

## **Package leaflet: Information for the user**

**RAMVE 2,5 mg, capsule, hard**  
**RAMVE 5 mg, capsule, hard**  
**RAMVE 10 mg, capsule, hard**

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

### **What is in this leaflet:**

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

### **1. What Ramipril Capsules are and what they are used for**

Ramipril Capsules contain the active ingredient Ramipril. Ramipril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors, which act on heart and blood vessels.

It works 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 of you having a heart attack or stroke
- 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. What you need to know before you take Ramipril Capsules

### Do not take Ramipril Capsules if you:

- Are allergic to ramipril, or other ACE inhibitor medicine or any of the other ingredients of this medicine listed in section 6.. Signs of an allergic reaction may include rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- 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
- Have taken or are currently taking sacubitril/ valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults.
- Are having dialysis or any other type of blood filtration. Depending on the medicine/membrane that is used, Ramipril may not be suitable for you.
- Have kidney problems where blood supply to your kidneys is reduced (renal artery stenosis)
- Have blood pressure which is abnormally low or unstable, your doctor will need to make this assessment
- Have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- Are in the last **6 months of pregnancy** (see section below on “Pregnancy and breastfeeding”)

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 or pharmacist before taking your medicine:

- 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 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
- 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) or vildagliptin, neprilysin (NEP) inhibitors (such as racecadontril) or sacubitril/valsartan. For sacubitril/valsartan, see section 2 “Do not take Ramipril Capsules”.

- If you have a 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 is 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”.

- 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 children and adolescents below 18 years of age, because the safety and efficacy of Ramipril 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.

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 indomethacin 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.

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:

- 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 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)
- Trimethoprim and co-trimoxazole (for infections caused by bacteria)
- Temsirolimus (for cancer)
- Everolimus, sirolimus (for prevention of graft rejection)
- Vildagliptin (used for treating type 2 diabetes)
- Racecadotril (used against 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 Ramipril capsules” and “Warnings and precautions”)

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.

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 this medicine, 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 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 13<sup>th</sup> 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 higher dose. If this happens, do not drive or use any tools or machines.

#### **Important information about some of the ingredients of Ramipril Capsules**

- **Ramipril Capsules contain methyl parahydroxy benzoate and propyl parahydroxy benzoate which** may cause allergic reactions (possibly delayed) and exceptionally bronchospasm
- **The 2.5mg, 5mg and 10mg capsules also contain colour carmoisine** which may cause allergic reactions
- **The 2.5mg capsules contain colour sunset yellow** which may cause allergic reactions
- **The 2.5mg and 5mg capsules also contain Ponceau 4R** which may cause allergic reactions

**Although Ramipril Capsules contains a very small amount of these, if you have been told by your doctor that you are allergic to these ingredients, contact your doctor or pharmacist before taking this medicine.**

### **3. How to take Ramipril Capsules**

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

#### **The recommended dose is:**

##### **Adults**

##### *Treatment of high blood pressure*

- The usual starting dose is 1.25 or 2.5mg of ramipril 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 Ramipril.

##### *To decrease the risk of you having a heart attack or stroke.*

- The usual starting dose is 2.5mg of ramipril 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 kidney 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 dose 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

*Patients with liver problems*

If you have liver problems, your doctor may initiate treatment with ramipril only under close medical supervision and the maximum daily dose is 2.5 mg Ramipril

*Elderly*

Your doctor will reduce initial dose and adjust your treatment more slowly

**Ramipril Capsules are not recommended for children and adolescents below 18 years of age, because safety and efficacy of Ramipril in children has not yet been established**

**Route and method of administration**

Take this medicine by mouth at the same time of the day each day. Ramipril has to be swallowed with liquid. It must not be chewed or crushed. If you have trouble swallowing the capsules, tell your doctor.

**If you take more Ramipril Capsules than you should**

If you take more capsules than you should or if you take the wrong strength of Ramipril Capsules, tell you doctor immediately or go to the nearest hospital A&E (casualty) department.

**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 without first talking with your doctor. If you stop taking this medication, your condition could become worse.

If you have any further questions on the use of this product, 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 Rampril 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 makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction.
- 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 pains, tightness in your chest or more serious problems including heart attacks 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.
- Kidney problems or failure. Symptoms may include reduced amount of urine, loss of appetite, fatigue, swelling of hands and feet, dry and itchy skin etc.

**Other side effects include:**

Please 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 heart beats
- 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 changed 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 skin, itchy, lumpy rash
- Nail problems (e.g. lessening 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 or 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)**

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
- Blood tests showing increase in antinuclear antibodies in your body
- 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
- Blisters on the skin and mucous membranes
- Aggravation of red, flaky, crusty patches of skin covered with silvery scales (Psoriasis)
- Raised bumps on the skin that are shiny
- Small spots on the mucous membranes
- Dull red, sharply demarcated scaly plaques on skin
- Change in the way things smell
- Hair loss
- 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.

### **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 national reporting system. 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 the capsules after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original blister pack.
- 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 in Ramipril Capsules is Ramipril
- The other ingredients of the power in Ramipril Capsules is pregelatinised maize starch
- The capsule shell for all strengths of Ramipril Capsules contains gelatine, titanium dioxide (E171), sodium laurilsulfate, methyl parahydroxy benzoate (E218) and propyl parahydroxy benzoate (E216).
- In addition the capsule shell for
- Ramipril 1.25mg capsules contains the colours yellow ferric oxide (E172)
- Ramipril 2,5mg capsules contains colours sunset yellow (E110), ponceau 4R (E124) and carmoisine (E122)
- Ramipril 5mg capsules contains colours ponceau 4R (E124), brilliant blue (E133) and carmoisine (E112)
- Ramipril 10mg capsules contains colours brilliant blue (E113), erythrosine (E127) and carmoisine (E122)

**What Ramipril capsules look like and content of the pack**

- Ramipril 1.25mg Capsules are ivory and white capsules
- Ramipril 2,5mg Capsules are orange and white capsules
- Ramipril 5mg Capsules are maroon and white capsules
- Ramipril 10mg Capsules are blue and white capsules.
- Ramipril capsules are supplied in packs containing 28, 30 capsules. Not all pack sizes may be marketed.

**This medicinal product is authorised in the member states of EEA under the following names:**

**UK:** Ramipril 1.25mg, 2.5mg, 5mg and 10mg capsules

**NL:** Ramipril Bristol 1,25mg, 2,5mg, 5mg and 10mg capsules, hard

**PL:** RAMVE 2,5 mg, 5mg and 10mg kapsułki twarde.

**Marketing Authorization Holder and Manufacturer:**

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