

Package leaflet: Information for the user

RamiLich® 2.5 mg tablets

Ramipril

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.

- Keep the package leaflet. You may want to read it again later.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What is RamiLich and what is it used for?
2. What should you consider before taking RamiLich?
3. How to take RamiLich?
4. What are the possible side effects?
5. How to store RamiLich?
6. Contents of the pack and other information

1. What is RamiLich and what is it used for?

RamiLich contains the active substance ramipril. This belongs to the class of medicines called ACE inhibitors (ACE = Angiotensin Converting Enzyme).

RamiLich works by

- reducing the body's production of substances that increase blood pressure,
- relaxing and widening your blood vessels,
- making it easier for the heart to pump blood around the body.

RamiLich is used for

- treating high blood pressure (hypertension),
- reducing the risk of having a heart attack or stroke,
- reducing the risk or slowing the progression of kidney problems (in both diabetic and non-diabetic patients),
- treating heart failure when the heart cannot pump enough blood around the body (heart failure),
- treatment following a heart attack (myocardial infarction) complicated with heart failure.

2. What should you consider before taking RamiLich?

RamiLich must not be taken

- if you are allergic to ramipril, any other ACE inhibitor, or any of the other ingredients of this medicine listed in section 6. Signs of an allergic reaction include rash, swallowing or breathing problems, swelling of the lips, face, throat, or tongue.

if you have ever had a severe allergic reaction called angioedema. Signs include itching, hives (urticaria), red marks on hands, feet, and neck, swelling of the throat and tongue, swelling around the eyes and lips, breathing and swallowing problems.

- if you have had a severe allergic reaction in the past, known as angioedema. Signs include itching, hives (urticaria), red spots on hands, feet, and neck, swelling of the throat and tongue, swelling around the eyes and lips, breathing and swallowing difficulties.
- if you are undergoing dialysis or another form of blood filtration, as RamiLich may not be suitable for you depending on the device used.
- if you have a kidney disease where the blood supply to the kidney is reduced (renal artery stenosis).
- during the last 6 months of pregnancy (see section 'Pregnancy and breastfeeding').
- if you have unusually low or fluctuating blood pressure. This is to be assessed by your doctor.
- if you have diabetes mellitus or impaired kidney function and are being treated with a blood pressure-lowering medicine that contains aliskiren.

You must not take RamiLich if any of the above apply to you. If you are unsure, consult your doctor before taking RamiLich.

Warnings and precautions

Please talk to your doctor or pharmacist before taking RamiLich,

- if you have heart, liver, or kidney disease.
- if you have lost large amounts of body salts or fluids (through vomiting, diarrhea, unusually heavy sweating, a low-salt diet, taking diuretics [water tablets] for a long time, or if you are a dialysis patient).
- if your allergy to bee or wasp stings is to be treated (desensitization).
- if you are to receive an anesthetic in connection with surgery or at the dentist. It may be necessary to stop your treatment with RamiLich one day beforehand; ask your doctor for advice.
- if you have a high potassium level in your blood (as shown in blood tests).
- if you are taking medicines or have conditions that can lower the sodium level in your blood; your doctor may conduct regular blood tests to check the concentration of sodium in your blood, especially if you are elderly.
- if you are using medicines known as mTOR inhibitors (e.g., temsirolimus, everolimus, sirolimus), vildagliptin, or racecadotril, as these can increase the risk of angioedema (a severe allergic reaction).
- if you suffer from a collagen disease, such as scleroderma or systemic lupus erythematosus.
- Inform your doctor if you suspect you are pregnant (or might become pregnant). Ramipril is not recommended during the first three months of pregnancy and can cause serious harm to your unborn child after three months of pregnancy (see section 'Pregnancy and breastfeeding').
- if you are taking any of the following medicines to treat high blood pressure:
 - an angiotensin II receptor antagonist (these are also known as sartans -
 - e.g., valsartan, telmisartan, irbesartan), especially if you have kidney problems due to diabetes mellitus. - Aliskiren.

Your doctor may check your kidney function, blood pressure, and electrolyte levels (e.g. potassium) in your blood at regular intervals.

