

PACKAGE LEAFLET: INFORMATION FOR THE USER

Valsartan Rowa 40 mg film-coated tablets

Valsartan Rowa 80mg film-coated tablets

Valsartan Rowa 160mg film-coated tablets

Valsartan

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

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- 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 symptoms are the same as yours.
- If any of the side effects gets serious, 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 Rowa is and what it is used for
2. What you need to know before you take Valsartan Rowa
3. How to take Valsartan Rowa
4. Possible side effects
5. How to store Valsartan Rowa
6. Contents of the pack and other information.

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

Valsartan Rowa belongs to a class of medicines known as angiotensin II receptor antagonist, 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 Rowa works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Valsartan Rowa 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 heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- **to treat adult patients after a recent heart attack** (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- **to treat symptomatic heart failure in adult patients.** Valsartan Rowa can be used to treat symptomatic heart failure in adult patients. Valsartan Rowa 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 medication to treat heart failure cannot be used.
Heart failure symptoms include shortness of breath and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

2. What you need to know before you take Valsartan Rowa

Do not take Valsartan Rowa:

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of Valsartan Rowa listed at the end of this leaflet (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 Rowa 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 Rowa.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Valsartan Rowa

- 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 Rowa, stop taking Valsartan Rowa 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 Rowa is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics)
- 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 receptors 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.

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

See also information under the heading "Do not take Valsartan Rowa"

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

Other medicines and Valsartan Rowa

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The effect of the treatment can be influenced if Valsartan Rowa 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 pills** (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.,) or aliskiren (*see also information under the headings “Do not take Valsartan Rowa” 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 Rowa.
- **lithium**, a medicine used to treat some types of psychiatric illness.

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 **ACE inhibitor** and other medicines to treat your heart failure which are known as **mineralocorticoid receptors antagonists (MRA)** (for example spironolactone, epleronone) or **beta blockers** (for example metoprolol) is not recommended.

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

Valsartan Rowa with food and drink

You can take Valsartan Rowa with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any 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 Rowa before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Valsartan Rowa. Valsartan Rowa 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 Rowa 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 Rowa affects you. Like many other medicines used to treat high blood pressure, Valsartan Rowa may in rare cases cause dizziness and affect the ability to concentrate.

Valsartan Rowa contains sorbitol

40mg: This medicine contains 4,6 mg sorbitol in each tablet.
80 mg: This medicine contains 9,25 mg sorbitol in each tablet.
160 mg: This medicine contains 18,5 mg sorbitol in each tablet.

Valsartan Rowa contains sodium

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

Valsartan Rowa contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose) contact your doctor before taking this medicinal product.

3. How to take Valsartan Rowa

Always take Valsartan Rowa exactly as your doctor 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. 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 Rowa 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 35 kg the usual 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 oral solution is recommended.

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

Adult patients with heart failure: Treatment starts generally with 40 mg twice daily. Your doctor will increase the 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 Rowa 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 Rowa with or without food. Swallow Valsartan Rowa with a glass of water. Take Valsartan Rowa at about the same time each day.

If you take more Valsartan Rowa 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 Rowa

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 Rowa

Stopping your treatment with Valsartan Rowa 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Valsartan Rowa 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), 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 and contact your doctor

straightaway (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

- angioedema (see section “Some side effects can be serious and 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.

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) 5

- 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 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 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 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 Rowa

Do not store above 30°C. Store in the original package in order to protect from moisture.

- Keep out of the sight and reach of children
- Do not use Valsartan Rowa after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.
- Do not use Valsartan Rowa if you notice that the pack is damaged or shows signs of tampering
- Do not throw away any medicines 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 Rowa contains

- The active substance is valsartan. Valsartan Rowa **40 mg**: each film-coated tablet contains 40 mg of valsartan; Valsartan Rowa **80 mg**: each film-coated tablet contains 80 mg of valsartan; Valsartan Rowa **160 mg**: each film-coated tablet contains 160 mg of valsartan.
- The other ingredients are: cellulose, microcrystalline (E 460), silica, colloidal anhydrous (E 551), sorbitol (E 420), magnesium carbonate (E 504), maize starch, pregelatinised, povidone K-25

(E 1201), sodium stearyl fumarate, sodium lauryl sulphate, crospovidone Type A (E 1202). Film-coating: lactose monohydrate, hypromellose (E 464), titanium dioxide (E 171), macrogol 4000.

