

## Ramipril 1.25mg - 2,5mg - 5mg 10mg tablets

ramipril

### What is ramipril and what is it used for?

Ramipril contains a medication called ramipril, which belongs to a group of medications called ACE inhibitors (Angiotensin-Converting Enzyme inhibitors). Ramipril works by:

- reducing the production of substances in your body that increase blood pressure;
- relaxing and widening your blood vessels;
- making it easier for your heart to pump blood around your body.
- Ramipril can be used to:
- treat high blood pressure (hypertension);
- reduce the risk of a heart attack or stroke;
- reduce or delay the worsening of kidney problems (regardless of whether or not you have diabetes);
- treat your heart if it cannot pump blood adequately to the rest of your body (heart failure);
- treat complications of heart failure following a heart attack (myocardial infarction).

### When should you not use this medication or take extra precautions?

#### When should you not use this medication?

- You are allergic to any of the substances in this medication.
- Signs of an allergic reaction may include: rash, difficulty swallowing or breathing, swelling of the lips, face, throat, or tongue.
- You have ever had a severe allergic reaction called "angioedema." Signs include itching, hives (urticaria), red stripes on the hands, feet, and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.
- You are undergoing dialysis or another type of blood filtration. Depending on the device used, this medication may not be suitable for you.
- You have kidney problems with reduced blood flow to your kidney (renal artery stenosis).
- You are in the last 6 months of pregnancy (see section below "Pregnancy and breastfeeding").
- Your blood pressure is abnormally low or unstable. Your doctor will need to assess this.
- You are using a blood pressure medication that contains aliskiren and you have diabetes.
- You are using sacubitril/valsartan, a medication used to treat a type of chronic heart failure in adults, as it increases the risk of angioedema (rapid subcutaneous swelling, in a place such as the throat).
- Do not take this medication if any of the above warnings apply to you. If you are unsure, consult your doctor before taking this medication.
- When should you take extra precautions with this medication?
- Contact your doctor or pharmacist for advice before using this medication:
- If you have heart, liver, or kidney problems.
- If you have lost a lot of body salts or fluids (due to nausea (vomiting), diarrhea, excessive sweating, following a low-salt diet, taking diuretics (water pills) for a long time, or undergoing dialysis).
- If you will undergo treatment to reduce your allergy to bee or wasp stings (desensitization).
- If you will receive anesthesia. This can be administered for surgery or dental procedures. It may be necessary to stop taking this medication the day before. Consult your doctor for advice.
- If you have high levels of potassium in your blood (as indicated in blood test results).
- If you are taking medications or have conditions that can lower the sodium level in your blood. Your doctor may perform regular blood tests, particularly to monitor the sodium level in your blood, especially if you are elderly.

If you are using any of the following medications, the risk of angioedema may be increased:

- Racecadotril, a medication used to treat diarrhea.
- Medications used to prevent organ transplant rejection and treat cancer (mTOR inhibitors, such as temsirolimus, sirolimus, everolimus).
- Vildagliptin and other medications belonging to the DPP-IV inhibitors group, used to treat diabetes.
- If you are using medications called mTOR inhibitors (such as temsirolimus, everolimus, sirolimus), vildagliptin, or racecadotril, as they may increase the risk of angioedema, a severe allergic reaction.
- If you have a connective tissue disease such as scleroderma or systemic lupus erythematosus.
- If you are using any of the following medications for the treatment of high blood pressure: [translation incomplete]

Please note that the translation provided above is incomplete. It is recommended to consult the complete and accurate information provided in the original patient information leaflet or consult a healthcare professional for further guidance.

Angiotensin II receptor antagonists (ARBs) (also known as sartans - for example, valsartan, telmisartan, irbesartan), especially if you have diabetes-related kidney problems;

**Aliskiren:** Your doctor may regularly monitor your kidney function, blood pressure, and electrolyte levels (e.g., potassium) in your blood. See also the information in the section "When should you not use this medication?". Tell your doctor if you think you are pregnant (or if you could become pregnant). The use of this medication is not recommended during the first three months of pregnancy and can have serious adverse effects on the baby if used from a gestational age of three months onwards (see section below "Pregnancy and breastfeeding").

Children and adolescents under 18 years

The use of this medication is not recommended in children and adolescents under 18 years of age because the safety and efficacy of this medication have not been established.

If any of the above warnings apply to you (or if you are unsure), consult your doctor before taking this medication.

#### **Are you taking any other medications?**

If you are taking other medications in addition to Ramipril, have recently taken them, or may take other medications in the near future, inform your doctor or pharmacist. This is because Ramipril may affect the way other medications work. Conversely, some medications may affect the way Ramipril works.

