early pregnancy, and should not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby up to that age (see section 4). If you are planning to become pregnant, your doctor may check your kidney function.

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

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 is taken with certain other medicines. Your doctor may need to change the dose, to take other precautions, or in some cases to take one of these medicines for a short period of time. Therefore if you are taking or might be taking any of the following medicines, tell your doctor. These medicines include:

• beta blockers (for example atenolol, propranolol, metoprolol) or calcium antagonists (for example diltiazem, nifedipine) or a medicine used to treat psychiatric illness (for example ketamine, buspirone).

• allopurinol.

• medications 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) (for example ibuprofen, aspirin, diclofenac).

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If you are pregnant or breast feeding, having taken, have recently taken or might take any other medicines.

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Taking Valsartan with food and drink

You can take Valsartan with or without food.
How to take Valsartan

Always take this medicine exactly as your doctor or pharmacist has prescribed it. If you are not sure, talk to your doctor or pharmacist before taking this medicinal product.

The tablet can be divided into equal doses and marked with a “V” on one side.

The tablet is oval, pink, biconvex, coated tablets, 8mm in diameter, with a scoreline on both sides and marked with a “V” on one side.

The tablet contains lactose and soya oil. If you are allergic to these, do not take this medicinal product.

1. How to take Valsartan

How to take Valsartan

You should take Valsartan once a day, at about the same time each day.

If it is almost time for your next dose, skip the dose you have missed and take your next dose as usual. This will ensure that you receive the correct amount of medicine for the whole day. Do not take a double dose to make up for the dose you missed.

Adults should take 80mg of valsartan once daily.

The usual dose is 160mg daily. In some cases your doctor may prescribe higher doses (the dose can range from 20mg to 80mg twice daily and a maximum of 320mg daily).

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.

Low blood pressure (hypotension) with or without symptoms such as dizziness, and fainting when standing up

If you accidentally take more than your total daily dose, take the next dose 8-12 hours after the overdose.

If you stop taking Valsartan

Regular check-ups with your doctor or pharmacist will ensure the treatment is suitable for you.

Valsartan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

Some symptoms need immediate medical attention:

•  hives, itching
•  low level of sodium in the blood (which can trigger tiredness, muscle spasms and abnormal heart rhythm in severe cases)
•  decreased kidney function (signs of renal impairment)
•  swelling of face, lips, tongue or throat
•  difficulty in breathing or swallowing
•  rash, itching
•  fever, sore throat or mouth ulcers due to infections (symptoms of bacterial or viral infections)
•  decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anemia in severe cases)
•  development of paleness in the skin (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)"

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Valsartan is usually given together with other medicines for heart or blood vessel disease, and your doctor will decide which treatment is suitable for you.

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Valsartan contains lactose and soya oil.

If you have been told by your doctor that you have intolerance to certain sugars, contact your doctor before taking this medicinal product.

Tell your doctor if you are breast-feeding or about to start breast-feeding.

You must tell your doctor if you think that you are (or might be) pregnant. Valsartan can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

Food and drink

Valsartan can be given together with other medicines for heart or blood vessel disease, and your doctor will decide which treatment is suitable for you.

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Contents of the pack and what other constituents contain

The active substance of Valsartan tablets is valsartan. Each film-coated tablet contains either 40mg, 80mg or 160mg of valsartan. The other ingredients are: microcrystalline cellulose, colloidal anhydrous silica; cellulose microcrystalline, croscarmellose sodium, povidone K29-32, lactose, magnesium stearate, talc, magnesium stearate, lactose monohydrate, hydroxypropyl methylcellulose, talcum powder, magnesium stearate, talc, magnesium stearate, lactose monohydrate, hydroxypropyl methylcellulose, talcum powder, magnesium stearate, lactose monohydrate, hydroxypropyl methylcellulose, talcum powder, magnesium stearate, lactose monohydrate, hydroxypropyl methylcellulose, talcum powder, magnesium stearate, lactose monohydrate, hydroxypropyl methylcellulose, talcum powder, magnesium stearate.