Package leaflet: information for the patient

Ramipril Sandoz 2.5 mg tablets
Ramipril Sandoz 5 mg tablets
Ramipril Sandoz 10 mg tablets

ramipril

Read the entire 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.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms 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.

Contents of this leaflet:

1. What is Ramipril Sandoz and what is it used for?

Ramipril Sandoz contains a medicine called ramipril. It belongs to a group of medicines called ACE inhibitors (angiotensin-converting enzyme inhibitors).

Ramipril Sandoz works by:
to reduce the production of substances in your body that can increase your blood pressure
to relax and widen your blood vessels
to help your heart pump blood more easily throughout your body.

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

2. When should you not take this medicine or be extra careful?

When should you not use this medicine?

You are allergic to ramipril, another medicine with an ACE inhibitor, or any of the other ingredients in this medicine. You can find these ingredients in section 6.
Signs of an allergic reaction include rash, swallowing or breathing problems, swelling of your lips, face, throat, or tongue.
If you have ever had a severe 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, breathing and swallowing difficulties.
If you are undergoing dialysis or any other type of blood filtration. Depending on the machine used, Ramipril Sandoz may not be suitable for you.
If you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis).
During the last 6 months of pregnancy (see section "Pregnancy and breastfeeding" for more information).
If your blood pressure is abnormally low or unstable. Your doctor needs to assess this.
If you have diabetes or impaired kidney function and you are taking a medicine containing aliskiren to lower your blood pressure
If you are using or have used sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (a rapid swelling under the skin, in an area such as the throat) is increased.

Do not take Ramipril Sandoz if any of the above points apply to you. If you are unsure, you should speak to your doctor before taking Ramipril Sandoz.

When should you be extra careful with this medicine?
Contact your doctor or pharmacist before taking this medicine:
if you have heart, liver, or kidney problems
if you have lost a lot of body salts or fluids (due to vomiting, diarrhea, more sweating than usual, a low-salt diet, taking diuretics (water tablets) for a long time, or if you have had dialysis)
if you are going to receive treatment to reduce your allergy to bee or wasp stings (desensitization)
if you are going to receive an anesthetic. This may be given for an operation or dental work. You may need to stop your treatment with Ramipril Sandoz one day in advance; ask your doctor for advice
if you have a high potassium concentration in your blood (as seen in blood test results)
if you are taking medicines or have conditions that can lower the sodium level in your blood. Your doctor may perform regular blood tests, especially to check the sodium level in your blood, particularly if you are elderly.
if you are taking any of the following medicines, the risk of angioedema may be increased:
- Racecadotril, a medicine for the treatment of diarrhea;
- Medicines used to prevent organ transplant rejection and in the treatment of cancer (e.g., temsirolimus, sirolimus, everolimus);
- Vildagliptin, a medicine for the treatment of diabetes.

if you have a vascular collagen disease such as scleroderma or systemic lupus erythematosus

if you are taking any of the following medicines used to treat high blood pressure: angiotensin II receptor blockers (ARBs) (also known as sartans – e.g., valsartan, telmisartan, irbesartan), especially if you have diabetes-related kidney problems. aliskiren.
Your doctor may regularly check your kidney function, blood pressure, and electrolyte levels (e.g.,
potassium) in your blood.
See also the information under "When should you not use this medicine?".
you must inform your doctor if you think you are pregnant (or might become pregnant). Ramipril Sandoz is not recommended during the first 3 months of pregnancy and can cause serious harm to your baby after the 3rd month of pregnancy (see section "Pregnancy and breastfeeding").

Children and adolescents up to 18 years
Ramipril Sandoz is not recommended for use in children and adolescents under 18 years of age because the safety and efficacy of ramipril in children have not yet been established.

If any of the above points apply to you (or if you are in doubt), you should speak to your doctor before taking Ramipril Sandoz.

Are you taking any other medicines?

