Package leaflet: Information for the user

Amlodipine/Valsartan Krka 5 mg/80 mg film-coated tablets
Amlodipine/Valsartan Krka 5 mg/160 mg film-coated tablets
Amlodipine/Valsartan Krka 10 mg/160 mg film-coated tablets
amlodipine/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 Amlodipine/Valsartan Krka is and what it is used for

Amlodipine/Valsartan Krka tablets contain two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.
- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.
- Valsartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Amlodipine/Valsartan Krka is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

2. What you need to know before you take Amlodipine/Valsartan Krka

Do not take Amlodipine/Valsartan Krka
- if you are allergic to amlodipine or to any other calcium channel blockers. This may involve itching, reddening of the skin or difficulty in breathing.
- if you are allergic to valsartan or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, talk to your doctor before taking Amlodipine/Valsartan Krka.
- if you have severe liver problems or bile problems such as biliary cirrhosis or cholestasis.
- if you are more than 3 months pregnant (it is also better to avoid Amlodipine/Valsartan Krka in early pregnancy, see Pregnancy section).
- if you have severe low blood pressure (hypotension).

- if you have narrowing of the aortic valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- if you suffer from heart failure after a heart attack.
- if you have a high level of sugar in the blood and you are suffering from type 2 diabetes (also called non-insulin-dependent diabetes mellitus) or impaired kidney function and you are treated with a blood pressure lowering medicine called aliskiren.

If any of the above applies to you, do not take Amlodipine/Valsartan Krka and talk to your doctor.

Warnings and precautions
Talk to your doctor before taking Amlodipine/Valsartan Krka:
- if you have been sick (vomiting or diarrhoea).
- if you have liver or kidney problems.
- if you have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.
- if you have a condition affecting the renal glands called "primary hyperaldosteronism".
- if you have had heart failure or have experienced a heart attack. Follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function.
- if your doctor has told you that you have a narrowing of the valves in your heart (called "aortic or mitral stenosis") or that the thickness of your heart muscle is abnormally increased (called "obstructive hypertrophic cardiomyopathy").
- if you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking Amlodipine/Valsartan Krka and contact your doctor straight away. You should never take Amlodipine/Valsartan Krka again.
- 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.

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

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

If any of these apply to you, tell your doctor before taking Amlodipine/Valsartan Krka.

Children and adolescents
The use of Amlodipine/Valsartan Krka in children and adolescents is not recommended (aged below 18 years old).

Other medicines and Amlodipine/Valsartan Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Your doctor may need to change the dose or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below:
- other medicines used to lower blood pressure, called ACE inhibitors or aliskiren;
- diuretics (a type of medicine also called "water tablets" which increases the amount of urine you produce);
- lithium (a medicine used to treat some types of depression);
- potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and

other substances that may increase potassium levels;
- certain types of painkillers called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function;
- anticonvulsant agents (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone);
- St. John's wort;
- nitroglycerin and other nitrates, or other substances called "vasodilators";
- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- antibiotics (medicines used to treat bacterial infections), such as rifampicin, erythromycin, clarithromycin, talithromycin;
- verapamil, diltiazem (heart medicines);
- simvastatin (a medicine used to control high cholesterol levels);
- dantrolene (infusion for severe body temperature abnormalities);
- medicines used to protect against transplant rejection (ciclosporin, tacrolimus).

Amlodipine/Valsartan Krka with food and drink
Grapefruit and grapefruit juice should not be consumed by people who are taking Amlodipine/Valsartan Krka. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Amlodipine/Valsartan Krka.

Pregnancy and breast-feeding
Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Amlodipine/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 Amlodipine/Valsartan Krka. Amlodipine/Valsartan Krka is not recommended in early pregnancy (first 3 months) and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Tell your doctor if you are breast-feeding or about to start breast-feeding. Amlodipine/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. Amlodipine has been shown to pass into breast milk in small amounts.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
This medicine may make you feel dizzy. This can affect how well you can concentrate. So, if you are not sure how this medicine will affect you, do not drive, use machinery, or do other activities that you need to concentrate on.

