Package leaflet: Information for the patient

Amlodipine/Valsartan/Hydrochlorothiazide Krka 5 mg/160 mg/12.5 mg film-coated tablets
Amlodipine/Valsartan/Hydrochlorothiazide Krka 5 mg/160 mg/25 mg film-coated tablets
Amlodipine/Valsartan/Hydrochlorothiazide Krka 10 mg/160 mg/12.5 mg film-coated tablets
amlodipine/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 Amlodipine/Valsartan/Hydrochlorothiazide Krka is and what it is used for

Amlodipine/Valsartan/Hydrochlorothiazide Krka tablets contain three substances called amlodipine, valsartan and hydrochlorothiazide.
All 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.
- Hydrochlorothiazide belongs to a group of substances called “thiazide diuretics”. Hydrochlorothiazide increases urine output, which also lowers blood pressure.

As a result of all three mechanisms, the blood vessels relax and blood pressure is lowered.

Amlodipine/Valsartan/Hydrochlorothiazide Krka is used to treat high blood pressure in adult patients whose blood pressure is already controlled while taking amlodipine, valsartan and hydrochlorothiazide and who may benefit from taking one tablet containing all three substances.

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

Do not take Amlodipine/Valsartan/Hydrochlorothiazide Krka:
- if you are more than 3 months pregnant. (It is also recommended to avoid Amlodipine/Valsartan/Hydrochlorothiazide Krka in early pregnancy – see Pregnancy section.)
- if you are allergic to amlodipine or to any other calcium channel blockers, valsartan, hydrochlorothiazide, sulphonamide-derived medicines (medicines used to treat chest or urinary infections), or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic, do not take Amlodipine/Valsartan/Hydrochlorothiazide Krka and talk to your doctor.

- if you have 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 problems or if you are having dialysis.
- if you are unable to produce urine (anuria).
- if the level of potassium or sodium in your blood is too low despite treatment to increase the potassium or sodium levels in your blood.
- if the level of calcium in your blood is too high despite treatment to reduce the calcium levels in your blood.
- if you have gout (uric acid crystals in the joints).
- 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 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 Amlodipine/Valsartan/Hydrochlorothiazide Krka and talk to your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Amlodipine/Valsartan/Hydrochlorothiazide Krka.

- if you have a low level of potassium or magnesium in your blood (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm).
- if you have a low level of sodium in your blood (with or without symptoms such as tiredness, confusion, muscle twitching, convulsions).
- if you have a high level of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness and twitching).
- if you have kidney problems, have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.
- if you have liver problems.
- if you have or have had heart failure or coronary artery disease, particularly if you are prescribed the maximum dose of Amlodipine/Valsartan/Hydrochlorothiazide Krka (10 mg/320 mg/25 mg).
- if you 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 suffer from aldosteronism. This is a disease in which the adrenal glands make too much of the hormone aldosterone If this applies to you, the use of Amlodipine/Valsartan/Hydrochlorothiazide Krka is not recommended.
- if you suffer from a disease called systemic lupus erythematosus (also called "lupus" or "SLE").
- if you have diabetes (high level of sugar in your blood).
- if you have high levels of cholesterol or triglycerides in your blood.
- if you experience skin reactions such as rash after sun exposure.
- if you had an allergic reaction to other high blood pressure medicines or diuretics (a type of medicine also known as "water tablets"), especially if you suffer from asthma and allergies
- if you have been sick (vomiting or diarrhoea).
- 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/Hydrochlorothiazide Krka and contact your doctor straight away. You should never take Amlodipine/Valsartan/Hydrochlorothiazide Krka again.
- if you experience dizziness and/or fainting during treatment with Amlodipine/Valsartan/Hydrochlorothiazide Krka, tell your doctor as soon as possible.
- 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 Amlodipine/Valsartan/Hydrochlorothiazide Krka. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- 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 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 Amlodipine/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 Amlodipine/Valsartan/Hydrochlorothiazide Krka, seek medical attention immediately.

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 Amlodipine/Valsartan/Hydrochlorothiazide Krka".

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

Children and adolescents
The use of Amlodipine/Valsartan/Hydrochlorothiazide Krka in children and adolescents under 18 years of age is not recommended.

