

# Ramipril 1.25mg, 2.5mg, 5mg and 10mg capsules

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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## **1 What Ramipril capsules are and what they are used for**

Ramipril capsules contain a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

**Ramipril capsules 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 capsules can be 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 Before you take**

**Do not take** Ramipril capsules and **tell** your doctor if:

- you are **allergic** (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the ingredients of Ramipril capsules 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 capsules 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 capsules if any of the above apply to you. If you are not sure, talk to your doctor before taking Ramipril capsules.

**Check with your doctor or pharmacist** before taking your medicine if you:

- have **heart, liver or kidney** problems
- 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 capsules treatment one day beforehand; ask your doctor for advice
- have **high amounts of potassium in your blood** (shown in blood test results)
- have **collagen vascular disease** such as scleroderma or systemic lupus erythematosus

- you must tell your doctor if you think that you are (or might become) **pregnant**. Ramipril capsules 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) in your blood at regular intervals.

See also information under the heading 'Do not take Ramipril capsules'

## **Children**

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

## **Taking Ramipril capsules with other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (including herbal medicines). This is because Ramipril capsules can affect the way some other medicines work. Also some medicines can affect the way Ramipril capsules work.

- Please tell your doctor if you are taking any of the following medicines. They can make Ramipril capsules 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 (norepinephrine) or adrenaline (epinephrine). 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 capsules:

- 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)
- medicines to **stop the rejection of organs after a transplant** such as ciclosporin and tacrolimus
- **diuretics** (water tablets) such as furosemide
- medicines which can **increase the amount of potassium in your blood** such as 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).

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

- medicines for **diabetes** such as oral glucose lowering medicines and insulin. Ramipril capsules may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Ramipril capsules
- **lithium** (for mental health problems). Ramipril capsules 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 capsules' and 'Warnings and precautions')

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

## **Food and alcohol**

Drinking alcohol with Ramipril capsules may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Ramipril capsules, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects. Ramipril capsules 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 capsules 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 capsules, 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 capsules if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

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

### Soya warning

Ramipril capsules contain soya lecithin. If you are allergic to peanut or soya, do not use this medicine.

## 3 How to take

Always take Ramipril capsules exactly as your doctor has told you. You should 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 capsules 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 capsules.

#### • 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 capsules 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 capsules

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 capsule.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4 Possible side effects

Like all medicines, Ramipril capsules can cause side effects, although not everybody gets them.

**Stop taking Ramipril capsules 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 capsules.
- 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).

**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** (affects less than 1 in 10 people)

- Headache or feeling tired
- Feeling dizzy. This is more likely to happen when you start taking Ramipril capsules 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
- Stomach or gut pain, diarrhoea, indigestion, feeling or being sick
- Skin rash with or without raised area

- Cramps or pain in your muscles
- Blood tests showing more potassium than usual in your blood.

**Uncommon** (affects less than 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** (affects less than 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** (affects less than 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.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5 How to store

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original container.

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

Medicines should not be disposed via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6 Further information

### What Ramipril capsules contain

The active substance is ramipril.

Each capsule contains either 1.25mg, 2.5mg, 5mg or 10mg of the active ingredient.

The other ingredients are starch pregelatinised, gelatin, water, black iron oxide (E172), titanium dioxide (E171), shellac (E904), soya lecithin (E322) and antifoam DC 1510.

2.5mg, 5mg and 10mg capsules also contain indigo carmine FD&C blue 2 (E132), yellow iron oxide (E172).

### What Ramipril capsules look like and contents of the pack

1.25mg capsules are hard, gelatin capsules, light grey body and light grey cap.

2.5mg capsules are hard, gelatin capsules, light grey body and light green cap.

5mg capsules are hard, gelatin capsules, light grey body and green cap.

10mg capsules are hard, gelatin capsules, light grey body and dark green cap.

Pack size is 28 capsules.

### Marketing Authorisation Holder

Actavis, Barnstaple, EX32 8NS, UK.

### Manufacturer

Actavis hf, Reykjavikurvegur 78, IS-220 Hafnarfjoudur, Iceland.

This leaflet was last revised in July 2014