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

3. How to take Amlodipine/Valsartan Krka

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. This will help you get the best results and lower the risk of side effects.

The usual dose of Amlodipine/Valsartan Krka is one tablet per day.
- It is preferable to take your medicine at the same time each day.
- Swallow the tablets with a glass of water.

– You can take Amlodipine/Valsartan Krka with or without food. Do not take Amlodipine/Valsartan Krka with grapefruit or grapefruit juice.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose. Do not exceed the prescribed dose.

Amlodipine/Valsartan Krka and older people (age 65 years or over)
Your doctor should exercise caution when increasing your dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you take more Amlodipine/Valsartan Krka than you should
If you have taken too many tablets of Amlodipine/Valsartan Krka or if someone else has taken your tablets, consult a doctor immediately.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If you forget to take Amlodipine/Valsartan Krka
If you forget to take this medicine, take it as soon as you remember. Then take your next dose at its usual time. 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 tablet.

If you stop taking Amlodipine/Valsartan Krka
Stopping your treatment with Amlodipine/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:
A few patients have experienced these serious side effects *(may affect up to 1 in 1,000 people)*. **If any of the following happen, tell your doctor straight away:**
Allergic reaction with symptoms such as rash, itching, swelling of face or lips or tongue, difficulty breathing, low blood pressure (feeling of faintness, light-headedness).

Other possible side effects of Amlodipine/Valsartan Krka:
Common (may affect up to 1 in 10 people): Influenza (flu); blocked nose, sore throat and discomfort when swallowing; headache; swelling of arms, hands, legs, ankles or feet; tiredness; asthenia (weakness); redness and warm feeling of the face and/or neck.

Uncommon (may affect up to 1 in 100 people): Dizziness; nausea and abdominal pain; dry mouth; drowsiness, tingling or numbness of the hands or feet; vertigo; fast heart beat including palpitations; dizziness on standing up; cough; diarrhoea; constipation; skin rash, redness of the skin; joint swelling, back pain; pain in joints.

Rare (may affect up to 1 in 1,000 people): Feeling anxious; ringing in the ears (tinnitus); fainting; passing more urine than normal or feeling more of an urge to pass urine; inability to get or maintain an erection; sensation of heaviness; low blood pressure with symptoms such as dizziness, light-headedness; excessive sweating; skin rash all over your body; itching; muscle spasm.

If any of these affect you severely, tell your doctor.

Side effects reported with amlodipine or valsartan alone and either not observed with Amlodipine/Valsartan Krka or observed with a higher frequency than with Amlodipine/Valsartan Krka:

Amlodipine

Consult a doctor immediately if you experience any of the following very rare, severe side effects after taking this medicine:

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing.
- Swelling of eyelids, face or lips.
- Swelling of the tongue and throat which causes great difficulty breathing.
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions.
- Heart attack, abnormal heart beat.
- Inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell.

The following side effects have been reported. If any of these cause you problems or if they last for more than one week, you should contact your doctor.

Common (may affect up to 1 in 10 people): Dizziness, sleepiness; palpitations (awareness of your heart beat); flushing, ankle swelling (oedema); abdominal pain, feeling sick (nausea).

Uncommon (may affect up to 1 in 100 people): Mood changes, anxiety, depression, sleeplessness, trembling, taste abnormalities, fainting, loss of pain sensation; visual disturbances, visual impairment, ringing in the ears; low blood pressure; sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis); indigestion, vomiting (being sick); hair loss, increased sweating, itchy skin, skin discolouration; disorder in passing urine, increased need to urinate at night, increased number of times of passing urine; inability to obtain an erection, discomfort or enlargement of the breasts in men, pain, feeling unwell, muscle pain, muscle cramps; weight increase or decrease.

Rare (may affect up to 1 in 1,000 people): Confusion.