Inform your doctor if you are taking any of the following medications. They may cause Ramipril to be less effective:

- Medications used to reduce pain and inflammation (e.g., non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or indomethacin, and acetylsalicylic acid).
- Medications used to treat low blood pressure, shock, heart failure, asthma, or allergies such as ephedrine, noradrenaline, or adrenaline. Your blood pressure will need to be monitored by your doctor.
- Inform your doctor if you are taking any of the following medications. They may increase the chance of side effects if taken together with Ramipril:
- Medications used to reduce pain and inflammation (e.g., non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen or indomethacin, and acetylsalicylic acid).
- Medications for cancer (chemotherapy).
- Temsirolimus (for cancer).
- Sirolimus, everolimus (to prevent rejection by the immune system after transplantation).
- Diuretics (water pills), such as furosemide.
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (such as spironolactone, triamterene, amiloride), and other medications that can increase the amount of potassium in your blood (such as trimethoprim and co-trimoxazole for bacterial infections; cyclosporine, an immunosuppressant used to prevent organ transplant rejection; and heparin, a medication used to thin the blood to prevent blood clot formation).
- Medications that can increase the amount of potassium in your blood, such as spironolactone, triamterene, amiloride, potassium salts, and heparin (to thin the blood).
- Steroids used for inflammation, such as prednisolone.
- Allopurinol (used to lower uric acid levels in your blood).
- Procainamide (for heart rhythm disorders).
- Vildagliptin (used in the treatment of type 2 diabetes).
- Racecadotril (for the treatment of diarrhea).

Your doctor may adjust your dose and/or take other precautions if you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also the information in the sections "When should you not use this medication?" and "When should you take extra precautions with this medication?"). Inform your doctor if you are taking any of the following medications.

They may be affected by Ramipril: Medications for diabetes, such as oral glucose-lowering medications and insulin. Ramipril can lower your blood sugar level. Monitor your blood sugar level closely while taking Ramipril.

Lithium (for mental problems). Ramipril can increase the amount of lithium in your blood. Your doctor will need to closely monitor the amount of lithium in your blood.

If any of the above warnings apply to you (or if you are unsure), consult your doctor before taking Ramipril.

What to be aware of regarding food and alcohol?

Drinking alcohol together with this medication can make you dizzy or lightheaded. If you are concerned about how much you can drink while taking this medication, discuss it with your doctor, as blood pressure-lowering medications and alcohol can have additional effects.

This medication can be taken with or without food.

#### **Pregnancy and breastfeeding**

**Pregnancy:** Tell your doctor if you think you are pregnant (or could become pregnant). This medication should not be taken during the first 12 weeks of pregnancy and not at all after the 13th week, as its use during pregnancy can cause possible harm to your baby.

If you become pregnant during treatment with this medication, immediately inform your doctor. Prior to a planned pregnancy, another suitable blood pressure-lowering medication will be prescribed instead of this medication.

**Breastfeeding:** You should not take this medication if you are breastfeeding.

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

**Driving and using machinery:** You may feel dizzy while taking this medication. This is more likely to occur when starting treatment with this medication or when starting a higher dose. If this happens, do not drive a vehicle or use tools or machinery.

#### **how to use this medication?**

Always use this medication exactly as prescribed by your doctor. If you are unsure about the correct usage, contact your doctor or pharmacist.

## How to take this medication?

- Take this medication orally, at the same time every day.
- Swallow the tablets whole with a little liquid.
- Do not chew or crush 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 dose until your blood pressure is under control.

The maximum dose is 10 mg once daily.

If you are already taking diuretics (water pills), your doctor may reduce or discontinue the diuretic before starting treatment with this medication.

To reduce the risk of heart attack or stroke: The usual starting dose is 2.5 mg of ramipril once daily.

Your doctor may then decide to increase the dose.

The usual dose is 10 mg once daily.

**Treatment to reduce or delay worsening of kidney problems:** You may start with a dose of 1.25 mg or 2.5 mg once daily.

Your doctor will adjust the dose as necessary.

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 dose as necessary.

The maximum dose is 10 mg per day. Twice-daily administration is preferred.

**Treatment after having a heart attack:** The usual starting dose is 1.25 mg once daily up to 2.5 mg twice daily.

Your doctor will adjust the dose as necessary.

The usual dose is 10 mg per day. Twice-daily administration is preferred.

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

## What to do if you have taken too much of this medication?

Consult a doctor or go to the nearest hospital emergency department immediately. Do not drive to the hospital yourself, have someone else drive you or call an ambulance. Take the packaging of the medication with you so that the doctor will know what you have taken.

## What to do if you forget to take this medication?

If you have missed a dose, take your regular dose when it is nearly time.

Do not take a double dose to make up for a missed tablet.

If you have any other questions about the use of this medication, contact your doctor or pharmacist.

## Possible Side Effects

Like any medication, this medication can cause side effects, although not everyone experiences them.