Are you taking, have you recently taken, or might you take any other medicines in addition to Ramipril Sandoz? If so, tell your doctor or pharmacist. This is because Ramipril Sandoz can affect the way some other medicines work. Also, some medicines can affect the way Ramipril Sandoz works.

Inform your doctor if you are taking any of the following medicines. They may cause Ramipril Sandoz to work less effectively:
medicines used to relieve pain and inflammation (e.g., non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, indomethacin, and acetylsalicylic acid)
medicines used to treat low blood pressure, shock, heart failure, asthma, or allergy such as ephedrine, noradrenaline, and adrenaline. Your doctor will need to check your blood pressure.

Inform your doctor if you are taking any of the following medicines. They may increase the risk of side effects if taken with Ramipril Sandoz:
medicines used to relieve pain and inflammation (e.g., non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, indomethacin, and acetylsalicylic acid)
medicines for cancer (chemotherapy)
diuretics (water tablets) such as furosemide
potassium supplements (including salt substitutes), potassium-sparing diuretics, and other medicines that can increase the amount of potassium in your blood (for example, trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immune-suppressing medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin the blood to prevent blood clots)
steroids for inflammation, such as prednisolone

allopurinol (used to lower uric acid levels in your blood) procainamide (for heart rhythm problems).
temsirolimus (for cancer)
sirolimus, everolimus (to prevent transplant rejection)
vildagliptin (used to treat type 2 diabetes).
racecadotril (used against diarrhea).

Your doctor may need to adjust your dosage and/or take other precautions:
If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also the information under "When should you not use this medicine?" and "When should you be extra careful with this medicine?").

Inform your doctor if you are taking any of the following medicines. They can be affected by Ramipril Sandoz:

medicines for diabetes such as oral antidiabetics and insulin. Ramipril Sandoz can lower your blood sugar level. Monitor your blood sugar level closely while taking Ramipril Sandoz.
lithium (for mental health problems). Ramipril Sandoz can increase the amount of lithium in your blood. Your lithium concentration should be closely monitored by your doctor.

If any of the above points apply to you (or if you are in doubt), you should speak to your doctor before taking Ramipril Sandoz.

What should you pay attention to with food and alcohol?

Drinking alcohol with Ramipril Sandoz can cause dizziness or light-headedness. If you are wondering how much you can drink while taking Ramipril Sandoz, you should discuss it with your doctor because medicines used to lower blood pressure and alcohol can have additive effects.
Ramipril Sandoz can be taken with or without food.

Pregnancy and breastfeeding

Pregnancy
You should inform your doctor if you think you are pregnant (or might become pregnant).
You should not take Ramipril Sandoz during the first 12 weeks of pregnancy and you should certainly not take it after the 13th week because its use during pregnancy could be harmful to the baby.
If you become pregnant while taking Ramipril Sandoz, you should inform your doctor immediately. In case of a planned pregnancy, a suitable alternative treatment should be switched to in advance.

Breastfeeding
You should not take Ramipril Sandoz if you are breastfeeding.

Consult your doctor or pharmacist before taking any medicine.

Driving and using machines

You may feel dizzy while taking Ramipril Sandoz. The chance of this is greater when you start taking Ramipril Sandoz or when you start taking a higher dosage. In that case, you should not drive or use tools or machines.

3. How to take this medicine?

Always take this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Taking this medicine
Take this medicine by mouth, at the same time every day.
Swallow the tablets whole with liquid.
Do not crush or chew the tablets.

How much should you take?

Treatment of high blood pressure
The usual starting dose is 1.25 mg or 2.5 mg once a day.
Your doctor will adjust the amount you take until your blood pressure is under control.
The maximum dose is 10 mg once a day.
If you are already taking diuretics (water tablets), your doctor may stop the diuretic or reduce the amount before starting treatment with Ramipril Sandoz.

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

Treatment to reduce or prevent worsening of kidney problems
You can start with a dose of 1.25 mg or 2.5 mg once a day.
Your doctor will adjust the amount you take.
The usual dose is 5 mg or 10 mg once a day.

