**Package leaflet: Information for the patient**

**Ramipril Krka 1.25 mg tablets**
**Ramipril Krka 2.5 mg tablets**
**Ramipril Krka 5 mg tablets**
**Ramipril Krka 10 mg tablets**
Ramipril

**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 Ramipril Krka is and what it is used for

Ramipril Krka contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors.

Ramipril Krka works by:
- decreasing your body's production of substances that could raise your blood pressure,
- making your blood vessels relax and widen,
- making it easier for your heart to pump blood around your body.

Ramipril Krka can be used:
- to treat high blood pressure (hypertension),
- to reduce the risk of you having a heart attack or stroke,
- to reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes),
- to treat your heart when it cannot pump enough blood to the rest of your body (heart failure),
- as treatment following heart attack (myocardial infarction) complicated with heart failure.

## 2. What you need to know before you take Ramipril Krka

**Do not take Ramipril Krka:**
- if you are allergic to ramipril, any other ACE inhibitor medicine, or any of the other ingredients of Ramipril Krka listed in section 6.
  Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you ever had a serious allergic reaction called "angioedema" The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.

- if you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Ramipril Krka may not be suitable for you.
- if you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis).
- during the last 6 months of pregnancy (see section below on "Pregnancy and breast-feeding").
- if your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Do not take Ramipril Krka if any of the above apply to you. If you are not sure, talk to your doctor before taking Ramipril Krka.

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Ramipril Krka:
- if you have heart, liver or kidney problems,
- if you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis),
- if you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization),
- if you are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your Ramipril Krka treatment one day beforehand; ask your doctor for advice,
- if you have high amounts of potassium in your blood (shown in blood test results),
- if you are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium in your blood especially if you are elderly.
  if you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:
  - racecadotril, a medicine used to treat diarrhoea;
  - temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs and for cancer);
  - vildagliptin, a medicine used to treat diabetes.
- if you have collagen vascular disease such as scleroderma or systemic lupus erythematosus,
- if you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), 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 Ramipril Krka".

You must tell your doctor if you think you are (or might become) pregnant. Ramipril Krka is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy (see section below on "Pregnancy and breast-feeding").

**Children and adolescents**
Ramipril Krka is not recommended for use in children and adolescents below 18 years of age because safety and efficacy of Ramipril Krka in children has not yet been established.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Ramipril Krka.

**Other medicines and Ramipril Krka**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (including herbal medicines). This is because Ramipril Krka can affect the way some other medicines work. Also some medicines can affect the way Ramipril Krka works.

Please tell your doctor if you are taking any of the following medicines. They can make Ramipril Krka work less well:
- medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin),
- medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.

Please tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with Ramipril Krka:
- medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin),
- medicines for cancer (chemotherapy),
- diuretics (water tablets) such as furosemide,
- potassium supplements (including salt substitutes), potassium-sparing diuretics (e.g. spironolactone, triamterene, amiloride) and other medicines that can increase the amount of potassium in your blood (e.g. heparin for thinning blood to prevent clots; and trimethoprim and co-trimoxazole also known as trimethoprim/sulfamethoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection),
- steroid medicines for inflammation such as prednisolone,
- allopurinol (used to lower the uric acid in your blood),
- procainamide (for heart rhythm problems),
- vildagliptin (used for treating type 2 diabetes),
- racecadotril (a medicine used to treat diarrhoea),
- medicines which are most often used to avoid rejection of transplanted organs (temsirolimus, sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section “Warnings and precautions”.

Please tell your doctor if you are taking any of the following medicines. They may be affected by Ramipril Krka:
- medicines for diabetes such as oral glucose lowering medicines and insulin. Ramipril Krka may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Ramipril Krka,
- lithium (for mental health problems). Ramipril Krka may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.

If any of the above apply to you (or you are not sure), talk to your doctor before taking Ramipril Krka.

Your doctor may need to change your dose and/or to take other precautions:
- if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Ramipril Krka” and “Warnings and precautions”).

**Ramipril Krka with food and drink**
- Drinking alcohol with Ramipril Krka may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Ramipril Krka, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.
- Ramipril Krka may be taken 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.

*Pregnancy*
You must tell your doctor if you think that you are (or might become) pregnant.
You should not take Ramipril Krka in the first 12 weeks of pregnancy, and you must not take them at all after the 13th week as their use during pregnancy may possibly be harmful to the baby.
If you become pregnant while on Ramipril Krka, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

*Breast-feeding*
You should not take Ramipril Krka if you are breast-feeding.
Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
You may feel sleepy or dizzy after taking Ramipril Krka. This is more likely to happen when you start taking Ramipril Krka or start taking a higher dose. If this happens, do not drive or use any tools or machines.

**Ramipril 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 Ramipril 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.

**Taking this medicine**
- Take this medicine by mouth at the same time of the day each day.
- Swallow the tablets whole with liquid.
- Do not crush or chew the tablets.

**How much to take**
*Treatment of high blood pressure*
- The usual starting dose is 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust the amount you take until your blood pressure is controlled.
- The maximum dose is 10 mg once daily.
- If you are already taking diuretics (water tablets), your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with Ramipril Krka.

*To reduce the risk of you having a heart attack or stroke*
- The usual starting dose is 2.5 mg once daily.
- Your doctor may then decide to increase the amount you take.
- The usual dose is 10 mg once daily.

*Treatment to reduce or delay the worsening of kidney problems*
- You may be started on a dose of 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust the amount you are taking.
- The usual dose is 5 mg or 10 mg once daily.