See also section "RamiLich must not be taken".

Children and adolescents

The use of RamiLich is not recommended in children and adolescents under 18 years of age, as the safety and efficacy of RamiLich in children have not yet been established.

If any of the above apply to you (or you are unsure), consult your doctor before taking RamiLich.

Taking RamiLich with other medicines

Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines. RamiLich can affect the action of other medicines, and its own action can be affected by other medicines.

Inform your doctor if you are taking/using any of the following medicines, as they may reduce the effect of RamiLich:

- Medicines for pain and inflammation (e.g. non-steroidal anti-inflammatory drugs [NSAID] such as ibuprofen, indomethacin, and acetylsalicylic acid),
- Medicines for treating low blood pressure, shock, heart failure, asthma, or allergies such as ephedrine, noradrenaline, or adrenaline. Your doctor needs to check your blood pressure.

Inform your doctor if you are taking/using any of the following medicines, as taking them with RamiLich increases the risk of side effects:

- Medicines for pain and inflammation (e.g. non-steroidal anti-inflammatory drugs [NSAID] such as ibuprofen, indomethacin, and acetylsalicylic acid),
- Medicines for cancer (chemotherapy),
- Medicines used to prevent rejection of a transplanted organ, such as ciclosporin,
- Diuretics (water tablets) such as furosemide,
- Medicines that can increase potassium levels in the blood, such as spironolactone, triamterene, amiloride, potassium salts, trimethoprim alone or in combination with sulfamethoxazole (for infections), and heparin (blood thinner),
- Steroid-containing medicines for inflammation such as prednisolone,
- Allopurinol (to lower uric acid levels in the blood),
- Procainamide (for heart rhythm disorders),
- Temsirolimus (for cancer),
- Sirolimus, everolimus (to prevent rejection of transplanted organs),
- Vildagliptin (for the treatment of type 2 diabetes mellitus),
- Racecadotril (for the treatment of diarrhea).
- Your doctor may need to adjust your dosage and/or take other precautions if you are taking an angiotensin II receptor antagonist or aliskiren (see also sections "RamiLich must not be taken" and "Warnings and precautions").

Inform your doctor if you are taking/using any of the following medicines, as their effect may be influenced by RamiLich:

- Medicines for diabetes such as oral blood sugar-lowering medicines and insulin. RamiLich can lower blood sugar levels. Therefore, blood sugar levels must be closely monitored while taking RamiLich.
- Lithium (for mental illnesses). RamiLich can increase lithium levels in the blood. Your doctor must carefully monitor lithium levels for this reason.

If any of the above points apply to you (or you are not sure), ask your doctor before taking RamiLich.

Taking RamiLich with food and alcohol

- Consuming alcohol while taking RamiLich can cause dizziness and drowsiness. If you are unsure about the amount of alcohol you can drink while taking RamiLich, ask your doctor, as blood pressure-lowering agents and alcohol can mutually enhance their effects.
- RamiLich can be taken with or without meals.

Pregnancy and breastfeeding

Pregnancy

Inform your doctor if you suspect you are pregnant (or might become pregnant).

You should not use Ramipril during the first twelve weeks of pregnancy and you must not use RamiLich after the 13th week of pregnancy, as taking RamiLich at this stage can cause serious harm to your unborn child.

If you become pregnant while taking Ramipril, please inform your doctor immediately. A switch to a more suitable treatment alternative should be considered in advance of a planned pregnancy.

Breastfeeding

You should not use Ramipril if you are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Dizziness may occur while taking RamiLich. The likelihood is highest at the start of treatment with RamiLich or when the dose is increased. In this case, you must not drive or operate tools or machines.

3. How to take RamiLich?

Always take this medicine exactly as agreed with your doctor. Ask your doctor or pharmacist if you are not sure.

Dosage of the medicine

Treatment of high blood pressure

- The usual starting dose is 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust the dose you take until your blood pressure is under control.
- The maximum dose is 10 mg once daily.
- If you are already taking diuretics (water tablets), your doctor may reduce the amount of diuretics before starting treatment with RamiLich or stop the medication altogether.

