Valsartan 80 mg capsules, hard
Valsartan 160 mg capsules, hard

Read all of this leaflet carefully before you start taking the medicine because it contains important information for you.

What is Valsartan and what is it used for

Valsartan capsules 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 causes blood pressure to increase. Valsartan capsules work by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Valsartan 40 mg capsules can be used for three different conditions to:
- 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, high blood pressure can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure or kidney failure.
- to treat sudden narrowing of the kidney artery.
- to treat adult patients after a recent heart attack (myocardial infarction, MI) or heart failure (heart failure symptoms include shortness of breath, swelling of the feet and legs due to fluid build-up). It is important to use it immediately after you have received the advice from your doctor or pharmacist.

Valsartan capsules may be taken with or without food.

How to take Valsartan

• if you are below 18 years of age and you take Valsartan in combination with other medicines that inhibit the rennin angiotensin aldosterone system (RAAS) (for example low blood pressure), your doctor may check your kidney function and the amount of potassium in your blood at regular intervals.
• if you suffer from alderosteronism. This is a disease in which your adrenal gland produces too much of the hormone aldosterone. If this applies to you, the use of Valsartan capsules is not recommended.
• if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or diuretics (water pills).
• you must tell your doctor if you think you are (or might become) pregnant. Valsartan capsules is not recommended in early pregnancy, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
• if you are taking any of the following medicines used to treat high blood pressure or heart failure:
  - an “ACE-inhibitor” (for example enalapril, lisinopril), in particular if you have diabetes-related kidney problems.
  - aliskiren
• if you are being treated with an ACE-inhibitor together with another medicine that affects the heart muscle, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone and eplerenone, etc.) or beta-blockers (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”.

• other medicines that lower blood pressure, especially water tablets (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.), and beta-blockers (which are drugs that reduce heart rate).
• medicines that increase the amount of potassium in your blood. These include potassium supplements, salt substitutes containing potassium, potassium-sparing medicines and heparin.
• certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs).
• some antibiotics (especially the group called macrolides) and drugs used to protect against transplant rejection (cyclosporin) or an antiretroviral drug for the treatment of HIV (ritonavir). These drugs may increase the effect of Valsartan.
• lithium, a medicine used to treat some types of psychiatric illness.
• aliskiren, a medicine used to treat high blood pressure, in patients with diabetes and/or moderate to severe kidney disease.

In addition:
• if you are being treated after a heart attack, a combination with ACE inhibitors (a medication to treat heart attack) is not recommended.
• if you are being treated for heart failure, a triple combination with a beta-blocker (for example metoprolol) and diuretics (medications to treat heart failure) is not recommended.

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

• if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valsartan” and “Warnings and precautions”) and you are pregnant.

• if you are being treated with an ACE-inhibitor together with another medicine that affects the heart muscle, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone and eplerenone) or beta-blockers (for example metoprolol).

• you must tell your doctor if you think that you are (or might become) pregnant. Valsartan capsules is not recommended in early pregnancy, 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 breastfeeding or about to start breastfeeding.

Valsartan capsules is not recommended for breastfeeding, and your doctor may choose another treatment for you if you wish to breast-feed. If your baby is newborn, or was born prematurely.

Driving and using machines

if you drive a vehicle or use tools or operate machines, or carry out other activities that require concentration, make sure you know how Valsartan affects you. Valsartan may affect some other medicines used to treat high blood pressure, such as salt substitutes containing potassium, which may cause dizziness and affect the ability to concentrate.

How to take Valsartan

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. In order to get the best results and reduce the risk of side effects. You should check with your doctor or pharmacist if you are not sure.
Adult patients with high blood pressure: The recommended starting dose is 40 mg daily. In certain cases your doctor may prescribe a lower dose (e.g. 20 mg or 30 mg). He may also combine Valsartan with other antihypertensive drugs (e.g. diuretics).

Children and adolescents (6 to 18 years of age) with high blood pressure: In patients who weigh less than 35 kg the recommended dose is 40 mg of valartan once daily. In patients who weigh 35 kg or more the recommended starting dose is 80 mg of valartan once daily. In certain cases your doctor may prescribe a lower dose (the dose can be increased to 160 mg and to a maximum of 320 mg).