Elderly (age 65 years and older)
Amlodipine/Valsartan/Hydrochlorothiazide Krka can be used by people aged 65 years and over at the same dose as for other adults and in the same way as they have already taken the three substances called amlodipine, valsartan and hydrochlorothiazide. Elderly patients, particularly those taking the maximum dose of Amlodipine/Valsartan/Hydrochlorothiazide Krka (10 mg/320 mg/25 mg), should have their blood pressure checked regularly.

Other medicines and Amlodipine/Valsartan/Hydrochlorothiazide 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 your dose and/or to take other precautions. In some cases you may have to stop using one of the medicines. This is especially important if you are using any of the medicines listed below:

<u>Do not take together with:</u>
- lithium (a medicine used to treat some types of depression);
- medicines or substances that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin;
- ACE inhibitors or aliskiren (see also information under the headings "Do not take Amlodipine/Valsartan/Hydrochlorothiazide Krka" and "Warnings and precautions").

<u>Caution should be used with:</u>
- alcohol, sleeping pills and anaesthetics (medicines allowing patients to undergo surgery and other procedures);
- amantadine (anti-Parkinson therapy, also used to treat or prevent certain illnesses caused by viruses);

- anticholinergic agents (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);
- anticonvulsant medicines and mood-stabilising medicines used to treat epilepsy and bipolar disorder (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone); cholestyramine, colestipol or other resins (substances used mainly to treat high levels of lipids in the blood);
- simvastatin (a medicine used to control high cholesterol levels);
- ciclosporin (a medicine used in transplantation to prevent organ rejection or for other conditions, e.g: rheumatoid arthritis or atopic dermatitis);
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide;
- digoxin or other digitalis glycosides (medicines used to treat heart problems);
- verapamil, diltiazem (heart medicines);
- iodine contrast media (agents used for imaging examinations);
- medicines for the treatment of diabetes (oral agents such as metformin or insulins);
- medicines for the treatment of gout, such as allopurinol;
- medicines that may increase blood sugar levels (beta blockers, diazoxide);
- 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 that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, amphotericin or penicillin G;
- medicines to increase blood pressure such as adrenaline or noradrenaline;
- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- medicines used for oesophageal ulceration and inflammation (carbenoxolone);
- medicines used to relieve pain or inflammation, especially non-steroidal anti-inflammatory agents (NSAIDs), including selective cyclooxygenase-2 inhibitors (Cox-2 inhibitors);
- muscle relaxants (medicines to relax the muscles which are used during operations);
- nitroglycerin and other nitrates, or other substances called "vasodilators";
- other medicines to treat high blood pressure, including methyldopa;
- rifampicin (used, for example, to treat tuberculosis), erythromycin, clarithromycin (antibiotics);
- St. John's wort;
- dantrolene (infusion for severe body temperature abnormalities);
- vitamin D and calcium salts.

Amlodipine/Valsartan/Hydrochlorothiazide Krka with food, drink and alcohol
Grapefruit and grapefruit juice should not be consumed by people who are prescribed Amlodipine/Valsartan/Hydrochlorothiazide 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/Hydrochlorothiazide Krka. Talk to your doctor before drinking alcohol. Alcohol may make your blood pressure fall too much and/or increase the possibility of dizziness or fainting.

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/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 Amlodipine/Valsartan/Hydrochlorothiazide Krka.
Amlodipine/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 used after the third month of pregnancy.

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

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

Driving and using machines
This medicine may make you feel dizzy, drowsy, nauseous or have a headache. If you experience these symptoms, do not drive or use tools or machines.

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

3. How to take Amlodipine/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 get the best results and lower the risk of side effects.

The usual dose of Amlodipine/Valsartan/Hydrochlorothiazide Krka is one tablet per day.
- It is best to take the tablet at the same time each day. Morning is the best time.
- Swallow the tablet whole with a glass of water.
- You can take Amlodipine/Valsartan/Hydrochlorothiazide Krka with or without food. Do not take Amlodipine/Valsartan/Hydrochlorothiazide 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.

If you take more Amlodipine/Valsartan/Hydrochlorothiazide Krka than you should
If you have accidentally taken too many Amlodipine/Valsartan/Hydrochlorothiazide Krka tablets, talk to a doctor immediately.You may require medical attention.

