

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Ramic 2.5 mg, 5 mg and 10 mg Capsules

Ramipril

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

In this leaflet:

1. What Ramic Capsules are and what they are used for
2. Before you take Ramic Capsules
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1. WHAT RAMIC CAPSULES ARE AND WHAT THEY ARE USED FOR

Ramic Capsules contain the active ingredient ramipril (belongs to a group of medicines called ACE inhibitors [Angiotensin Converting Enzyme inhibitors]) which:

- decrease the body's production of substances that could raise blood pressure
- relax and widen blood vessels
- make it easier for the heart to pump blood around the body.

You have been prescribed Ramic Capsules for one or more of the following reasons:

- to treat high blood pressure
- to help treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- as an additional therapy to diuretics, with or without cardiac glycosides
- to help reduce the risk of having a heart attack or stroke in type 2 diabetes patients and those heart patients already on standard therapy, who have an increased risk of heart attack
- to help prevent further weakening of your heart if it has been weakened by a heart attack
- to treat or prevent worsening of some kidney diseases including those caused by diabetes.

2. BEFORE YOU TAKE RAMIC CAPSULES

Do NOT take Ramic Capsules if you:

- are **allergic** (hypersensitive) to ramipril or any of the other ingredients in the product (see Section 6)
- have a history of **angioneurotic oedema** (a serious allergic reaction, signs of which include itching, hives, red marks on the hands, feet and throat, swelling of the throat, tongue and around the eyes and lips, difficulty breathing and swallowing) related to previous use of an ACE inhibitor
- are more than **three months pregnant** (see '*Pregnancy and breast-feeding*' section below).
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

These capsules must NOT be used in children.

Take special care with Ramic Capsules and consult your doctor if you:

- have any **heart** problems; ramipril should not be used if you have aortic stenosis (narrowing of the aortic valve)
- have **kidney** problems; you will be assessed before and during treatment with this medicine and may require reduced/less frequent doses as there is a risk of developing high potassium levels in your blood
- are on **haemodialysis or apheresis**; your doctor may have to arrange alternative membranes for this process or prescribe different blood pressure lowering drugs as you may have an anaphylactic reaction (serious reaction)
- suffer from **high blood pressure** (also because of risk of high blood potassium levels), particularly if you are already taking a diuretic (water tablet such as furosemide); either your dose of ramipril will be reduced or you will be instructed to stop taking the diuretic
- have **liver** problems; you should be closely monitored
- are on a **low salt diet** or dialysis, have diarrhoea or vomiting, have salt depletion due to taking diuretics, or have severe heart failure as you may get symptomatic hypotension (drop in blood pressure)
- need to have an **operation** or an **anaesthetic**; tell the doctor or dentist that you are taking Ramic Capsules
- have **collagen vascular disease** (e.g. lupus erythematosus or scleroderma); urine tests may be necessary to measure white blood cells and protein levels
- have a history of **angioneurotic oedema** unrelated to ACE inhibitor therapy; you may suffer hypersensitivity reactions (see section 2: "*Do not take Ramic Capsules if you*")
- are less than three months **pregnant** or trying for a baby (see '*Pregnancy and breast-feeding*' section below); unless ramipril use is considered essential, your doctor will advise alternative blood pressure lowering treatment.
- suffer from **agranulocytosis** (severe dangerous low white blood cell count) and **bone marrow depression** (where the bone marrow is unable to produce normal amounts of red and white blood cells and platelets). Have been reported in rare cases with the use of this type of medicine. This is more likely if you have kidney problems and a collagen vascular disease. The symptoms of this are fever, rigors (exaggerated shivering) and sore throat or dizziness, severe chest pain, heartbeats are getting rapid or irregular. If you suffer from any of these symptoms please speak with your doctor.
- 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, telmisartan, 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) in your blood at regular intervals.

See also information under the heading 'Do NOT take Ramic Capsules if you'

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, but particularly if you are taking:

- antidiabetic drugs (i.e. insulin, oral blood sugar lowering agents); these may eventually cause abnormally low blood sugar levels, especially in the first two weeks and in patients with kidney problems.
- NSAIDs (non-steroidal anti-inflammatory drugs) such as ibuprofen, aspirin, acetylsalicylic acid, indomethacin; the blood pressure lowering effect of Ramic Capsules may be increased.

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 Ramic Capsules if you' and 'Take special care with Ramic Capsules and consult your doctor if you')

Taking Ramic Capsules with food and drink

These capsules can be taken with or without food. Avoid consuming alcohol when taking this medicine.

Pregnancy and breast-feeding

You must tell your doctor if you think you are (or might become) pregnant; he/she will normally advise you to take another medicine instead of Ramic Capsules. These capsules are not recommended in early pregnancy, and must NOT be taken when more than three months pregnant. These capsules are not recommended for nursing mothers; your doctor may choose another treatment if you wish to breast-feed, especially if your baby is newborn or was born prematurely. Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines

You may feel sleepy or dizzy after taking Ramic Capsules, particularly at the start of treatment, when changing over from other medicines and if you drink alcohol at the same time. Do not drive or operate dangerous machinery for several hours until you know how these capsules affect you.

3. HOW TO TAKE RAMIC CAPSULES

Always take this medicine exactly as your doctor has told you; you should check with him/her if you are not sure.

Ramic Capsules can be taken at mealtimes or without food, swallowed whole with plenty of liquid.

Regular monitoring by your doctor is recommended.

Laboratory tests may be affected for patients with kidney problems or those pretreated with a diuretic. 24LF01293PD

DOSE

Patients with high blood pressure: if you are not on diuretics and do not have heart failure, the usual starting dose is 2.5 mg once a day. The dose will then be increased gradually at intervals of 1 – 2 weeks to a maximum of 10 mg once a day. If 10 mg is not effective then your doctor will consider giving you additional medication.