Stop taking this medication and seek immediate medical attention if you experience any of the following serious side effects – you may require urgent medical treatment:

Swelling of the face, lips, or throat, which may cause difficulty swallowing or breathing, as well as itching and rash. This may be a sign of a severe allergic reaction to this medication.

Severe skin reactions, including rash, mouth ulcers, worsening of pre-existing skin disease, redness, blistering, or peeling of the skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, or erythema multiforme).

**Immediately inform your doctor if you experience the following:** Rapid heartbeat, irregular or forceful heartbeats (palpitations), chest pain, a tight feeling in your chest, or more serious problems including a heart attack and stroke. Shortness of breath or cough. These could be signs of lung problems. Easily bruising, longer bleeding than usual, any signs of bleeding (e.g., gum bleeding), purple spots, skin spots, or more frequent infections than usual, sore throat and fever, feeling tired, weak or dizzy, or having pale skin. These may be signs of blood or bone marrow problems. Severe abdominal pain that may radiate to your back. This may be a sign of pancreatitis (inflammation of the pancreas). Fever, chills, fatigue, decreased appetite, abdominal 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 symptoms become severe or last for more than a few days:

**Common side effects (affecting less than 1 in 10 users):** Headache, feeling tired. Feeling dizzy. This is more likely when starting treatment with this medication or when starting a higher dose. Fainting, hypotension (abnormally low blood pressure), especially when getting up or sitting up quickly. Dry, hacking cough, sinus inflammation (sinusitis) or bronchitis, shortness of breath. Stomach or intestinal pain, diarrhea, indigestion, feeling nauseous. Skin rash with or without raised areas. Chest pain.

Muscle cramps or pain.

Blood tests showing higher than usual levels of potassium in your blood.

**Uncommon side effects (affecting less than 1 in 100 users):**

- Balance disorders (vertigo).
- Itching and unusual skin sensations such as numbness, tingling, prickling, or a burning or tingling sensation on your skin (paresthesia).
- Decreased taste or a change in taste.
- Sleep disorders.
- Feeling depressed, anxious, or more nervous than usual, or restlessness.
- Stuffy nose, difficulty breathing, or worsening of asthma.
- Swelling in your intestines called "intestinal angioedema," characterized by symptoms such as abdominal pain, vomiting, and diarrhea.
- Heartburn, constipation, or dry mouth.
- Increased urination throughout the day.
- Increased sweating than usual.
- Loss of appetite or decreased appetite (anorexia).
- Increased or irregular heartbeat.
- Swollen arms and legs. This may be a sign that your body is retaining more water than usual.
- Flushing.
- Blurred vision.
- Joint pain.
- Fever.
- Sexual impotence in men, decreased sexual libido in men or women.
- Increased number of certain white blood cells (eosinophilia) shown in a blood test.
- Blood tests showing changes in the way your liver, pancreas, or kidneys function.
- Rarely (occur in less than 1 in 1000 users):
  - Feeling shaky or confused.
  - Red and swollen tongue.
  - Severe peeling or shedding of the skin, itchy rash with bumps.
  - Nail problems (e.g., loss of nail substance and detachment of a nail from its bed).
  - Skin rash or bruising.
  - Spots on your skin and cold extremities.
  - Red, itchy, swollen, or watery eyes.
  - Hearing disorders and ringing in the ears.
  - Feeling weak.
  - Blood tests showing a decrease in the number of red blood cells, white blood cells, or platelets, or a decrease in hemoglobin.

**Very rarely (occur in less than 1 in 10,000 users):**

- Increased sensitivity to sunlight than usual.
- Other reported side effects:
  - Inform your doctor if any of the following side effects become severe or last for more than a few days.
  - Unknown frequency (frequency cannot be determined from available data):
    - Concentrated urine (dark in color), nausea or vomiting, muscle cramps, confusion, and epileptic seizures that may result from impaired secretion of ADH (antidiuretic hormone). Contact your doctor as soon as possible if you experience these symptoms.
      - Concentration disorders.
      - Swollen mouth.
      - Blood tests showing low blood cell count.
      - Blood tests showing lower than usual sodium levels in your blood.
        - Fingers and toes that change color when you're cold and then tingle or become painful when you warm up (Raynaud's phenomenon).
        - Breast enlargement in men.
        - Delayed or disrupted reactions.
        - Burning sensation.
        - Changes in the way things smell.
        - Hair loss.

**How to store this medicine?** Keep out of sight and reach of children.

- Do not use this medicine after the expiry date stated on the box and blister pack after "Exp:". The expiry date refers to the last day of that month.
- Store below 25°C. Store in the original packaging to protect from moisture.
- Do not dispose of medications in wastewater or household waste. Ask your pharmacist how to dispose of medications that are no longer needed. These measures will help to protect the environment.