

- 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 oral solution”.

#### Children and adolescents

Ramipril oral solution is not recommended for use in children and adolescents below 18 years of age because the safety and efficacy of Ramipril oral solution 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 oral solution.

#### Other medicines and Ramipril oral solution

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

Tell your doctor if you are taking any of the following medicines. They can make Ramipril oral solution 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 oral solution:

- Sacubitril/valsartan – used for treating a type of long term (chronic) heart failure in adults (see section 2 “Do not take Ramipril oral solution”)
- 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)
- Temsrolimus (for cancer)
- Sirolimus, everolimus (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 oral solution” and “Warnings and precautions”).

Tell your doctor if you are taking any of the following medicines. They may be affected by Ramipril oral solution:

- Medicines for diabetes such as oral glucose lowering medicines and insulin. Ramipril oral solution may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Ramipril oral solution.
- Lithium (for mental health problems). Ramipril oral solution 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 oral solution.

#### Ramipril oral solution with food and alcohol

Drinking alcohol with Ramipril oral solution may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking Ramipril oral solution, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.

Ramipril oral solution may be taken with or without food.

#### Pregnancy and breastfeeding

**Pregnancy**  
You must tell your doctor if you think that you are (or might become) pregnant.  
You should not take Ramipril oral solution in the first 12 weeks of pregnancy and you must not take them at all from the 13th week as their use during pregnancy may possibly be harmful to the baby. If you become pregnant while on Ramipril oral solution, 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 oral solution 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 oral solution. This is more likely to happen when you start taking Ramipril oral solution or start taking a higher dose. If this happens, do not drive or use any tools or machines.

#### Ramipril oral solution contains Benzoic acid (E 210), Propylene glycol (E 1520) and Sodium:

**Benzoic acid (E 210):** This medicine contains 5mg benzoic acid in each 5ml dose. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

**Propylene glycol (E 1520):** This medicine contains 750mg propylene glycol in each 5ml dose. If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

**Sodium:** This medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially ‘sodium-free’.

### 3. How to take Ramipril oral solution

Always take this medicine exactly as your 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 2.5ml (1.25mg) or 5ml (2.5mg) once daily.
- Your doctor will adjust the amount you take until your blood pressure is controlled.
- The maximum dose is 20ml (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 oral solution.

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

- The usual starting dose is 5ml (2.5mg) once daily.
- Your doctor may then decide to increase the amount you take.
- The usual dose is 20ml (10mg) once daily.

##### Treatment to reduce or delay the worsening of kidney problems

- You may be started on a dose of 2.5ml (1.25mg) or 5ml (2.5mg) once daily.
- Your doctor will adjust the amount you take.
- The usual dose is 10ml (5mg) or 20ml (10mg) once daily.

##### Treatment of heart failure

- The usual starting dose is 2.5ml (1.25mg) once daily.
- Your doctor will adjust the amount you take.
- The maximum dose is 20ml (10mg) daily. Two administrations per day are preferable.

##### Treatment after you have had a heart attack

- The usual starting dose is 2.5ml (1.25mg) once daily to 5ml (2.5mg) twice daily.
- Your doctor will adjust the amount you take.
- The usual dose is 20ml (10mg) daily. Two administrations per day are preferable.

##### Elderly

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

#### Taking this medicine

Take this medicine by mouth at the same time of the day each day using the measuring cup provided.

#### If you take more Ramipril oral solution 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 Ramipril oral solution

- 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 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 oral solution 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 oral solution
- 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 Ramipril oral solution 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 problem (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.

#### 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 or pharmacist. 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](http://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 oral solution

- 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 bottle label after EXP. The expiry date refers to the last day of that month.
- Once opened use within 60 days.
- Store in a refrigerator (2°C – 8°C).
- 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 oral solution contains

- The active substance is ramipril. Each 5ml of Ramipril oral solution contains 2.5mg of the active ingredient ramipril.
- The other ingredients are propylene glycol (E 1520), benzoic acid (E 210), sodium saccharin (E 954), hydrochloric acid and purified water.

#### What Ramipril oral solution looks like and contents of the pack

Ramipril oral solution is a clear, colourless solution supplied in an amber glass bottle containing 150ml and sealed with a child-resistant, tamper-evident cap. It contains a measuring cup with multiple graduations.

#### Marketing Authorisation Holder and Manufacturer

**Marketing Authorisation Holder**  
Roma Pharmaceuticals Ltd  
Gibraltar House, Centrum 100, Burton-upon-Trent DE14 2WE

#### Manufacturer

Labomed Pharmaceutical Company S.A.  
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This leaflet was last revised in June 2024

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