

Package leaflet: Information for the user

Ramiliv 2.5 mg tablets

Ramiliv 5 mg tablets

Ramiliv 10 mg tablets

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 only you. 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.

In this leaflet:

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

1. What Ramiliv is and what it is used for

Ramiliv contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

Ramiliv 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.

Ramiliv 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 Ramiliv

Do not take Ramiliv

- If you are allergic to ramipril, to any other ACE inhibitor medicine or to any of the ingredients of this medicine (listed in section 6).
Signs of an allergic reaction may include a transitory rash, swallowing 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 around 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.
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- If you are having dialysis or any other type of blood filtration. Depending on the machine used, Ramiliv 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 under treatment with a medicine for reducing the blood pressure that contains aliskiren.

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

Warnings and precautions

Check with your doctor or pharmacist before taking ramipril:

- If you have heart, liver or kidney problems.
- If you have lost a lot of body salts or fluids (through being sick (vomiting), have diarrhoea, sweating more than usual, are on a low salt diet, take diuretics (water tablets) for a long time or have 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 anesthetic. This may be given for an operation or any dental work. You may need to stop your Ramiliv 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, neprilysin (NEP) inhibitors (such as racecadotril) or sacubitril/valsartan. For sacubitril/valsartan, see section 2 "Do not take Ramiliv".
- If you have 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. Ramiliv 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 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 level of electrolytes (e.g., potassium) in your blood at regular intervals. See also the information in section "Do not take Ramiliv".

Children and adolescents

Ramiliv is not recommended for use in children and adolescents below 18 years of age because to insufficient data on safety and efficacy.

If any of the above apply to you or if you are not sure, talk to your doctor before taking Ramiliv.

Other medicines and Ramiliv

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This is because Ramiliv can affect the way some other medicines work. Also, some medicines can affect the way Ramiliv works.

Tell your doctor if you are taking any of the following medicines. They can make Ramiliv works less well:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and acetylsalicylic acid),
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- 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 Ramiliv:

- Sacubitril/valsartan – used for treating a type of long term (chronic) heart failure in adults (see section 2 "Do not take Ramiliv")
- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), such as ibuprofen or indometacin and acetylsalicylic acid),
- Medicines for cancer (chemotherapy),
- Medicines used to stop the rejection of organs after a transplant, such as ciclosporin,
- Diuretics (medicines that increase water elimination) 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),
- Corticosteroids used to treat inflammation such as prednisolone,
- Allopurinol (used to lower the concentration of 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)
- 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 Ramiliv" and "Warnings and precautions").

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

- Medicines for diabetes such as oral glucose lowering medicines and insulin. Ramiliv may lower your blood sugar levels. Check your blood sugar levels closely while taking Ramiliv.
- Lithium (for mental health problems). Ramiliv may increase the level of lithium in your blood. Your lithium level 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 Ramiliv.

Ramiliv with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

Before taking this medicine, you must ask your doctor or pharmacist for recommendations if you are pregnant or breast-feeding, or if you think that you are or might become pregnant.

Pregnancy

You must tell your doctor if you think that you are (or might become) pregnant.

You should not take Ramiliv 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.

A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

Breast-feeding

You should not take Ramiliv 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 Ramiliv. This is more likely to happen when you start taking Ramiliv or when you start taking a higher dose. If this happens, do not drive or use any tools or machines.

Ramiliv contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Ramiliv

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

How much to take Ramiliv

Ramiliv cannot be divided into equal doses. For dosages, which cannot be achieved with Ramiliv other strengths of ramipril medicinal products are available.”

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 Ramiliv.

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 kidney problems

- You may start with 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.

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.
- Ramiliv may be taken with or without food.
- Swallow the tablets whole, with liquid.

Do not crush or chew the tablets because they may have an unpleasant taste.

If you take more Ramiliv 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 Ramiliv

- 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 missed tablet.

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 Ramiliv 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 to Ramiliv.
- 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 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:

Please tell your doctor if any of the following side effects 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 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, diarrhea, 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 (paresthesia)
 - 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
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- A swelling in your gut called “intestinal angioedema”, presenting symptoms like abdominal pain, vomiting and diarrhea
- Heartburn, constipation or dry mouth
- Passing more 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 on to 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 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 hemoglobin.

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):

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 color 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
- Smell disturbance
- Hair loss

Reporting of suspected adverse reactions

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 listed in Appendix V.* By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Ramiliv

Keep out of sight and reach of children.

Do not use Ramiliv after the expiry date printed on the package after EXP. The expiry date refers to the last day of that month.

Ramiliv 2.5 mg, Ramiliv 5 mg

Store below 30°C in the original package in order to protect from light.

Ramiliv 10 mg

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Ramiliv contains

Ramiliv 2.5 mg

- The active substance is ramipril. Each tablet contains 2.5 mg of ramipril.
- The other ingredients are: hydroxypropyl cellulose, cellulose microcrystalline 101, maize starch, mannitol (E421), pregelatinized maize starch, yellow iron oxide (E172), stearyl sodium fumarate.

Ramiliv 5 mg

- The active substance is ramipril. Each tablet contains 5 mg of ramipril.
- The other ingredients are: hydroxypropyl cellulose, cellulose microcrystalline 101, maize starch, mannitol (E 421), pregelatinized maize starch, red iron oxide (E 172), stearyl sodium fumarate.

Ramiliv 10 mg

- The active substance is ramipril. Each tablet contains 10 mg of ramipril.
- The other ingredients are: hydroxypropyl cellulose, cellulose microcrystalline 101, maize starch, mannitol (E 421), pregelatinized maize starch, stearyl sodium fumarate.

What Ramiliv looks like and contents of the pack

Ramiliv 2.5 mg

Yellowish to mottled yellow, round, biconvex and uncoated tablets of 7 mm diameter. Ramiliv cannot be divided into equal doses

Ramiliv 5 mg

Mottled pink, round, biconvex and uncoated tablets of 7 mm diameter. Ramiliv cannot be divided into equal doses

Ramiliv 10 mg

White or almost white, round and biconvex tablets of 7 mm diameter. Ramiliv cannot be divided into equal doses

Packaging:

Carton with OPA-IA-PVC / Al blisters of 10 or 14 tablets

Pack sizes:

2,5 mg and 5 mg: 28, 30, 56, 100, 250 and 500 tablets

10 mg: 28, 30, 100, 250 and 500 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
<[To be completed nationally]>

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