Reducing the risk of having a heart attack or stroke

- The usual starting dose is 2.5 mg once daily.
- Your doctor may then decide to increase the dose.
- The usual dose is 10 mg once daily.

Treatment to reduce the risk or slow the progression of Kidney dysfunction

- Your initial dose is either 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust your dose.
- The usual dose is 5 mg or 10 mg once daily.

Treatment of heart failure

- The usual initial dose is 1.25 mg once daily.
- Your doctor will adjust your dose.
- The maximum dose is 10 mg daily. It is recommended to divide the dose into two administrations daily.

Treatment after a heart attack

- The usual initial dose is 1.25 mg once daily to 2.5 mg twice daily.
- Your doctor will adjust your dose.
- The usual dose is 10 mg daily. It is recommended to divide the dose into two administrations daily.

Elderly patients

Your doctor will start with a lower initial dose and increase it more slowly during the course of treatment.

Taking the medication

- Take the medication at the same time every day.
- Take the tablets with sufficient liquid.
- The tablets must not be crushed or chewed.

If you have taken more RamiLich than you should

Inform your doctor immediately or go to the emergency department of the nearest hospital. You must not drive yourself to the hospital. Ask someone else to do so or call an ambulance. Take the medicine package with you so that the attending doctor knows what you have taken.

If you forget to take RamiLich

- If you miss a dose, take the next dose at the next scheduled time.
- 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. What side effects are possible?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking RamiLich immediately and contact your 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 may cause difficulty in swallowing or breathing, as well as itching and skin rashes. This may be signs of a severe allergic reaction to RamiLich.
- Severe skin reactions including rash, mouth ulcers (aphthae), worsening of a pre-existing skin condition, redness, blistering, or peeling of the skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme).

Inform your doctor immediately if you experience

- rapid heart rate, irregular or strong heartbeat (palpitations), chest pain or tightness, or more serious events such as heart attack or stroke,
- shortness of breath or cough, which may be signs of a lung disorder,
- easy bruising, bleeding that lasts longer than normal, any signs of bleeding (e.g., bleeding gums), purplish spots on the skin, or increased susceptibility to infections, sore throat and fever, fatigue, weakness, dizziness or pale skin, which may be signs of a blood or bone marrow disorder,
- severe abdominal pain that may radiate to the back and may be signs of pancreatitis,
- fever, chills, fatigue, loss of appetite, abdominal pain, feeling unwell, yellowing of the skin or eyes (jaundice), which may be signs of liver diseases such as hepatitis (liver inflammation) or liver damage.

Other possible side effects

Inform your doctor if any of the listed side effects significantly affect you or last more than a few days.

Common (may affect up to 1 in 10 people treated)

- Headache or fatigue
- Dizziness. The likelihood is greater at the start of treatment with RamiLich or when the dose is increased.
- Fainting, hypotension (unusually low blood pressure), especially when standing or suddenly standing up
- Dry irritating cough, sinusitis or bronchitis, shortness of breath
- Stomach or intestinal pain, diarrhea, indigestion, nausea or vomiting
- Rash with or without raised skin
- Chest pain
- Muscle cramps or pain
- Increased potassium levels in the blood

Occasionally (may affect up to 1 in 100 people treated)

- Balance disorders (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or tingling (paresthesia)
- Loss or change of taste sensation
- Sleep disorders
- Depressed mood, anxiety, unusual nervousness or restlessness
- Blocked nose, breathing difficulties or worsening of asthma
- Swelling in the intestine, a so-called intestinal angioedema, with symptoms such as abdominal pain, vomiting and diarrhea
- Heartburn, constipation or dry mouth
- Increased urination (diuresis) during the day

- Excessive sweating
- Loss of appetite or decreased appetite (anorexia)
- Increased or irregular heartbeat
- Swollen arms and legs, possible signs of fluid retention in the body
- Skin redness with a feeling of heat
- Blurred vision
- Joint pain
- Fever
- Sexual dysfunction in men, decreased sexual desire in men and women
- An increase in the number of certain white blood cells (eosinophilia)
- Blood values indicating dysfunction of the liver, pancreas, or kidneys

