Package leaflet: Information for the patient

Valsartan Viatris 320 mg film-coated tablets
valsartan

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.

What is in this leaflet

1. 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 vessels relax and blood pressure is lowered.

Valsartan 320 mg film-coated tablets **can be used:**
- **to treat high blood pressure in adults and in children and adolescents 6 to less than 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. What you need to know before you take Valsartan

Do not take Valsartan
- if you are **allergic** to valsartan or any of the other ingredients of this medicine (listed in section 6)
- if you have **severe liver disease**
- if you are **more than 3 months pregnant** (it is also better to avoid Valsartan in early pregnancy – see pregnancy section)
- if you 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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Valsartan
- 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 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 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 is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- you must tell your doctor if you think you are (or might become) pregnant. Valsartan 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).
- 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, stop taking Valsartan immediately and never take it again. See also section 4 'Possible side effects'.
- 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.

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

If any of these apply to you, tell your doctor before you take Valsartan.

Patients may find this medicinal product has an unusual odour and/or taste. This is normal and characteristic of the active substance valsartan.

Other medicines and Valsartan
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 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).**
- **lithium**, a medicine used to treat some types of psychiatric illness.

- 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.

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').

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 (<u>or might become</u>) pregnant**. Your doctor will normally advise you to stop taking Valsartan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan. Valsartan 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 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 affects you. Like many other medicines used to treat high blood pressure, Valsartan may in rare cases cause dizziness and affect the ability to concentrate.

Valsartan 320 mg Film-coated Tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

3. How to take Valsartan

Always take this medicine exactly as your doctor 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 80 mg daily. In some cases your doctor may prescribe higher doses (e.g. 160 mg or 320 mg). He may also combine Valsartan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to less than 18 years of age) with high blood pressure: In patients who weigh less than 35 kg the recommended dose is 40 mg of valsartan once daily. In patients who weigh 35 kg or more the usual starting dose is 80 mg of valsartan once daily. In some cases your doctor may prescribe higher doses (the dose can be increased to 160 mg and to a maximum of 320 mg).
For children who are unable to swallow tablets, the use of the valsartan oral solution is recommended.

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

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

If you forget to take Valsartan
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
Stopping your treatment with Valsartan may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

If you have 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.

STOP taking your medicine and contact a doctor or visit your nearest hospital emergency department immediately if you experience any of the following side effects:

Uncommon (may affect up to 1 in 100 people)
- angioedema (a specific allergic reaction) with symptoms such as
  - swollen face, lips, tongue or throat
  - difficulty in breathing or swallowing
  - hives, itching
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

Not known (frequency cannot be estimated from the available data)
- severe blistering of the skin (bullous dermatitis)

Other side effects:

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)
- 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)
- headache
- cough
- abdominal pain
- nausea
- diarrhoea
- tiredness
- weakness

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)

- allergic reactions 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, 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)

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 patients treated with high blood pressure than in 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
HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valsartan

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/bottle after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.

Do not throw 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.

6. Contents of the pack and other information

What Valsartan contains

The active substance is valsartan. Each film-coated tablet contains 320 mg of valsartan.

The other ingredients are: microcrystalline cellulose, crospovidone, povidone, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.

The coating includes hypromellose (E464), titanium dioxide (E171), macrogol, vanillin, iron oxide yellow (E172), iron oxide black (E172), iron oxide red (E172).

What Valsartan looks like and contents of the pack

Valsartan 320 mg film-coated tablets are dark grey, oval-shaped, biconvex, film-coated tablets debossed with 'VN 4' on one side and 'M' on the other side.

Valsartan is available in blister packs of 7, 10, 14, 28, 30, 56, 90, 98, 100 tablets; in a blister multipack of 98 comprising 2 cartons (each containing 49 tablets), HDPE bottles containing 56, 98, 500, 1000 tablets and HDPE bottles with desiccant pack containing 28, 30 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder

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This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

France: Valsartan Viatris
Germany: Valsartan dura
Ireland: Valsartan Viatris
Italy: Valsartan Mylan Generics
Portugal: Valsartan Mylan
Spain: Valsartan Viatris
The Netherlands: Valsartan Viatris
United Kingdom (Northern Ireland): Valsartan

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