- Valsartan Rowa **40 mg** film-coated tablet contains additionally: yellow iron oxide (E 172).
- Valsartan Rowa **80 mg** film-coated tablets additionally red iron oxide (E 172).
- Valsartan Rowa **160 mg** film-coated tablets additionally yellow iron oxide (E 172) and brown iron oxide (E 172).

What Valsartan Rowa looks like and contents of the pack

Valsartan Rowa 40 mg: are cylindrical, coated, scored on one side, yellow film coated tablets.

Valsartan Rowa 80 mg: are cylindrical, coated, scored on one side, pink film-coated tablets.

Valsartan Rowa 160 mg: are cylindrical, coated, scored on one side, ochre film-coated tablets

The tablet can be divided into equal doses.

Pack size of 7, 14, 28, 56, 98 or 280 film-coated tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Rowa Pharmaceuticals Ltd.

Newtown

Bantry

Co Cork

Ireland

Manufacturer

Laboratorios LICONSA, S.A.

Avda. Miralcampo, Nº 7, Polígono Industrial Miralcampo

19200 Azuqueca de Henares (Guadalajara), Spain

Laboratorios CINFA, S.A.

Olaz Chipi, 10, Polígono Areta

31620 Huarte (Pamplona), Spain

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

The Netherlands: Vamadrid Valsartan Xiromed 40 mg filmomhulde tabletten
Vamadrid Valsartan Xiromed 80 mg filmomhulde tabletten
Vamadrid Valsartan Xiromed 160 mg filmomhulde tabletten

Bulgaria: Vamadrid 40 mg филмирани таблетки
Vamadrid 80 mg филмирани таблетки
Vamadrid 160 mg филмирани таблетки

Estonia:	Vamadrid 40 mg õhukese polümeerikattega tablett Vamadrid 80 mg õhukese polümeerikattega tablett Vamadrid 160 mg õhukese polümeerikattega tablett
Hungary:	Vamadrid 40 mg filmtabletta Vamadrid 80 mg filmtabletta Vamadrid 160 mg filmtabletta
Ireland:	Valsartan Rowa 40 mg film-coated tablets Valsartan Rowa 80 mg film-coated tablets Valsartan Rowa 160 mg film-coated tablets
Luxembourg:	Vamadrid 40 mg comprimés pelliculés Vamadrid 80 mg comprimés pelliculés Vamadrid 160 mg comprimés pelliculés
Poland:	Valsartan Medical Valley Valsartan Medical Valley Valsartan Medical Valley
Portugal	Vamadrid 40 mg comprimidos revestidos por película Vamadrid 80 mg comprimidos revestidos por película Vamadrid 160 mg comprimidos revestidos por película Vamadrid 80 mg comprimidos revestidos por película

160mg film-coated tablets:

The Netherlands:	Valsartan Xiromed 160 mg filmomhulde tablet
Bulgaria:	Vamadrid 160 mg филмирани таблетки
Estonia:	Vamadrid
Hungary:	Vamadrid 160 mg bevont tablett
Ireland:	Valsartan Rowa 160 mg film-coated tablets
Italy:	Vamadrid 160 mg compressa rivestita con film
Lithuania:	Vamadrid 160 mg plėvele dengtos tabletės
Latvia:	Vamadrid 160 mg apvalkotās tabletes
Luxembourg:	Vamadrid 160 mg comprimé pelliculé
Poland:	Valsartan Medical Valley
Portugal:	Vamadrid 160 m

This leaflet was last approved on /{
01/2025

