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

Package leaflet: Information for the user

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. How to take Ramipril tablets
3. Possible side effects
4. How to store Ramipril tablets
5. Contents of the pack and other information

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
- reducing the risk of developing kidney problems
- 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 in people who have diabetes or other conditions that affect the kidneys
- as treatment for heart failure
- as treatment following heart attack (myocardial infarction)

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, alcohol or any of the ingredients of Ramipril tablets listed in section 6. Contents of the pack and other information.
- if you have had a serious allergic reaction called “angioedema” The signs include itching, hives (urticaria), redness or swelling on the hands, feet or throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.
- if you have had any other serious allergic reaction called anaphylaxis or any other type of blood filtration
- depending on the machine that is used, Ramipril tablets may not be suitable for you.
- if you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis)
- if you are not 4 months pregnant (see section below on pregnancy and breastfeeding).
- if your blood pressure is abnormally low or unstable.
- your doctor may need to make this assessment
- if you are breast-feeding or plan to breast-feed during treatment 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 weak or kidney problems
- you have had an allergic reaction to any medicines containing aliskiren.
- you have lost a lot of body fluids or fluids (through being sick (vomiting), sweating, becoming more thirsty, being on a low salt diet, taking diuretics (water tablets) for a long time or having had diabetics.
- you are going to have treatment to reduce your allergy to bee or wasp stings (anaphylaxis) or allergy to peanuts (anaphylaxis). 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.
- you have high amounts of potassium in your blood (shown in blood test results)
- you 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 if you are elderly.
- you have collagen vascular disease such as scleroderma or systemic lupus erythematosis
- you 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 breastfeeding.”
- you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin receptor blocker (ARB) also known as sartans – for example valsartan, telmesartan, 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 or sodium) in your blood at regular intervals.

If you are taking any of the following medicines, the risk of angioedema (swelling under the skin in areas such as the throat) is increased:

- angiotensin, sympathic and other medicines belonging to the class of MR blockers (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.

- if you are taking any of the following medicines:
  - medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)), such as ibuprofen or omeprazole and aspirin.
  - medicines which are used to reduce blood pressure or shock, cardiac failure, asthma or allergies such as omeprazole, montelukast or montelukast sodium.
- 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 Ramipril tablets.
  - medicines used to reduce blood pressure (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)), such as ibuprofen or omeprazole and aspirin.
  - medicines for cancer (chemotherapy/oral 1.25mg.
  - medicines which are most often used to avoid rejection of transplanted organs (e.g. cyclosporine, immunosuppressants and other immunosuppressants).
  - medicines for cancer (chemotherapy/oral 1.25mg.
  - medicines which are used to reduce blood pressure (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)), such as ibuprofen or omeprazole and aspirin.
- medicines for cancer (chemotherapy/oral 1.25mg.
If you are taking an angiotensin II receptor blocker (ARB) or aldosterone (see also information under the heading ‘Do not take Ramipril tablets’). Ramipril tablets may increase the amount of lithium in your blood.

Your doctor may need to change your dose and/or to take other precaution(s).

If you are taking an angiotensin II receptor blocker (ARB) or aldosterone (see also information under the heading ‘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 (vertigo) which may make it difficult for you to stand up quickly. 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 breastfeeding

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 31st 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 other medicines.

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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 any of the following side effects are severe or if you notice any of the following side effects and they get worse:

• Inability to pass urine or sudden severe weakness
• Severe skin reaction such as a rash, nettle rash, or swelling of the mouth, throat or eyes
• Chest pain
• Severe infections
• Difficulty breathing, swelling of the face, chest, or lips

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.

Precautions

Before you start the treatment

Tell your doctor if any of the following gets serious or lasts longer. These measures will help protect the environment.

• Do not dispose of medicines through wastewater or in household waste. Ask your pharmacist how to throw away medicines you no longer use.

• The expiry date refers to the last day of that month.

• 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.

How to store Ramipril tablets

Keep this medicine out of the sight of 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 pack.

The expiry date refers to the last day of that month.

Do not throw away medicines no longer needed. Ask your pharmacist how to dispose of medicines you no longer use.

Contents of the pack and other information

What Ramipril tablets contain

The active substance is ramipril.

Each tablet contains either 1.25mg, 2.5mg or 10mg of the active substance: Ramipril.

The other ingredients are: Sodium hydrogen carbonate, lactose monohydrate, magnesium stearate, povidone.

The tablets are coated with hydroxypropylmethylcellulose, colloidal silicon dioxide (Aerosil 200).

The other ingredients are: Sodium hydrogen carbonate, lactose monohydrate, magnesium stearate and povidone.

Each tablet contains either 1.25mg, 2.5mg, 5mg or 10mg of the active substance: Ramipril.

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Each tablet contains either 1.25mg, 2.5mg, 5mg or 10mg of the active substance: Ramipril.

The other ingredients are: Sodium hydrogen carbonate, lactose monohydrate, magnesium stearate and povidone.

Pack size is 28 tablets.

Marketing Authorisation Holder

Actavis, Barnstaple, EX32 8NS, UK.

Manufacturer

Actavis, Barnstaple, EX32 8NS, UK.

Actavis Bulgaria

19/02/18

C.Grant

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