



Package leaflet: Information for the user

Valsartan Ranbaxy
40 mg, 80 mg & 160 mg 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

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2. What you need to know before you take Valsartan Ranbaxy tablets
3. How to take Valsartan Ranbaxy tablets
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1. What Valsartan Ranbaxy tablets are and what are they used for

Valsartan Ranbaxy contains valsartan that 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 works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered. Valsartan Ranbaxy 40 mg, 80 mg and 160 mg tablets can be used for three different conditions

- **to treat high blood pressure in adult and 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 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 beta blockers (another 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 Ranbaxy tablets

Do not take Valsartan Ranbaxy tablets:

- if you are **allergic** (hypersensitive) to valsartan or any of the other ingredients of Valsartan Ranbaxy listed at the end of this leaflet.
- if you have **severe liver disease**.
- if you are **more than 3 months pregnant** (it is also better to avoid valsartan Ranbaxy tablets in early pregnancy - see pregnancy section).'
- if you have diabetes mellitus or impaired kidney function and you are treated with aliskiren (medicines used to treat high blood pressure).

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan Ranbaxy tablets:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 'Possible side effects'),
- 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 Ranbaxy 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 Ranbaxy tablets 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 Ranbaxy tablets 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 Ranbaxy tablets.

Other medicines and Valsartan Ranbaxy Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you have diabetes mellitus or impaired kidney function, you must not take aliskiren while taking valsartan.

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.
- 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 inhibitors and beta blockers** (medications to treat heart failure) is not recommended.

Taking Valsartan Ranbaxy tablets with food and drink

You can take Valsartan Ranbaxy tablets with or without food.

Pregnancy, breast-feeding and fertility

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 Ranbaxy tablets before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of valsartan Ranbaxy tablets. Valsartan Ranbaxy tablets 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 Ranbaxy tablets 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.

3. How to take Valsartan Ranbaxy tablets

Always take this medicine exactly as your doctor or pharmacist 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. The recommended dose is as follows:

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).

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

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

Use in children and adolescents:

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).

You can take Valsartan Ranbaxy tablets with or without food. Swallow these tablets with a glass of water.

Take these tablets at about the same time each day.

If you take more Valsartan Ranbaxy tablets 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 Ranbaxy tablets

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 Ranbaxy tablets

Stopping your treatment with this medicine 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, this medicine can cause side effects, although not everybody gets them.

Some symptoms 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, see a doctor immediately.

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)
- 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

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)
- purplished-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 blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma.

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. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST

Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

5. How to store Valsartan Ranbaxy tablets

- Keep out of the sight and reach of children.
- Do not use these tablets after the expiry date which is stated on the pack after "EXP". The expiry date refers to the last day of that month.
- Do not use these tablets 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 doctor or 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 Ranbaxy tablet contains

The active substance in Valsartan Ranbaxy tablets is Valsartan.

Valsartan Ranbaxy tablets are available in three strengths: 40 mg, 80 mg and 160 mg tablets.

Each Valsartan Ranbaxy 40 mg Tablets contains 40 mg Valsartan, each Valsartan Ranbaxy 80 mg Tablets contains 80 mg Valsartan and each Valsartan Ranbaxy 160 mg Tablets contains 160 mg Valsartan.

The other ingredients are:

Cellulose microcrystalline, Crospovidone (Type A), Silica colloidal anhydrous, Magnesium stearate, Starch pregelatinised, Talc, Hypromellose 6cP, Titanium dioxide, Macrogol (PEG 400), Iron oxide (E172).

What Valsartan Ranbaxy tablet looks like and contents of the pack

Valsartan Ranbaxy 40mg Tablets are Yellow coloured, film-coated, oval tablets debossed with 'V& 3' on either side of breakline on one side and breakline on the other side. The tablet can be divided into equal halves. They are supplied in blister pack containing 14 or 28 tablets.

Valsartan Ranbaxy 80mg Tablets are Orange coloured, film-coated tablets debossed with 'V&2' on either side of breakline on one side and breakline on the other side. The tablet can be divided into equal halves. They are supplied in blister pack containing 28, 56 or 98 tablets.

Valsartan Ranbaxy 160mg Tablets are Pink coloured, film-coated, oval tablets debossed with 'V & 1' on either side of breakline on one side and breakline on the other side. The tablet can be divided into equal halves.

The following packs are available:

28, 56 or 98 tablets

Not all pack sizes may be marketed

Marketing Authorisation Holder:

Ranbaxy Ireland Limited
Spafield, Cork Road
Cashel, Co. Tipperary
Ireland
Manufacturers:
Ranbaxy Ireland Limited
Spafield, Cork Road
Cashel, Co. Tipperary
Ireland

Basics GmbH
Hemmelrather Weg 201,
D-51377 Leverkusen,
Germany

Terapia SA
124 Fabricii Str., 400632 Cluj-Napoca,
Romania

Ranbaxy Pharmacie Generiques
11-15, quai de Dion Bouton,
92800 Puteaux
France

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Black

Valsartan Rx
PI size : 140 x 400 mm
Market : Ireland
RLL/PKGDEV : AK15/09/11-V01,
J23/09/11-V02, AK05/04/13-V03, V04,
AK17/06/13-V06, V07, CG20/06/13-V08, V09,
AK11/07/13-V10

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