Package leaflet: Information for the user

Valsartan/hydrochlorothiazide Krka 320 mg/25 mg film-coated tablets
valsartan/hydrochlorothiazide

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/hydrochlorothiazide Krka is and what it is used for

Valsartan/hydrochlorothiazide Krka film-coated tablets contain two active substances called valsartan and hydrochlorothiazide. Both of these substances help to control high blood pressure (hypertension).
- **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.
- **Hydrochlorothiazide** belongs to a group of medicines called thiazide diuretics (also known as "water tablets"). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

Valsartan/hydrochlorothiazide Krka is used to treat high blood pressure which is not adequately controlled by a single substance alone.

High blood pressure increases the workload of 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/hydrochlorothiazide Krka

Do not take Valsartan/hydrochlorothiazide Krka
- if you are allergic to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or to any of the other ingredients of this medicine (listed in section 6),
- if you are **more than 3 months pregnant** (it is also better to avoid Valsartan/hydrochlorothiazide Krka in early pregnancy – see pregnancy section.),
- if you have **severe** liver disease, destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the build up of bile in the liver (cholestasis),
- if you have **severe** kidney disease,
- if you are unable to produce urine (anuria),
- if you are treated with an artificial kidney,
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium

in your blood is higher than normal despite treatment,
- if you have gout,
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above applies to you, do not take this medicine and speak to your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking Valsartan/hydrochlorothiazide Krka.
- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you are suffering from heart failure or have experienced a heart attack. Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- if you are suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- if you suffer from hyperaldosteronism. 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/hydrochlorothiazide Krka is not recommended.
- if you have liver or kidney disease.
- 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/hydrochlorothiazide Krka, stop taking Valsartan/hydrochlorothiazide Krka immediately and never take it again. See also section 4, "Possible side effects".
- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering agents of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Valsartan/hydrochlorothiazide Krka. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this.
- it may cause increased sensitivity of the skin to sun.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Valsartan/hydrochlorothiazide Krka.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Valsartan/hydrochlorothiazide Krka, seek medical attention immediately.
- 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/hydrochlorothiazide Krka”.

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

If any of these apply to you, talk to your doctor.

You must tell your doctor of you think that you are (or might become) pregnant.
Valsartan/hydrochlorothiazide 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).

Children and adolescents
The use of Valsartan/hydrochlorothiazide Krka in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and Valsartan/hydrochlorothiazide 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/hydrochlorothiazide 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 especially applies to the following medicines:
- lithium, a medicine used to treat some types of psychiatric diseases,
- medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or salt substitutes, containing potassium, potassium-sparing medicines and heparin,
- medicines that may reduce the amount of potassium in your blood, such as diuretic (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G,
- 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/hydrochlorothiazide Krka,
- medicines that may induce “torsades de pointes” (irregular heart beat), such as antiarrhythmics (medicines used to treat heart problems) and some antipsychotics,
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics,
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone,
- therapeutic vitamin D and calcium supplements, medicines for the treatment of diabetes (oral agents such as metformin or insulins),
- other medicines to lower your blood pressure, including methyldopa,
- medicines to increase blood pressure, such as noradrenaline or adrenaline,
- digoxin or other digitalis glycosides (medicines used to treat heart problems),
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers,
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide,
- pain killers such as non-steroidal anti-inflammatory agents (NSAIDs), including selective cyclooxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g,
- muscle relaxing medicines, such as tubocurarine,
- anti-cholinergic medicines (medicines used to treat a variety of disorders, such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia),
- amantadine (medicine used to treat Parkinson’s disease and also used to treat or prevent certain illnesses caused by viruses),
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood),
- ciclosporin, a medicine used for organ transplant to avoid organ rejection,
- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery),

- iodine contrast media (agents used for imaging examinations),
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valsartan/hydrochlorothiazide Krka” and “Warnings and precautions”).

Valsartan/hydrochlorothiazide Krka with food, drink and alcohol
You can take Valsartan/hydrochlorothiazide Krka with or without food.
Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant.
Your doctor will normally advise you to stop taking Valsartan/hydrochlorothiazide 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/hydrochlorothiazide Krka. Valsartan/hydrochlorothiazide 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.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding.
Valsartan/hydrochlorothiazide 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/hydrochlorothiazide Krka affects you. Like many other medicines used to treat high blood pressure, Valsartan/hydrochlorothiazide Krka may occasionally cause dizziness and affect the ability to concentrate.

Valsartan/hydrochlorothiazide 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/hydrochlorothiazide Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. This will help you to get the best results and lower 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 your doctor even if you are feeling well.

Your doctor will tell you exactly how many tablets of Valsartan/hydrochlorothiazide Krka to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
- The usual dose of Valsartan/hydrochlorothiazide Krka is one tablet per day.
- Do not change the dose or stop taking the tablets without consulting your doctor.
- The medicine should be taken at the same time each day, usually in the morning.
- You can take Valsartan/hydrochlorothiazide Krka with or without food.
- Swallow the tablet with a glass of water.

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

If you forget to take Valsartan/hydrochlorothiazide Krka
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/hydrochlorothiazide Krka
Stopping your treatment with Valsartan/hydrochlorothiazide Krka may cause your high blood pressure 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 should see your doctor immediately if you experience symptoms of angioedema, such as:
  - swollen face, tongue or pharynx
  - difficulty in swallowing
  - hives and difficulties in breathing
- Severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis)
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- Fever, sore throat, more frequent infections (agranulocytosis)
- Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

These side effects are very rare or of frequency not known.