Rare (may affect up to 1 in 1,000 people treated)

- Feeling of trembling or confusion
- Red and swollen tongue
- Severe peeling or detachment of the skin, itchy, raised skin rash
- Nail problems (e.g., loosening or detachment of a toenail or fingernail)
- Rash or bruising
- Spots on the skin and cold extremities
- Red, itchy, swollen, or watery eyes
- Hearing disorders or ringing in the ears
- Feeling of weakness
- Reduction in the number of red blood cells, white blood cells, or platelets, or a low hemoglobin level in blood tests

Very rare (may affect up to 1 in 10,000 treated)

- Increased sensitivity to sunlight

Other possible side effects

Inform your doctor if any of the listed side effects significantly affect you or persist for more than a few days.

- Difficulty concentrating
- Swollen mouth
- Blood count with too few blood cells
- Low sodium levels in the blood
- Concentrated urine (dark color), nausea or vomiting, muscle cramps, confusion, and seizures, which may be due to inappropriate ADH secretion (antidiuretic hormone secretion). Contact your doctor immediately if these symptoms occur.
- Discoloration of fingers and toes when cold, and tingling or pain upon warming (Raynaud's syndrome)
- Breast enlargement in men
- Slowed or impaired responsiveness
- Burning sensation
- Altered sense of smell
- Hair loss

Reporting of side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects directly to the

Federal Institute for Drugs and Medical Devices
Dept. of Pharmacovigilance
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
Website: www.bfarm.de

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store RamiLich?

Keep this medicine out of the reach of children.

Do not use this medicine after the expiry date stated on the carton, blister pack, and bottle after 'Use by'. The expiry date refers to the last day of that month.

No special storage conditions are required for this medicine.

Do not dispose of medicines via wastewater. Ask your pharmacist how to dispose of medicines you no longer use. This helps protect the environment.

6. Contents of the pack and other information

What RamiLich 2.5 mg tablets contain

The active substance is ramipril.

1 tablet contains 2.5 mg of ramipril.

The other ingredients are:

Hypromellose
Pregelatinized starch (maize starch)
Microcrystalline cellulose
Sodium stearyl fumarate (Ph. Eur.)
Iron(III) hydroxide oxide (E 172).

What RamiLich 2.5 mg tablets look like and contents of the pack

RamiLich 2.5 mg tablets are yellowish white to yellow, oblong tablets with a score line and a size of 8 x 4 mm. The top side is embossed with "2.5" and the company logo, the bottom side with "HMR" and "2.5". The tablet can be divided into equal doses.

RamiLich 2.5 mg tablets are available in packs of 7, 10, 14, 15, 18, 20, 28, 30, 45, 50, 60, 90, 98, 99, and 100 tablets in PVC/Alu blister packs.

Not all pack sizes may be marketed.

Pharmaceutical entrepreneur
Winthrop Arzneimittel GmbH

65927 Frankfurt am Main

Co-distribution

Zentiva Pharma GmbH

65927 Frankfurt am Main

Phone: (01 80) 2 02 00 10*

Fax: (01 80) 2 02 00 11*

Manufacturer S.C. Zentiva S.A.

B-dul Theodor Pallady no. 50, sector 3,

032266 Bucharest

Romania

or

Sanofi S.p.A.

Strada Statale 17, km 22

67019 Scoppito (L'Aquila)

Italy

or

Delpharm Dijon

6 Boulevard de l'Europe

21800 Quetigny

France

This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

Germany: RamiLich 2.5 mg tablets

France: Ramipril Zentiva 2.5 mg tablets

Italy: Ramipril Zentiva 2.5 mg tablets

Romania: Zenra 2.5 mg tablets

Hungary: Ramipril Zentiva 2.5 mg tablet

This package leaflet was last revised in February 2017.

Prescription only.

Other available strengths include RamiLich 5 mg tablets with 5 mg Ramipril and RamiLich 10 mg tablets with 10 mg Ramipril.

*0.06 €/call (German landline); max. 0.42 €/min (mobile).