

PACKAGE LEAFLET

Package leaflet: Information for the user

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

1. What Valsartan ratiopharm is and what it is used for

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

Valsartan ratiopharm **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 ratiopharm

Do not take Valsartan ratiopharm

- 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 ratiopharm 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, tell your doctor and do not take Valsartan ratiopharm

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan ratiopharm

- 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 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 ratiopharm, stop taking Valsartan ratiopharm 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 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 ratiopharm 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 ratiopharm 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 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.

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 ratiopharm”

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

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

Other medicines and Valsartan ratiopharm

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 ratiopharm 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), **ACE-inhibitor** or **aliskiren** (see also information under the headings “Do not take Valsartan ratiopharm” and “Warnings and precautions”).
- **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 (ciclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Valsartan ratiopharm.
- **lithium**, a medicine used to treat some types of psychiatric illness.

Valsartan ratiopharm with food and drink

You can take Valsartan ratiopharm with or without food.

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

Valsartan ratiopharm contains sodium

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

3. How to take Valsartan ratiopharm

Always take this medicine exactly as your doctor has told you. 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 ratiopharm 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 starting dose is 40 mg of Valsartan ratiopharm once daily.

In patients who weigh 35 kg or more the recommended starting dose is 80 mg of Valsartan ratiopharm 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).

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

Take Valsartan ratiopharm at about the same time each day.

The tablet can be divided into equal doses.

If you take more Valsartan ratiopharm than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lay down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

If you forget to take Valsartan ratiopharm

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 ratiopharm

Stopping your treatment with Valsartan ratiopharm 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 side effects can be serious and need immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction) an uncommon side effect, such as

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

If you get any of these symptoms, stop taking Valsartan ratiopharm and contact your doctor straight away (see also section 2 “Warnings and precautions”).

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*)

- 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
- increase of level of serum creatinine (which can indicate abnormal kidney function)

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)
- 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 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 (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 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 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 ratiopharm

- 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 pack. The expiry date refers to the last day of that month.
- Blister packages: Do not store above 30 °C. Store in the original package in order to protect from moisture.
- Bottles: Store in the original package in order to protect from moisture.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- Do not throw away any medicines via wastewater. 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 ratiopharm contains

The active substance is valsartan.

Each film-coated tablet contains 320 mg valsartan.

The other ingredients are

Tablet core: Microcrystalline cellulose, povidone (K-30), colloidal anhydrous silica, croscarmellose sodium, magnesium stearate.

Film coating:

Opadry II brown containing polyvinyl alcohol (partially hydrolyzed), titanium dioxide (E171), macrogol, talc, iron oxide red (E172), iron oxide black (E172).

What Valsartan ratiopharm looks like and contents of the pack

Valsartan ratiopharm are dark grey-violet, biconvex, capsule shaped, scored and film-coated tablets (dimension approx. 8.1 x 17.7 mm).

Blisters:

Packs of 10, 14, 28, 30, 56, 60, 90, 98 and 100 film-coated tablets.

Bottles:
100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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

[To be completed nationally]

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