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/Hydrochlorothiazide Krka
If you forget to take a dose of this medicine, take it as soon as you remember and then take the next dose at its usual time. If it is almost time for your next dose you should simply take the next tablet at the usual time. Do not take a double dose (two tablets at once) to make up for a forgotten tablet.

If you stop taking Amlodipine/Valsartan/Hydrochlorothiazide Krka
Stopping your treatment with Amlodipine/Valsartan/Hydrochlorothiazide Krka may cause your disease to get worse. Do not stop taking
your medicine unless your doctor tells you to.

Always take this medicine, even if you are feeling well
People who have high blood pressure often do not notice any signs of the problem. Many feel normal. It is very important that you take this medicine exactly as your doctor tells you to get the best results and reduce the risk of side effects. Keep your appointments with the doctor even if you are feeling well.

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.

As for any combination containing three active substances, side effects associated with each individual component cannot be excluded. The side effects reported with Amlodipine/Valsartan/Hydrochlorothiazide Krka or one of its three active substances (amlodipine, valsartan and hydrochlorothiazide) are listed below and may occur with the use of Amlodipine/Valsartan/Hydrochlorothiazide Krka.

Some side effects can be serious and need immediate medical attention.
Consult a doctor immediately if you experience any of the following serious side effects after taking this medicine:
Common (may affect up to 1 in 10 people):
- dizziness
- low blood pressure (feeling of faintness, light-headedness, sudden loss of consciousness)

Uncommon (may affect up to 1 in 100 people):
- severely decreased urine output (decreased kidney function)

Rare (may affect up to 1 in 1,000 people):
- spontaneous bleeding
- irregular heart beat
- liver disorder

Very rare (may affect up to 1 in 10,000 people):
- sudden wheeziness, chest pain, shortness of breath or difficulty 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
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell
- weakness, bruising, fever and frequent infections
- stiffness

Other side effects may include:
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):
- sleepiness
- palpitations (awareness of your heart beat)
- flushing
- ankle swelling (oedema)
- abdominal pain
- stomach discomfort after meal
- tiredness
- headache
- frequent urination

- high level of uric acid in the blood
- low level of magnesium in the blood
- low level of sodium in the blood
- dizziness, fainting on standing up
- reduced appetite
- nausea and vomiting
- itchy rash and other types of rash
- inability to achieve or maintain erection

Uncommon (may affect up to 1 in 100 people):
- fast heart beat
- spinning sensation
- vision disorder
- stomach discomfort
- chest pain
- increase of urea nitrogen, creatinine and uric acid in the blood
- high level of calcium, fat or sodium in the blood
- decrease of potassium in the blood
- breath odour
- diarrhoea
- dry mouth
- weight increase
- loss of appetite
- disturbed sense of taste
- back pain
- joint swelling
- muscle cramps/weakness/pain
- pain in extremity
- inability to either stand or walk in a normal manner
- weakness
- abnormal coordination
- dizziness on standing up or after exercising
- lack of energy
- sleep disturbances
- tingling or numbness
- neuropathy
- sudden, temporary loss of consciousness
- low blood pressure on standing up
- cough
- breathlessness
- throat irritation
- excessive sweating
- itching
- swelling, reddening and pain along a vein
- skin reddening
- trembling
- mood changes
- anxiety
- depression
- sleeplessness
- taste abnormalities
- fainting
- loss of pain sensation
- visual disturbances
- visual impairment
- ringing in the ears

- sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis)
- altered bowel habits
- indigestion
- hair loss
- itchy skin
- skin discolouration
- disorder in passing urine
- increased need to urinate at night
- increased number of times of passing urine
- discomfort or enlargement of the breasts in men
- pain
- feeling unwell
- weight decrease

Rare (may affect up to 1 in 1,000 people):
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin)
- sugar in the urine
- high level of sugar in the blood
- worsening of the diabetic metabolic state
- abdominal discomfort
- constipation
- liver disorders which can occur together with yellow skin and eyes, or dark-coloured urine (haemolytic anaemia)
- increased sensitivity of skin to sun
- purple skin patches
- kidney disorders
- 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)
- swelling of the gums
- abdominal bloating (gastritis)
- 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
- disorders combining rigidity, tremor and/or movement disorders
- fever, sore throat or mouth ulcers, more frequent infections (lack or low level of white blood cells)
- pale skin, tiredness, breathlessness, dark-coloured urine (haemolytic anaemia, abnormal breakdown of red blood cells either in the blood vessels or elsewhere in the body)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis)
- severe upper stomach ache (inflammation of the pancreas)
- difficulty breathing with fever, coughing, wheezing, breathlessness (respiratory distress, pulmonary oedema, pneumonitis)
- facial rash, joint pain, muscle disorder, fever (lupus erythematosus)
- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis)
- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis)
- acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion)