*Treatment of heart failure*
- The usual starting dose is 1.25 mg once daily.
- Your doctor will adjust the amount you take.
- The maximum dose is 10 mg daily. Two administrations per day are preferable.

*Treatment after you have had a heart attack*
- The usual starting dose is 1.25 mg once daily to 2.5 mg twice daily.
- Your doctor will adjust the amount you take.

- The usual dose is 10 mg daily. Two administrations per day are preferable.

*Elderly*
- Your doctor will reduce the initial dose and adjust your treatment more slowly.

**If you take more Ramipril Krka than you should**
Tell a doctor or go to the nearest hospital casualty department straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you. This is so the doctor knows what you have taken.

**If you forget to take Ramipril Krka**
- If you miss a dose, take your normal dose when it is next due.
- Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Ramipril Krka**
Keep taking your medicine until your doctor tells you to stop. Do not stop taking Ramipril Krka just because you feel better. If you stop, your illness may return.

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.

**Stop taking Ramipril Krka and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:**
- Swelling of the face, lips or throat which makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ramipril Krka.
- Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiform).

**Tell your doctor immediately if you experience:**
- Faster heart rate, uneven or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke.
- Shortness of breath or a cough. These could be signs of lung problems.
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems.
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas).
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

**Other side effects include:**
Please tell your doctor if any of the following gets serious or lasts longer than a few days.

**Common** (may affect up to 1 in 10 people)
- Headache or feeling tired.
- Feeling dizzy. This is more likely to happen when you start taking Ramipril Krka or start taking a higher dose.
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly.
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath.

- Stomach or gut pain, diarrhoea, indigestion, feeling or being sick.
- Skin rash with or without raised area.
- Chest pain.
- Cramps or pain in your muscles.
- Blood tests showing more potassium than usual in your blood.

**Uncommon** (may affect up to 1 in 100 people)
- Balance problems (vertigo).
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia).
- Loss or change in the way things taste.
- Sleep problems.
- Feeling depressed, anxious, more nervous than usual or restless.
- Blocked nose, difficulty breathing or worsening of asthma.
- A swelling in your gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea.
- Heartburn, constipation or dry mouth.
- Passing more water (urine) than usual over the day.
- Sweating more than usual.
- Loss or decrease of appetite (anorexia).
- Increased or irregular heartbeats.
- Swollen arms and legs. This may be a sign of your body holding onto more water than usual.
- Flushing.
- Blurred vision.
- Pain in your joints.
- Fever.
- Sexual inability in men, reduced sexual desire in men or women.
- An increased number of certain white blood cells (eosinophilia) found during a blood test.
- Blood tests showing changes in the way your liver, pancreas or kidneys are working.

**Rare** (may affect up to 1 in 1,000 people)
- Feeling shaky or confused.
- Red and swollen tongue.
- Severe flaking or peeling of the skin, itchy, lumpy rash.
- Nail problem (e.g. loosening or separation of a nail from its bed).
- Skin rash or bruising.
- Blotches on your skin and cold extremities.
- Red, itchy, swollen or watery eyes.
- Disturbed hearing and ringing in your ears.
- Feeling weak.
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin.

**Very rare** (may affect up to 1 in 10,000 people)
- Being more sensitive to the sun than usual.

**Not Known** (frequency cannot be estimated from the available data)
- concentrated urine (dark in colour), feeling or being sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible.

**Other side effects reported:**
Please tell your doctor if any of the following gets serious or lasts longer than a few days.
- Difficulty concentrating.
- Swollen mouth.
- Blood tests showing too few blood cells in your blood.

- Blood tests showing less sodium than usual in your blood.
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon).
- Breast enlargement in men.
- Slowed or impaired reactions.
- Burning sensation.
- Change in the way things smell.
- Hair loss.

**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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Ramipril 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 25°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 Ramipril Krka contains**
- The active substance is ramipril.
  Each tablet contains 1.25 mg ramipril.
  Each tablet contains 2.5 mg ramipril.
  Each tablet contains 5 mg ramipril.
  Each tablet contains 10 mg ramipril.
- The other ingredients (excipients) are sodium hydrogen carbonate (E500); lactose monohydrate; croscarmellose sodium; pregelatinized starch, maize; sodium stearyl fumarate; yellow iron oxide (E172) - only in 2.5 mg and 5 mg tablets and red iron oxide (E172) - only in 5 mg tablets. See section 2 “Ramipril Krka contains lactose and sodium”.

**What Ramipril Krka looks like and contents of the pack**
Ramipril Krka 1.25 mg tablets are white to whitish oblong flat tablets, dimensions 8.0 x 4.0 mm.
Ramipril Krka 2.5 mg tablets are yellow oblong flat tablets, dimensions 10.0 x 5.00 mm.
Ramipril Krka 5 mg tablets are pink oblong flat tablets, dimensions 8.8 x 4.4 mm.
Ramipril Krka 10 mg tablets are white to whitish oblong flat tablets, dimensions 11.0 x 5.5 mm.

Ramipril Krka tablets are available in boxes of 10, 20, 30, 50, 60, 90, 100 tablets in blisters.
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, Hungary | Amprilan |
| Estonia, Lithuania, Latvia, Poland, | Ampril (only strength 2.5 mg, 5 mg, 10 mg) |
| Slovakia, Bulgaria | Ampril |
| Austria, Denmark, Ireland, Sweden, Slovenia | Ramipril Krka |

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