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

Treatment after a heart attack
The usual starting dose is 1.25 mg once a day up to 2.5 mg twice a day.
Your doctor will adjust the amount you take.
The usual dose is 10 mg per day. Two administrations per day are preferable.

Elderly
Your doctor will lower the starting dose and will adjust your treatment more slowly.

Have you taken too much of this medicine?

If you have used or taken too much Ramipril Sandoz, contact your doctor, pharmacist, or the Poison Control Center (070/245.245) immediately.
Inform your doctor or go immediately to the emergency department of the nearest hospital. Do not drive to the hospital, have someone else transport you or call an ambulance. Take the medicine packaging with you. Then the doctor will know what you have taken.

Have you forgotten to take this medicine?
If you have missed a dose, take your normal dose at the usual time.
Do not take a double dose to make up for a forgotten tablet.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. Possible side effects

Like any medicine, this medicine can have side effects, although not everyone gets them.

Stop taking this medicine and see a doctor immediately if you notice any of the following serious side effects - you may need urgent medical treatment:
swelling of the face, lips, or throat, making it difficult to swallow or breathe, itching and skin rash. This may be a sign of a serious allergic reaction to this medicine
severe skin reactions such as rash, sores in your mouth, worsening of a pre-existing skin condition, redness, blistering or peeling of the skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or erythema multiforme).

Inform your doctor immediately if you experience:
a faster heartbeat, an irregular or strong heartbeat (palpitations), chest pain, tightness in your chest, or more serious problems such as heart attack and stroke
shortness of breath or coughing. These may be signs of lung problems
bruising more easily, bleeding longer than normal, any sign of bleeding (e.g., gum bleeding), purple spots on the skin, or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy, or having pale skin. These may be signs of blood or bone marrow problems
severe stomach pain that may radiate to your back. This may be a sign of pancreatitis (inflammation of the pancreas)
fever, chills, fatigue, loss of appetite, stomach pain, nausea, yellowing of your skin or eyes (jaundice). These may be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

Other side effects include:

Inform your doctor if any of the following side effects become severe or last longer than a few days.

Common (may affect up to 1 in 10 people)
Headache or feeling tired

Feeling dizzy. This is more likely when you start taking Ramipril Sandoz or if you increase the dosage
Fainting, hypotension (abnormally low blood pressure), especially if you stand up or sit up too quickly
Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
Stomach or intestinal pain, diarrhea, indigestion, nausea, or vomiting
Skin rash with or without raised area
Chest pain
Cramps or pain in your muscles
Blood tests indicating that you have more potassium in your blood than normal.

Sometimes (may occur in up to 1 in 100 people)
Balance problems (vertigo)
Itching and unusual skin sensations such as numbness, tingling, prickling, burning, or crawling sensation on your skin (paresthesia)
Loss of taste or change in the taste of things
Sleep problems
Feeling more depressed, anxious, nervous than usual or feeling restless
Blocked nose, breathing difficulties or worsening of asthma
A swelling of your intestines, called "intestinal angioedema", with symptoms such as abdominal pain, vomiting, and diarrhea
Heartburn, constipation, or dry mouth
Urinating more (urine) than usual during the day
Sweating more than usual
Loss of or decreased appetite (anorexia)
Stronger or irregular heartbeat
Swollen arms and legs. This may indicate that your body is retaining more water than usual
Flushing
Blurred vision
Joint pain
Fever
Sexual impotence in men, decreased libido in men or women
An increased number of certain white blood cells (eosinophilia) in blood tests
Abnormalities in the function of the liver, pancreas, or kidneys in blood tests.

