Package leaflet: Information for the patient

Valsartan Krka 40 mg film-coated tablets
Valsartan Krka 80 mg film-coated tablets
Valsartan Krka 160 mg film-coated tablets
Valsartan Krka 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 Krka is and what it is used for

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

Valsartan Krka 40 mg film-coated tablets **can be used for three different conditions:**
- **to treat high blood pressure 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.
- **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 Krka 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 medications 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.

Valsartan Krka 80 mg and 160 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure in adult 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.
- **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 Krka 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 medications 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.

Valsartan Krka 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 Krka

Do not take Valsartan Krka
- 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 Krka 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 Krka.

Warnings and precautions
Talk to your doctor or pharmacist before taking Valsartan Krka:
- 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 Krka, stop taking Valsartan Krka 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 Krka 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.

See also information under the heading "Do not take Valsartan Krka".

You must tell your doctor if you think you are (or might become) pregnant. Valsartan Krka 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 Krka.

Other medicines and Valsartan Krka
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 Krka 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 inhibitors (such as enalapril, lisinopril, etc.,) or aliskiren (see also information under the headings "Do not take Valsartan Krka" 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 Krka.
- **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 inhibitors and and other medicines to treat your heart failure**, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or betablockers (for example metoprolol) is not recommended**.**

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

Valsartan Krka contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

3. How to take Valsartan Krka

Always take Valsartan Krka exactly as your doctor or pharmacist has told you. This will help you to get the best results and lower 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 Krka 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 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).

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

If you take more Valsartan Krka 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 Krka
Do not take a double dose to make up for a forgotten dose.

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.

If you stop taking Valsartan Krka
Stopping your treatment with Valsartan Krka 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) 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 Krka 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):
- 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
- diarrhea
- tiredness
- weakness.

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)
- 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 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 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 Krka

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

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

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 Krka contains
- The active substance is valsartan. Each film-coated tablet contains 40 mg, 80 mg, 160 mg or 320 mg valsartan.
- The other ingredients in the tablet core are lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate.
- The other ingredients in the film-coating of 40 mg tablets are hypromellose, titanium dioxide (E171), macrogol 4000 and yellow iron oxide (E172).
- The other ingredients in the film-coating of 80 mg tablets are hypromellose, titanium dioxide (E171), macrogol 4000 and red iron oxide (E172).
- The other ingredients in the film-coating of 160 mg tablets are hypromellose, titanium dioxide (E171), macrogol 4000, yellow iron oxide (E172) and red iron oxide (E172).
- The other ingredients in the film-coating of 320 mg tablets are hypromellose, titanium dioxide (E171), macrogol 4000, yellow iron oxide (E172) and red iron oxide (E172).
- See section 2 “Valsartan Krka contains lactose and sodium”.

What Valsartan Krka looks like and contents of the pack
The 40 mg film-coated tablets are yellow-brown, round, slightly biconvex film-coated tablets scored on one side, tablet diameter 6 mm.
The 80 mg film-coated tablets are pink, round, biconvex film-coated tablets scored on one side, tablet diameter 8 mm.
The 160 mg film-coated tablets are yellow-brown, oval, biconvex film-coated tablets scored on one side, tablet dimensions 13.5 mm x 7 mm.
The 320 mg film-coated tablets are light brown, capsule shaped, biconvex film-coated tablets

scored on one side, tablet dimensions 16 mm x 8.5 mm.
Tablets of all four strengths can be divided into equal doses.

For strengths 40 mg, 80 mg and 160 mg, boxes of 7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 98, 120 and 180 film-coated tablets in blister are available.
For strength 320 mg, boxes of 7, 10, 14, 20, 28, 30, 56, 60, 84, 90 and 98 film-coated tablets in blister are available.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Czech Republic, Slovakia, Slovenia, Estonia, Hungary, Ireland, Lithuania	Valsartan Krka
Poland	Walsartan Krka

This leaflet was last revised in