Not known (frequency cannot be estimated from the available data):
- changes in blood tests for kidney function, increase of potassium in your blood, low level of red blood cells
- abnormal red blood cell test
- low level of a certain type of white blood cell and blood platelet
- increase of creatinine in the blood
- abnormal liver function test
- severely decreased urine output
- inflammation of blood vessels
- weakness, bruising and frequent infections (aplastic anaemia)
- 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)
- breathlessness
- severely decreased urine output (possible signs of renal disorder or renal failure)
- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (erythema multiforme)
- muscle spasm
- fever (pyrexia)
- blistering skin (sign of a condition called dermatitis bullous)
- skin and lip cancer (non-melanoma skin cancer)

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/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.

This medicine does not require any special storage conditions.

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 Amlodipine/Valsartan/Hydrochlorothiazide Krka contains
- The active substances are amlodipine, valsartan and hydrochlorothiazide.
  5 mg/160 mg/12.5 mg:
  Each film-coated tablet contains 5 mg amlodipine (as amlodipine besilate), 160 mg valsartan and 12.5 mg hydrochlorothiazide.
  5 mg/160 mg/25 mg:
  Each film-coated tablet contains 5 mg amlodipine (as amlodipine besilate), 160 mg valsartan and 25 mg hydrochlorothiazide.
  10 mg/160 mg/12.5 mg:
  Each film-coated tablet contains 10 mg amlodipine (as amlodipine besilate), 160 mg valsartan and 12.5 mg hydrochlorothiazide.

- The other ingredients (excipients) are microcrystalline cellulose, povidone K25, croscarmellose sodium, sodium laurilsulfate, mannitol, colloidal anhydrous silica, magnesium stearate (E470b) in the tablet core and poly(vinyl alcohol), macrogol 3350, titanium dioxide (E171), talc, red iron oxide (E172) – only for 10 mg/160 mg/12.5 mg and yellow iron oxide (E172) – only for 5 mg/160 mg/25 mg in film coating. See section 2 "Amlodipine/Valsartan/Hydrochlorothiazide Krka contains sodium".

What Amlodipine/Valsartan/Hydrochlorothiazide Krka looks like and contents of the pack
5 mg/160 mg/12.5 mg:
Film-coated tablets (tablets) are white or almost white, oval, biconvex, engraved with mark K1 on one side of the tablet, dimensions approximately 13 x 8 mm.
5 mg/160 mg/25 mg:
Film-coated tablets (tablets) are light yellow, oval, biconvex, engraved with mark K3 on one side of the tablet, dimensions approximately 13 x 8 mm.
10 mg/160 mg/12.5 mg:
Film-coated tablets (tablets) are pink, oval, biconvex, engraved with mark K2 on one side of the tablet, dimensions approximately 13 x 8 mm.

Amlodipine/Valsartan/Hydrochlorothiazide Krka is available in boxes containing:
- 7, 10, 14, 28, 30, 56, 60, 84, 90, 98, 100, 7 x 1, 10 x 1, 14 x 1, 28 x 1, 30 x 1, 56 x 1, 60 x 1, 84 x 1, 90 x 1, 98 x 1 and 100 x 1 film-coated tablets in blisters,
- 7, 14, 28, 56, 84, 98, 7 x 1, 14 x 1, 28 x 1, 56 x 1, 84 x 1 and 98 x 1 film-coated tablets in blisters, calendar packs.

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 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**
Belgium, Ireland, Denmark, Norway, Finland	Amlodipine/Valsartan/Hydrochlorothiazide Krka
Greece	Amlodipine+Valsartan+Hydrochlorothiazide/TAD
Spain	Amlodipino/Valsartan/Hidroclorotiazida Krka
Portugal	Amlodipina + Valsartan + Hidroclorotiazida Krka

This leaflet was last revised in