Patients treated with diuretics: you should stop taking the diuretic 2 - 3 days before taking these capsules. If your diuretic cannot be stopped, the starting dose of these capsules should be 1.25 mg a day.

Patients with kidney problems: the usual dose range is 1.25 mg - 5mg once a day, depending on the severity of your condition. For those with severe kidney problems, the recommended initial dose is also 1.25 mg once a day and the maximum dose of 2.5 mg once a day should not be exceeded.

Patients with liver problems: your dose should be reduced and you will be under close medical supervision. Your doctor will advise you what dose to take.

Patients with heart failure: if you have been stabilised on diuretic therapy, your starting dose will be 1.25 mg once a day. The dose may then be doubled at intervals of 1 – 2 weeks to a maximum of 10mg once a day. Daily doses of 2.5 mg or more may be taken as a single dose or in two divided doses. To minimise the risk of low blood pressure, patients on a previous high dose diuretics should have the diuretic dose before starting Ramipril.

Patients who have just had a heart attack: the usual dose ranges from 1.25 - 10 mg ramipril a day, depending on your condition. The initial dose is usually started in hospital. The starting dose is 2.5 mg twice a day which is increased to 5 mg twice a day after 2 days. If the initial 2.5 mg dose is not tolerated, a dose of 1.25 mg twice a day should be given for two days before increasing to 2.5 mg and 5 mg twice a day. If the dose cannot be increased to 2.5 mg twice a day, treatment should be withdrawn. Maintenance dose 2.5 mg to 5 mg twice a day.

Patients with kidney disease including those caused by diabetes: the usual dose is 1.25 mg Ramipril once daily. Your doctor will increase this to 2.5 mg at intervals of 2-3 weeks. Maximum permitted daily dose: 5 mg.

Elderly: your dose will be adjusted according to the level of blood pressure control required. Care should be taken if suffering from heart, liver or kidney problems or if taking diuretics (water tablets) at the same time.

Children: Ramipril is not recommended for use in children and adolescents below 18 years of age because safety and efficacy of Ramipril in children has not yet been established.

If you take more Ramipril Capsules than you should

If you, or someone else, have taken too much medicine, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the pack with you. Long-lasting low blood pressure may occur as a result of overdose.

If you forget to take Ramipril Capsules

If you miss a dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining dose at the correct time. Do not take a double dose to make up for a forgotten dose.

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 may cause side effects, although not everybody gets them.

STOP taking these capsules and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps
- hair loss, fever, muscle and joint pains.

Initial dose or increase in dose

- nausea, dizziness and headaches (may also occur in individuals who have low blood salt levels (i.e. those on haemodialysis, taking diuretics or who have heart failure))
- low blood pressure
- dry, tickly cough, hay fever, runny nose, inflammation of the lungs, tightening of the chest.

Rare

- feeling faint on standing up
- inflammation of the pancreas
- swelling of the face, limbs, lips, tongue, throat; stop taking the capsules and inform your doctor immediately.

Other

- risk of heart attack, potentially severe low blood pressure in high risk patients, chest pain, palpitations, disturbances in heart rhythm and angina
- kidney problems
- dryness of the mouth, irritation and/or inflammation of the lining of the mouth, disturbances in food digestion, constipation, diarrhoea, nausea, vomiting, stomach pain, upper abdominal discomfort, increases in liver enzymes, jaundice (yellowing of the skin and whites of eyes) and liver problems (including inflammation)
- reddening of the skin with heat sensation, conjunctivitis, itching, skin blisters, pronounced hair loss, development or worsening of Raynaud's syndrome (a condition that affects the extremities)
- skin reactions e.g. blood blisters and psoriasis, sensitivity of the skin to light
- loosening of nails
- imbalance, nervousness, restlessness, terror, sleep disorders, confusion, loss of appetite, depressed mood, anxiety, numbness and tingling of the skin ("pins and needles"), altered taste, muscle cramps, impotence and reduced sex drive
- laboratory tests may be affected for patients with kidney problems or those pre-treated with a diuretic.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2: Tel: + 353 1 6764971: Fax: +353 1 6762517: Website: www.hpra.ie: e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RAMIPRIL CAPSULES

Keep out of the reach and sight of children. Do not use Ramipril Capsules after the expiry date stated on the carton and blister. The expiry date refers to the last day of that month. Do not store the product above 25°C. Keep in the original package to protect from moisture. Medicines should not be disposed of 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 2.5 mg, 5 mg or 10 mg per capsule.
- **other** ingredients: pregelatinised starch, gelatin, black iron oxide (E172) and titanium dioxide (E171). The 2.5 mg, 5 mg and 10 mg capsules also contain yellow iron oxide (E172) and indigo carmine blue 2 (E132).

What Ramipril Capsules look like and contents of the pack

Ramipril 2.5 mg Capsules are hard with light grey capsule body and light green capsule cap, marked R on cap and 2.5 on body.

Ramipril 5 mg Capsules are hard with light grey capsule body and green capsule cap, marked R on cap and 5 on body.

Ramipril 10 mg capsules are hard with light grey capsule body and dark green capsule cap, marked R on cap and 10 on body.

All capsules contain a white or almost white powder.

The capsules are supplied in aluminium blister strips of pack size 7, 21, 28, 30, 50 and 100. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Pinewood Laboratories Ltd., Ballymacarby, Clonmel, Co. Tipperary, Ireland.

Manufacturers

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

Actavis Ltd, B16, Bulebel Industrial Estate, Zetjun ZTN 08, Malta.

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