Very rare (may affect up to 1 in 10,000 people): Decreased number of white blood cells, decrease in blood platelets which may result in unusual brusing or easy bleeding (red blood cell damage); excess sugar in blood (hyperglycaemia); swelling of the gums, abdominal bloating (gastritis); abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests; increased muscle tension; inflammation of blood vessels often with skin rash, sensitivity to light.

Not known (frequency cannot be estimated from the available data): Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

Valsartan

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): Decrease in red blood cells, fever, sore throat or mouth sores due to infections; spontaneous bleeding or bruising; high level of potassium in the blood; abnormal liver test results; decreased renal functions and severely decreased renal functions; swelling mainly of the face and the throat; muscle pain; rash, purplish-red spots; fever; itching; allergic reaction; blistering skin (sign of a condition called dermatitis bullous).

If you experience any of these, tell your doctor straight away.

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 Amlodipine/Valsartan Krka

Keep this medicine out of the sight and reach of children.

Do not use Amlodipine/Valsartan Krka after the expiry date which is stated on the box and the blister. The expiry date refers to the last day of that month.

Store below 30 °C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Amlodipine/Valsartan Krka contains
- The active substances are valsartan and amlodipine.
  5 mg/80 mg film-coated tablet
  Each 5 mg/80 mg film-coated tablet contains 5 mg amlodipine (as amlodipine besilate) and 80 mg valsartan.
  5 mg/160 mg film-coated tablet
  Each 5 mg/160 mg film-coated tablet contains 5 mg amlodipine (as amlodipine besilate) and 160 mg valsartan.
  10 mg/160 mg film-coated tablet
  Each 10 mg/160 mg film-coated tablet contains 10 mg amlodipine (as amlodipine besilate) and 160 mg valsartan.
- The other ingredients are microcrystalline cellulose, magnesium stearate, croscarmellose sodium, povidone K25, sodium laurilsulfate, mannitol and colloidal anhydrous silica in the tablet core and poly(vinyl alcohol), titanium dioxide (E171), macrogol 3000, talc and yellow iron oxide (E172) in the film coating. See section 2: "Amlodipine/Valsartan Krka contains sodium".

What Amlodipine/Valsartan Krka looks like and contents of the pack
Amlodipine/Valsartan Krka 5 mg/80 mg film-coated tablets (tablets): this medicinal product is presented as brownish yellow, round, slightly biconvex, film-coated tablets with bevel edges and with possible dark spots (tablet diameter: 8 mm, thickness 3.0 mm – 4.3 mm).
Amlodipine/Valsartan Krka 5 mg/160 mg film-coated tablets (tablets): this medicinal product is presented as brownish yellow, oval, biconvex, film-coated tablets with possible dark spots (tablet dimension: 13 mm x 8 mm, thickness: 3.8 mm – 5.4 mm).
Amlodipine/Valsartan Krka 10 mg/160 mg film-coated tablets (tablets): this medicinal product is presented as pale brownish yellow, oval, biconvex, film-coated tablets (tablet dimension: 13 mm x 8 mm, thickness: 3.8 mm – 5.4 mm).

5 mg/80 mg tablets: Blister (OPA/Alu/PVC-Alu foil): 14, 28, 30, 56, 90, 98 and 100 tablets, in a box.
5 mg/160 mg and 10 mg/160 mg tablets: Blister (OPA/Alu/PVC-Alu foil): 28, 30, 56, 90, 98 and 100 tablets, in a box.

Not all pack sizes may be marked.

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
KRKA - FARMA d.o.o., V. Holjevca 20/E**,** 10 450 Jastrebarsko**,** Croatia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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**
Hungary	Amlodipin/Valzartán Krka
Finland, Norway, Sweden	Amlodipin/Valsartan Krka
Belgium, Ireland, France	Amlodipine/Valsartan Krka
Spain	Amlodipino/Valsartán Krka
Austria	Amlodipin/Valsartan TAD
Greece	Amlodipine+Valsartan/TAD
Portugal	Amlodipina + Valsartan TAD

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