Rare (may occur in up to 1 in 1,000 people)
Feeling shaky or confused
Red, swollen tongue
Severe peeling or scaling of the skin, itchy, raised skin rash
Nail problems (e.g., detachment or separation of a nail from the nail bed)
Skin rash or bruising
Spots on your skin and cold extremities
Red, itchy, swollen, or watery eyes
Hearing impairment and ringing in the ears
Feeling weak
Decrease in the number of red blood cells, white blood cells, or platelets, or in the amount of hemoglobin in blood tests.

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

Other side effects that have been reported:

Inform your doctor if any of the following side effects become serious or last longer than a few days.

Unknown (the frequency cannot be determined from the available data)
Concentration disorders
Swollen mouth
Too few blood cells in your blood during blood tests
Lower sodium in your blood than normal during blood tests
Concentrated urine (dark in color), feeling nauseous or vomiting, muscle cramps, confusion, and seizures that may be due to a deficient secretion of ADH (antidiuretic hormone). If you have these symptoms, contact your doctor as soon as possible
Color change of the fingers and toes when cold, followed by tingling or painful sensation when warming up (Raynaud's phenomenon)
Enlargement of the breasts in men
Slower or impaired reactions
Burning sensation
Change in how things smell
Hair loss.

Reporting side effects
If you experience side effects, contact your doctor or pharmacist.
This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Federal Agency for Medicines and Health Products, Vigilance Division, P.O. Box 97, B-1000 BRUSSELS Madou, Website: www.eenbijwerkingmelden.be, email: adr@fagg.be. By reporting side effects, you help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the blister pack, strips, tablet container, and carton after “EXP”. It includes a month and a year. The last day of that month is the expiry date.

Store below 25°C. Keep in the original packaging to protect from moisture.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?
The active ingredient is ramipril.
Each tablet contains 2.5 mg ramipril.
Each tablet contains 5 mg ramipril.
Each tablet contains 10 mg ramipril.

The other ingredients are microcrystalline cellulose, pregelatinized starch, precipitated silica, glycine hydrochloride, glycerol dibehenate, yellow iron oxide (E172) (only for 2.5 mg), red iron oxide (E172) (only for 5 mg).

What does Ramipril Sandoz look like and what is in a package?
2.5 mg tablets:
Light yellow, lightly speckled, tablet-shaped with a score line on one side.
The tablet can be divided into equal doses.

5 mg tablets:
Light pink, lightly speckled, tablet-shaped with a score line on one side.
The tablet can be divided into equal doses.

10 mg tablets:
White to off-white, tablet-shaped with a score line on one side.
The tablet can be divided into equal doses.

The tablets are packed in aluminum/aluminum strip packs, aluminum/aluminum blister packs or PP container with HDPE closure, contained in a cardboard box.

Package sizes:
Al/Al strip packs: 14, 28, 56, and 98 tablets
Al/Al blister packs: 14, 28, 56, and 98 tablets
PP container: 20, 28, 30, 50, 100, 250 tablets

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer
Marketing authorization holder:
Sandoz nv/sa., Telecom Gardens, Medialaan 40, B-1800 Vilvoorde

Manufacturers:
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany
Lek S.A, ul.Podlipie 16, 95-010 Stryków, Poland
Lek S.A. ul. Domaniewska 50 C, 02-672 Warsaw, Poland
Sandoz GmbH, Biochemiestrasse 10, 6250 Kundl, Austria

Marketing authorization numbers for Ramipril Sandoz 2.5 mg tablets:
BE277611 (blister pack), BE293194 (strip), BE277627 (tablet container).

Ramipril Sandoz 5 mg tablets:
BE277636 (blister pack), BE293203 (strip), BE277645 (tablet container).

Ramipril Sandoz 10 mg tablets:
BE277654 (blister pack), BE293212 (strip), BE277663 (tablet container).

Method of delivery
Prescription-only medicine.

This medicine is registered in EEA member states under the following names:

BE	Ramipril Sandoz 2.5 mg tablets Ramipril Sandoz 5 mg tablets Ramipril Sandoz 10 mg tablets
IT	RAMIPRIL SANDOZ

This leaflet was last approved in 03/2021.