

Ramipril 1.25mg, 2.5mg, 5mg and 10mg tablets

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, pharmacist or nurse.
- This medicine has been prescribed for you. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1 What Ramipril tablets are and what they are used for**
- 2 What you need to know before you take Ramipril tablets**
- 3 How to take Ramipril tablets**
- 4 Possible side effects**
- 5 How to store Ramipril tablets**
- 6 Contents of the pack and other information**

1 What Ramipril tablets are and what they are used for

Ramipril tablets contain the active ingredient ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

Ramipril tablets work 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 tablets are used:

- to treat high blood pressure (hypertension)
- 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 tablets

Do not take Ramipril tablets if:

- you are **allergic** (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the ingredients of Ramipril tablets 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
- you have 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
- you are having **dialysis** or any other type of **blood filtration**. Depending on the machine that is used, Ramipril tablets may not be suitable for you
- you have **kidney problems** where the blood supply to your kidney is reduced (renal artery stenosis)
- you are in the **last 6 months of pregnancy** (see section below on "Pregnancy and breast-feeding")
- your **blood pressure** is abnormally **low or unstable**. Your doctor will need to make this assessment.
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing **aliskiren**.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ramipril tablets if you:

- have **heart, liver or kidney** problems
- have **hypoadosteronism** (affecting potassium and sodium levels in the body)
- 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)
- are going to have **treatment to reduce your allergy to bee or wasp stings** (desensitization)
- are going to receive an **anaesthetic**. This may be given for an operation or any dental work. You may need to stop your Ramipril tablets treatment one day beforehand; ask your doctor for advice
- have **high amounts of potassium in your blood** (shown in blood test results)
- have **low sodium levels in your blood** or have conditions which may lower your blood sodium levels. Your doctor may carry out regular blood tests, to check the levels of sodium in your blood, especially if you are elderly.

- have **collagen vascular disease** such as scleroderma or systemic lupus erythematosus
- think that you are (or might become) **pregnant**. Ramipril tablets are not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy, see section "Pregnancy and breast-feeding".
- 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, telmesartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - Aliskerin

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium or sodium) in your blood at regular intervals.

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:

- sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

See also information under the heading '**Do not take** Ramipril tablets'.

Children

Ramipril tablets are not recommended for use in children and adolescents below 18 years of age because safety and efficacy of Ramipril tablets 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 tablets.

Other medicines and Ramipril tablets

Tell your doctor, pharmacist or nurse if you are taking or have recently taken or might take any other medicines. This is because Ramipril tablets can affect the way some other medicines work. Also some medicines can affect the way Ramipril tablets work.

Please tell your doctor if you are taking any of the following medicines. They can make Ramipril tablets 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 tablets:

- 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/temsirolimus)
- medicines which are most often used to **avoid rejection of transplanted organs** (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions".
- **diuretics** (water tablets) such as furosemide
- medicines which can **increase the amount of potassium in your blood** such as ciclosporin, spironolactone, triamterene, amiloride, potassium salts and heparin (for thinning blood)
- **steroid medicines for inflammation** such as prednisolone
- **allopurinol** (used to lower the uric acid in your blood)
- **procainamide** (for heart rhythm problems)
- **trimethoprim** and co-trimoxazole also known as trimethoprim/sulfamethoxazole (for infections caused by bacteria).

Please tell your doctor if you are taking any of the following medicines. They may be affected by Ramipril tablets:

- medicines for **diabetes** such as oral glucose lowering medicines and insulin. Ramipril tablets may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Ramipril tablets
- **lithium** (for mental health problems). Ramipril tablets may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.

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 tablets' and 'Warnings and precautions')

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

Ramipril tablets with food and alcohol

Drinking alcohol with Ramipril tablets may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Ramipril tablets, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects. Ramipril tablets may be taken with or without food.

Pregnancy and breast-feeding

You must tell your doctor if you think that you are (or might become) pregnant.

You should not take Ramipril tablets 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 tablets, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

You may feel dizzy, while taking Ramipril tablets. This is more likely to happen when you start taking Ramipril tablets or start taking a higher dose. If this happens, do not drive or use any tools or machines.

Ramipril tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Ramipril tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take this medicine by mouth at the same time of the day each day. **Swallow the tablets with liquid.**

Doses:

• Treatment of high blood pressure

The usual starting dose is 1.25mg or 2.5mg once daily. Your doctor will adjust the amount you take until your blood pressure is controlled. The maximum dose is 10mg 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 tablets.

• Treatment to reduce or delay the worsening of kidney problems

You may be started on a dose of 1.25mg or 2.5mg once daily. Your doctor will adjust the amount you are taking. The usual dose is 5mg or 10mg once daily.

• Treatment of heart failure

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

• Treatment after you have had a heart attack

The usual starting dose is 1.25mg once daily to 2.5mg twice daily. Your doctor will adjust the amount you take. The usual dose is 10mg 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 tablets than you should

Symptoms associated with overdose may include abnormally slow heart action and renal failure. 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 tablets

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 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 tablets and contact your 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 which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ramipril tablets.
- 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 multiforme).

Contact your doctor immediately, if you notice any of the following:

- 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.

Tell your doctor if you notice any of the following side effects or they get worse:

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 tablets 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, prickling, 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.

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.

Frequency not known: concentrated urine (dark in colour), feel or are 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.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Ramipril tablets

Keep this medicine out of the sight and reach of children. Store below 25°C.

Do not use this medicine after the expiry date which is stated on the carton and the blister or the tablet container. The expiry date refers to the last day of that month.

Do not throw away 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 tablets contain

The active substance is ramipril. Each tablet contains either 1.25mg, 2.5mg, 5mg or 10mg of the active ingredient.

The other ingredients are: Sodium hydrogen carbonate, lactose monohydrate, croscarmellose sodium, pregelatinised starch 1500, sodium stearyl fumarate, yellow iron oxide (E172) (2.5mg and 5mg tablets only) and red iron oxide red (E172) (5mg tablets only).

What Ramipril tablets look like and contents of the pack

Ramipril 1.25mg tablets: white to off white, capsule-shaped, uncoated, tablets.

Ramipril 2.5mg tablets: yellow, capsule-shaped, uncoated, flat tablets, scored on one side and side walls, marked R2.

Ramipril 5mg tablets: pink, capsule-shaped, uncoated, flat tablets, scored on one side and side walls, marked R3.

Ramipril 10mg tablets: white to off-white, capsule-shaped, uncoated, flat tablets, scored on one side and side walls, marked R4.

Pack size is 28 tablets.

Marketing Authorisation Holder

Actavis, Barnstaple, EX32 8NS, UK.

Manufacturer

Balkanpharma – Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria

Actavis Ltd

BLB015-016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

Actavis UK Limited

Whiddon Valley, Barnstaple, N Devon, UK EX32 8NS

This leaflet was last revised in March 2018