

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 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 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 you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet:

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

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 (hypertension)
- to help treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- to help reduce the risk of having a heart attack or stroke
- 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. WHAT YOU NEED TO KNOW 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). Signs of allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- If you 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).

- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Ramip Capsules 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 more than **three months pregnant** (see ‘*Pregnancy and breast-feeding*’ section below)
- If your blood pressure is abnormally low or unstable, your doctor will need to advise you
- If you 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.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Ramip Capsules

- If you have any **heart** problems; ramipril should not be used if you have aortic stenosis (narrowing of the aortic valve)
- If you 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
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitisation)
- If you 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)
- If you 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
- If you have **liver** problems; you should be closely monitored
- If you 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)
- If you need to have an **operation** or an **anaesthetic**; tell the doctor or dentist that you are taking Ramip Capsules
- If you have **collagen vascular disease** (e.g. systemic lupus erythematosus or scleroderma); urine tests may be necessary to measure white blood cells and protein levels
- If you are taking medicines called mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus) or vildagliptin or racecadotril as they may increase the risk of angioedema, a serious allergic reaction
- 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, you doctor will advise alternative blood pressure lowering treatment
- If you 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). These conditions 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

- If you 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.
- If you have high amounts of potassium in your blood (shown in blood test results)
- If you are taking medicines or have conditions which may decrease sodium levels in your blood. Your doctor may carry out regular blood tests, particularly for checking the levels of sodium especially if you are elderly.

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’

Children and adolescents

Ramic Capsules are not recommended for use in children and adolescents below 18 years of age because the safety and efficacy of Ramic 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 Ramic Capsules.

Other medicines and Ramic Capsules

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including those obtained without prescription. This is because Ramic Capsules can affect the way some other medicines work. Also some medicines can affect the way Ramic Capsules work.

Tell your doctor if you are taking any of the following medicines. They can make Ramic Capsules work less well:

- NSAIDs (non-steroidal anti-inflammatory drugs) such as ibuprofen, aspirin, acetylsalicylic acid, indomethacin; the blood pressure lowering effect of Ramic Capsules may be increased.
- 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.

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 Ramic Capsules

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin)
- Medicines for cancer (chemotherapy)
- Medicines to stop the rejection of organs after a transplant such as ciclosporin
- Diuretics (water tablets) such as furosemide
- Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium salts, trimethoprim alone or in combination with sulfamethoxazole (for infections) 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)
- Temsirolimus (for cancer)
- Sirolimus, everolimus (for prevention of graft rejection)
- Vildagliptin (used for treating type 2 diabetes)
- Racecadotril (used to treat diarrhoea)
- 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” and “Warnings and precautions”).

Tell your doctor if you are taking any of the following medicines. They may be affected by Ramic Capsules:

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

If any of the above apply to you (or you are not sure), talk to your doctor before taking Ramic Capsules. Your doctor may need to change your dose and/or to take other precautions.

Ramic Capsules with food and drink

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

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. You should not take Ramic 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 Ramic Capsules, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

Breast-feeding

These capsules are not recommended for nursing mothers; you 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 dizzy while taking Ramic Capsules. This is more likely to happen when you start taking Ramic Capsules or start a higher dose .If this happens, do not drive or use any tools or machines.

3. HOW TO TAKE RAMIC CAPSULES

Always take this medicine exactly as the doctor has told you; you should check with your doctor or pharmacist if you are not sure.

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 amount you take until your blood pressure is controlled.
- The maximum dose is 10 mg 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 Ramic Capsules.

To reduce the risk of you having a heart attack or stroke

- The usual starting dose is 2.5 mg once daily.
- Your doctor may then decide to increase the amount you take.
- The usual dose is 10 mg once daily.

Treatment to reduce or delay the worsening of kidneys problems

- You may be started on a dose of 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust the amount you are taking.
- The usual does 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 amount you take.
- The maximum dose is 10 mg daily. Two administrations per day are preferable.

Treatment after you have had a heart attack

- The usual starting dose is 1.25 mg once daily to 2.5 mg twice daily.
- Your doctor will adjust the amount you take.
- The usual dose is 10 mg daily. Two administrations per day are preferable.

Elderly:

Your doctor will reduce the initial dose and adjust you treatment more slowly.

Taking your medicine

- Take this medicine by mouth at the same time of the day
- Swallow the tablets whole with liquid
- Do not crush or chew the tablets

If you take more Ramic 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 Ramic 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 the 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, Ramic Capsules may cause side effects, although not everybody gets them.

Stop taking Ramic Capsules and see a doctor straight away, 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 with Ramic 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.)

Tell your doctor immediately if you experience:

- 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.

Other side effects include:

Tell your doctor if any of the following gets serious or lasts longer than a few days.

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 Ramic 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, 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, 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 (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:

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
- 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
- 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.

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 RAMIC CAPSULES

Keep this medicine out of the sight and reach of children.

Do not use Ramic Capsules after the expiry date stated on the carton and blister. The expiry date refers to the last day of the 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 protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Ramic 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 Ramic Capsules look like and contents of the pack

Ramic 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.

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

Ramic 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 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., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

Manufacturers

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