


		Colours Used	 Black
		 Keyline	 Unvarnish area
Artwork No.	190124/1		
Customer	Ennogen		
Description	Ramipril Leaflet		
Market	UK		
Language	English		
Dimensions	170 x 600 mm		
Min. Font Size	Arial, 9 pt		
Version No.	1		
Date	19-01-24		

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ramipril 1.25mg Capsules Ramipril 2.5mg Capsules Ramipril 5mg Capsules Ramipril 10mg 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, pharmacist or nurse.
- This medicine has been prescribed for you only. 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

- What Ramipril Capsules are and what they are used for
- What you need to know before you take Ramipril Capsules
- How to take Ramipril Capsules
- Possible side effects
- How to store Ramipril Capsules
- Contents of the pack and other information

1. WHAT RAMIPRIL CAPSULES ARE AND WHAT THEY ARE USED FOR

Ramipril Capsules contain ramipril which belongs to a group of medicines called ACE (angiotensin converting enzyme) inhibitors. They work by widening the blood vessels which makes it easier for the heart to pump blood through them, to all parts of the body. This helps to reduce blood pressure. It can also help to make the heart work better if it does not pump as well as needed.

Ramipril Capsules are used to:-

- Reduce the risk of a heart attack, heart disease and stroke and decrease the risk of requiring surgery to increase blood flow to the heart
- Treat high blood pressure.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RAMIPRIL CAPSULES

Do not take Ramipril Capsules:

- If you are allergic to ramipril, other ACE inhibitors or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction may include a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue.
- If 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 of the eyes and lips, difficulty breathing and swallowing.
- If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults.
- If 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.
- If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis).
- During the last 6 months of pregnancy (see section below on "Pregnancy and breast-feeding").
- If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- If 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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ramipril Capsules:

- If you have heart, liver or kidney problems
- If you 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)
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
- If you are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your ramipril treatment one day beforehand; ask your doctor for advice.
- 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 in your blood especially if you are elderly.
- If you are taking medicines that may increase the risk of angioedema, a serious allergic reaction, such as mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus), vildagliptin or neprilysin (NEP) inhibitors (such as sacubitril).
- If you have a collagen vascular disease such as scleroderma or systemic lupus erythematosus
- 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 below on "Pregnancy and breast-feeding").
- 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.

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 and adolescents

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.

Other medicines and Ramipril Capsules

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

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").

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 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 Ramipril Capsules:

- Sacubitril/valsartan - used for treating a type of long-term (chronic) heart failure in adults (see section 2 "Do not take 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
- 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 against diarrhoea).

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. Check your blood sugar closely while taking Ramipril Capsules.
- Lithium (for mental health problems). Ramipril Capsules may increase the amount of lithium in your blood. Your lithium levels 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 Ramipril Capsules.

Ramipril Capsules with 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

Pregnancy
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.

Breast-feeding

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.

Ramipril 2.5mg Capsules contain Carmoisine (E122) and Brilliant blue (E133)

This may cause allergic reactions.

Ramipril 5mg Capsules contain Ponceau 4R (E124) and Brilliant blue (E133)

This may cause allergic reactions.

3. HOW TO TAKE RAMIPRIL CAPSULES

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Take this medicine by mouth at the same time of the day each day.

Swallow the capsules with liquid. Do not crush or chew the capsules.

The recommended 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.

- 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 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.

- Patients with kidney impairment**

The usual starting dose is 1.25 mg once daily. The maximum dose is 5 mg once daily. In patients with severe kidney impairment the usual starting dose is 1.25 mg. The maximum dose is 2.5 mg once daily.

- Patients with liver impairment**

The usual starting dose is 1.25 mg and you will be monitored closely by your doctor.

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.

Symptoms of overdose can include:

- You may feel dizzy or lightheaded due to a lowering of your blood pressure
- Your heart may beat slower
- You may feel tired, and feel like vomiting which may be due to changing levels of salts and minerals in your blood
- You may feel weak, have a shortness of breath, swelling of your legs, ankles or feet which may be a sign of kidney failure.

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 dose.

If you stop taking Ramipril Capsules
Do not stop taking Ramipril Capsules without first consulting your doctor, as your original symptoms will return.

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 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 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 multiforme).

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 low platelet counts
- 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
- Signs of changes in kidney function, including kidney failure, can include production of less urine, nausea and vomiting, confusion, high blood pressure, stomach pains, slight backache, and build-up of fluid in the body.

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 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, 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 heartbeat
- 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 problems (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.

Not known (frequency cannot be estimated from the available data)

- 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
- An increase in antinuclear antibodies in the blood (this would be picked up during a blood test)
- Various skin conditions including blisters on the skin and mucous membranes (pemphigus), worsening of a condition causing red, flaky, crusty patches of skin (psoriasis), a rash resembling psoriasis (dermatitis psoriasiform) or a rash (pemphigoid or lichenoid exanthema or enanthema).

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE RAMIPRIL CAPSULES

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

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

Do not store above 25°C. Store in the original package.

Do not throw away any 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 Capsules contain
The active substance is ramipril. Each capsule contains either 1.25mg, 2.5mg, 5mg or 10mg ramipril.

The other ingredients are starch pregelatinised, gelatin, titanium dioxide (E171), black iron oxide (E172), polyethylene glycol, shellac (E904), dehydrated alcohol (E1510), isopropyl alcohol, butyl alcohol, propylene glycol (E1520), strong ammonia solution (E527), potassium hydroxide (E525) and purified water.

Ramipril 2.5mg Capsules also contain brilliant blue (E133) (see section 2), carmoisine (E122) (see section 2) and yellow iron oxide (E172).

Ramipril 5mg Capsules also contain ponceau 4R (E124) (see section 2), brilliant blue (E133) (see section 2) and yellow iron oxide (E172).

Ramipril 10mg Capsules also contain indigo carmine (E132) and yellow iron oxide (E172).

What Ramipril Capsules look like and contents of the pack

Ramipril 1.25mg: Hard gelatin capsule. Capsule body: light grey. Capsule cap: light grey. Capsule contains white or almost white powder. Marked with "R" on cap and "1.25" on body.

Ramipril 2.5mg: Hard gelatin capsule. Capsule body: light grey. Capsule cap: light green. Capsule contains white or almost white powder. Marked with "R" on the cap and "2.5" on the body.

Ramipril 5mg: Hard gelatin capsule. Capsule body: light grey. Capsule cap: dark green. Capsule contains white or almost white powder. Marked with "R" on the cap and "5" on the body.

Ramipril 10mg: Hard gelatin capsule. Capsule body: light grey. Capsule cap: dark green. Capsule contains white or almost white powder. Marked with "R" on the cap and "10" on the body.

Ramipril Capsules are available in pack sizes of 7, 21, 28, 30, 50, or 100 capsules.

Not all pack sizes may be marketed.

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This leaflet was last revised in January 2024.