Adult patients after a recent heart attack: After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20 mg twice daily. You obtain the 20 mg dose by dividing the 40 mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate.

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

You can take Valsartan capsules with or without food. Swallow Valsartan capsules with a glass of water.

Take all your doses at a similar time each day.

If you take more Valsartan than you should
If you experience severe dizziness and/or fainting, contact your doctor immediately, and be done. If you have accidentally taken too many capsules, contact your doctor, pharmacist or hospital.

If you forget to take Valsartan
If you forget to take your morning dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Valsartan
Stopping your treatment with Valsartan capsules may cause your blood pressure to increase, which can be dangerous for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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)
• swelling of extremities (oedema)
• severely decreased kidney function (signs of acute renal failure)
• severe hyperkalaemia (high potassium in the blood)
• breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure)
• rash
• cough
• abdominal pain
• nausea
• dizziness
• tiredness
• weakness

Not known (frequency cannot be estimated from the available data):
• blistering skin (symptom of dermatitis bullosus)
• flushing of hands and wrists and lower extremities (symptom of flushing of hands and legs)
• fever
• swollen joints and chest pain, muscle pain, swelling of limbs and/or fingers (symptoms of Raynaud's disease)
• fever
• skin rash (which may indicate that the medicine is not suitable for you)
• severe hyperkalaemia (high potassium in the blood which can trigger muscle spasms and abnormal heart rhythm in some people)
• elevated liver function values (which can indicate liver damage) including 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 creatinine (which can indicate abnormal kidney function)
• low level of albumin in the blood (which can trigger thirst, confusion, muscle twitching and/or convulsions in severe cases)

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

AED Reporting (Validity of this service is shown on the Yellow Card Scheme)
Website: www.mhra.gov.uk/yellowcard

5. How to store Valsartan

Store in the original package in order to protect from light and reach of children.

Store below 30 °C.

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the label, carton, bottle or blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Valsartan contains
The active ingredient in Valsartan. Each hard capsule contains 40 mg of valartan 80 mg of valartan. The other ingredients are:

Capsule content:

• microcrystalline cellulose, silicon dioxide, ethylenediamine tetraacetic acid, crospovidone (Type-B), preoxidation (K 30), sodium lauryl sulphate, magnesium stearate.

Capsule shell:

• Poloxamer 407 (E143), propylene glycol, black iron oxide, titanium dioxide, potassium hydroxide.

What Valsartan looks like and contents of the pack

Capsule, hard

Valsartan 40 mg Capsules

Opaque grey light red/Fluorescent light grey body, size ‘4’ hard gelatin capsules imprinted in black ink with ‘1’ on cap and ‘20’ on body, filled with white to off white granular powder.

Valsartan 80 mg Capsules

Opaque light grey red/Flash opaque body, size ‘3’ hard gelatin capsules imprinted in black ink with ‘1’ on cap and ‘71’ on body, filled with white to off white granular powder.

Valsartan 160 mg Capsules

Opaque grey dark red/Flash opaque body, size ‘1’ hard gelatin capsules imprinted in black ink with ‘1’ on cap and ‘72’ on body, filled with white to off white granular powder.

Package:

Capsule: Hard gelatin capsule - Aluminium blister

28 capsules, hard

Information on this leaflet is based on the Summary of Product Characteristics contained in the product licence. This licence is available at:

30 days of stoppage of therapy, hard

Not all pack sizes may be marketed.

Marketing Authorization Holder

UK - Milpharm Limited

Aires Block, Odyssey Business Park
West End Road
Rushall
B32 1QD

MT - Aubrindo Pharma (Malta) Limited

Vault 14, Level 2, Valletta Waterfront
Floriana FRN 1913

Malta

Manufacturers:

APL Swift Services (Malta) Limited

HP25, Har Industrial Estate, Hal Far Industrial Estate, Bbuga, Buggiba, BBG 3000 Malta

or

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