If you get any of these symptoms, stop taking Valsartan/hydrochlorothiazide Krka and contact your doctor straight away (see also section 2 "Warnings and precautions").

Other side effects include:

Uncommon (may affect up to 1 in 100 people)
- cough
- low blood pressure
- light-headedness
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin)
- muscle pain
- tiredness
- tingling or numbness
- blurred vision
- noises (e.g. hissing, buzzing) in ears

Very rare (may affect up to 1 in 10,000 people)
- dizziness
- diarrhea

- joint pain

Not known (frequency cannot be estimated from the available data)
- breathing difficulty
- severely decreased urine output
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)
- low level of potassium in the blood (sometimes with muscle weakness, muscle spasms, abnormal heart rhythm)
- low level of white cells in the blood (with symptoms such as fever, skin infections, sore throat or mouth ulcers due to infections, weakness)
- the level of bilirubin increased in blood (which can, in severe cases, trigger yellow skin and eyes)
- the level of blood urea nitrogen and creatinine increased in blood (which can indicate abnormal kidney function)
- the level of uric acid in blood increased (which can, in severe cases, trigger gout)
- syncope (fainting)

The following side effects have been reported with products containing valsartan or hydrochlorothiazide alone:

Valsartan

Uncommon (may affect up to 1 in 100 people)
- spinning sensation
- abdominal pain

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)
- skin rash with or without itching together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms
- rash, purplished-red spots, fever, itching (symptoms of inflammation of blood vessels)
- low level of blood platelets (sometimes with unusual bleeding or bruising)
- high level of potassium in the blood (sometimes with muscle spasms, abnormal heart rhythm)
- allergic reactions (with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness)
- swelling mainly of the face and throat; rash; itching
- elevation of liver function values
- the level of haemoglobin decreased and the percentage of red cells decreased in the blood (which both can, in severe cases, trigger an anaemia)
- kidney failure
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)

Hydrochlorothiazide

Very common (may affect more than 1 in 10 people)
- low level of potassium in the blood
- increase of lipids in the blood

Common (may affect up to 1 in 10 people)
- low level of sodium in the blood
- low level of magnesium in the blood
- high level of uric acid in the blood

- itchy rash and other types of rash
- reduced appetite
- mild nausea and vomiting
- dizziness, fainting on standing up
- inability to achieve or maintain erection.

Rare (may affect up to 1 in 1,000 people)
- swelling and blistering of the skin (due to increased sensitivity to sun)
- high level of calcium in the blood
- high level of sugar in the blood
- sugar in the urine
- worsening of diabetic metabolic state
- constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes
- irregular heart beat
- headache
- sleep disturbances
- sad mood (depression)
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin)
- dizziness
- tingling or numbness
- vision disorder

Very rare (may affect up to 1 in 10,000 people)
- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis)
- rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reactions)
- facial rash, joint pain, muscle disorder, fever (lupus erythematosus)
- severe upper stomach pain (pancreatitis)
- difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema)
- pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia)
- fever, sore throat or mouth ulcers due to infections (leucopenia)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis)

Not known (frequency cannot be estimated from the available data)
- skin and lip cancer (non-melanoma skin cancer)
- weakness, bruising and frequent infections (aplastic anemia)
- severely decreased urine output (possible signs of renal disorder or renal failure)
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme)
- muscle spasm
- fever (pyrexia)
- weakness (asthenia)

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/hydrochlorothiazide 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 light and 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/hydrochlorothiazide Krka contains
- The active substances are valsartan and hydrochlorothiazide.
  Each Valsartan/hydrochlorothiazide Krka 320 mg/25 mg film-coated tablet contains 320 mg valsartan and 25 mg hydrochlorothiazide.
- The other ingredients are cellulose, microcrystalline (E460); lactose monohydrate; magnesium stearate (E470b); croscarmellose sodium; povidone and silica, colloidal anhydrous in the tablet core and hypromellose; titanium dioxide (E171); macrogol 4000; iron oxide yellow (E172) in the film coating. See section 2 “Valsartan/hydrochlorothiazide Krka contains lactose and sodium”.

What Valsartan/hydrochlorothiazide Krka looks like and contents of the pack
Valsartan/hydrochlorothiazide Krka 320 mg/25 mg film-coated tablets are pale yellow, oval, biconvex, one side scored. The tablet can be divided into equal doses.

Valsartan/hydrochlorothiazide Krka are available in boxes of 10, 14, 28, 30, 56, 60, 84, 90, 98, 100, 280, 56 x 1, 98 x 1 and 280 x 1 film-coated tablet in blisters.
Not all pack sizes may be marketed.

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

Manufacturers
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany.
KRKA-POLSKA Sp. z o.o., ul. Równoległa 5, 02-235 Warszawa, Poland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Name of the Member State	**Name of the medicine**
Germany	Valsacor comp.
Czech Republic	Valsacombi
Slovak Republic	Co-Valsacor
Latvia	Valsacombi
Lithuania	Valsacombi
Estonia	Valsacombi
Poland	Co-Valsacor
Hungary	Co-Valsacor
Bulgaria	Ко-Валсакор Co-Valsacor
Greece	Co-Valsareta
Finland	Valsartan/Hydrochlorothiazide Krka
Denmark	Valsartan/Hydrochlorothiazide Krka
Norway	Valsartan/Hydrochlorothiazide Krka
Sweden	Valsartan/Hydrochlorothiazide Krka
Spain	Valsartán/hidroclorotiazida Kern Pharma

Slovenia	Valsacombi
Austria	Valsartan/Hydrochlorothiazid Krka
Ireland	Valsartan/hydrochlorothiazide Krka

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