

## Package leaflet: Information for the use

## Ramipril 2.5mg/5ml Oral Solution

- 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.
- 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 your.
  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

- What Ramipril oral solution is and what it is used for
   What you need to know before you take Ramipril oral
- 2. What you need to know before you take kall solution
  3. How to take Ramipril oral solution
  4. Possible side effects
  5. How to store Ramipril oral solution
  6. Contents of the pack and other information

## 1. What Ramipril oral solution is and what it is used for

1. What Ramipril oral solution is and what it is used for Ramipril 2.5mg/Sml Oral Solution (called Ramipril oral solution in this leaflet) contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors). Ramipril oral solution 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.

**①** 

Ramipril oral solution can be used:

- rampin oral solution and te user:

  To Treat high blood pressure (hypertension)

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

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

  To reduce the risk of 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.



solution

Do not take Ramipril oral solution:

• If you are allergic (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the ingredients of this medicine

Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or

- or breathing provens, according to the catter of the catte
- failure in adults.

  If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, Ramipril oral solution 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, lowarder modifician containing.

- treated with a blood pressure lowering medicine containing

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Ramipril oral

- solution:

  If you have heart, liver or kidney problems.

  If you have lost a lot of body salts or fluids (through being sick (womiting), having diarrhees, sweating more than usual, being on a low sairt diet, taking diuretics (water tables) for a long time or having had diahysis).

  If you are going to have treatment to reduce your allergy to bee or wasp strings (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 Ramipfill oral solution 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
- 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 allengic reaction, such as mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus), vidagliptin, neprilyini (NEP) inhibitors (such as racecadontril) or sacubitril/valsartan, see section 2. "One of take Pensirol or Journal of the properties of the proper
- or sacubitril/valsartan. For sacubitril/valsartan, see section 2 "On ont take Ramipril oral solution".

   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 oral solution 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 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 sartans – for example valsartan, telmisartan, ir besartar in particular if you have diabetes-related kidney proble

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

- 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:

- effects if you take them with Hamipri oral sourcon:

   Scaubirli/Neatran 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 (INSAIDs) such as
  ibuprofer or indometacin and asplini)

   Medicines to stop the rejection of organs after a transplant
  such as cidosporin
- 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 wit sulfamethoxazole (for infections) and heparin (for thinning
- blood)
  Steroid medicines for inflammation such as prednisole
  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)
- \*nacceadotril (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

- Tell your doctor if you are taking any of the following medicines. They may be affected by Ramipril or 13 olution:

   Medicines for diabetes such as oral glucose lowering medicines and Insulin. Ramipril oral solution may lower yo 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 lithium amount will need to be closely checked by your

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 feed dizy 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

You must ten your notion in you amin.

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

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 no

### How much to take

- 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
- 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 are taking.

   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.

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 departme straight away. Do not drive to the hospital, get somebody els to take you or call for an ambulance. Take the medicine pack

with you. This is so the doctor knows what you have take

- 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 sewere allergic reaction to Ramipril oral
- De a sign of a scale of the solution of the solution of 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
- and these of the and a cought. Hese count to sights of un-problems

   Brusing more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spot blotching on the skin or getting infections more easily than susal, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone w problems
- Severe stomach pain which may reach through to your back.
  This could be a sign of pancreatitis (inflammation of the
- nancreas).

  Fever, fillis, 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 happenshire, thorthose of hippath
- bronchitis, shortness of breath Stomach or gut pain, diarrhoea, indigestion, feeling or being
- Skin rash with or without raised area
- Chest pain
  Cramps or pain in your muscles
  Blood tests showing more potassium than usual in your

- 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)
- - Feeling depressed, anxious, more nervous than usual or

- Loss or decrease of appetite (anorexia)
- Loss or decrease of appetite (anorexa)
   Increased or inregular 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

- 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

- 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.

## 5. How to store Ramipril oral solution



- 6. Contents of the pack and other information What Ramipril oral solution contains
  • The active substance is ramipril. Each 5ml of Ramipril oral
- The other ingredients armipril. Each 5ml of Ramipril oral solution contains 2.5mg of the active ingredient ramipril.

  The other ingredients are propylene glycol (£ 1520), benzoic acid (£ 210), sodium saccharin (£ 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 namber 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 Manufacture

Marketing Authorisation Holder Roma Pharmaceuticals Ltd Gibraltar House, Centrum 100, Burton-upon-Trent DE14 2WE Manufacturer Labomed Pharmaceutical Company S.A.

84 Ioannou Metaxa str. Koropi, Attica, 19441, Greece This leaflet was last revised in June 2024

For information in other formats contact medinfo@romapharma.co.uk









Loss or change in the way things taste
 Sleep problems
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Fever
 Sexual inability in men, reduced sexual desire in men or

- Skin rash or bruising
   Blotches on your skin and cold extremities
   Red, itchy, swollen or watery eyes
   Disturbed hearing and ringing in your ears

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 less sodium than usual 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
  Halr loss.

Reporting of side effects 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 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.

