

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Ramipril Inovamed 2.5 Ramipril Inovamed 5 Ramipril Inovamed 10 Tablets

Active ingredient:

Each Ramipril Inovamed 2.5 tablet contains: Ramipril 2.5 mg

Each Ramipril Inovamed 5 tablet contains: Ramipril 5 mg

Each Ramipril Inovamed 10 tablet contains: Ramipril 10 mg

Inactive ingredients: see section 6. Also see 'Important information about some of the ingredients of the medicine' in section 2.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is used for the treatment of hypertension, to reduce the risk of a heart attack or stroke, to reduce the risk or delay progression of kidney problems (in patients with or without diabetes), for the treatment of heart failure, for treatment after a heart attack associated with heart failure.

Therapeutic group: Antihypertensive, from the ACE inhibitors group.

2. BEFORE USING THE MEDICINE

Do not use the medicine:

- if you are sensitive (allergic) to the active ingredient ramipril, or to another preparation from the ACE inhibitors group, or to any of the additional ingredients contained in the medicine (see section 6). Signs of an allergic reaction can include: rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue.
 - if you have suffered in the past from a severe allergic reaction called angioedema, whose signs include: tingling, urticaria, red patches on the hands, feet and neck, swelling of the throat and tongue, swelling around the eyes and lips, difficulties breathing and swallowing.
 - if you have taken or are taking sacubitril/valsartan, a medicine used to treat a type of chronic heart failure in adults.
 - if you are undergoing hemodialysis or another kind of hemofiltration. Depending on the type of machine being used, Ramipril Inovamed may not be suitable for you.
 - if you suffer from a kidney problem in which the blood supply to the kidney is reduced – renal artery stenosis.
 - in the last six months of pregnancy (see “Pregnancy, breastfeeding and fertility” section).
 - if you have low or unstable blood pressure. This will be evaluated by the doctor.
 - if you suffer from diabetes or impaired kidney function and are being treated with an antihypertensive containing aliskiren.
- Do not take Ramipril Inovamed if the above apply to you. In case of doubt, consult the doctor before taking Ramipril Inovamed.

Special warnings regarding use of the medicine: Before treatment with the medicine, tell the doctor if:

- you are suffering from heart, liver or kidney problems.
- you are suffering from excessive loss of salts or fluids (as the result of vomiting, diarrhea, increased sweating, low-salt diet, prolonged use of diuretics or if you underwent dialysis).
- you are due to undergo treatment to reduce allergy to bee or wasp stings (desensitization).
- you are due to receive anesthesia during surgery or dental treatment. You may need to discontinue treatment with Ramipril Inovamed one day before; consult the doctor.
- your blood potassium level is high (as per blood test results).
- you are taking medicines that may reduce your blood sodium level or are suffering from a medical condition that may reduce your blood sodium level. Your doctor may refer you for periodic tests of your blood sodium level, especially if you are elderly.
- you are taking medicines that may increase the risk for a severe allergic reaction called angioedema, such as mTOR inhibitors (e.g., temsirolimus, everolimus, sirolimus), vildagliptin, neprilysin inhibitors (NEP inhibitors, e.g., rasecadotril) or sacubitril/valsartan. For sacubitril/valsartan, also see “Do not use the medicine” section.
- you suffer from connective tissue diseases, such as scleroderma or lupus (systemic lupus erythematosus).
- Tell your doctor if you think you are pregnant or might be pregnant. Ramipril Inovamed is not recommended in the first 3 months of pregnancy and may cause serious damage to the unborn baby after the third month (see “Pregnancy, breastfeeding and fertility” section).
- you are taking one of the following antihypertensives:
 - medicines that inhibit the angiotensin II receptor (angiotensin-II receptor blockers, also known as sartans. For example, valsartan, telmisartan, irbesartan), especially if you are suffering from kidney problems related to diabetes.

- aliskiren.

Your doctor may perform periodic kidney function, blood pressure and blood electrolyte (e.g., potassium) level tests. Also see “Do not use the medicine” section.

Children and adolescents:

Ramipril Inovamed is not recommended for use in children and adolescents under 18 years of age, since the effectiveness and safety of the medicine in children has still not been determined.

If the aforementioned applies to you (or in case of doubt), please consult the doctor before taking Ramipril Inovamed.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. This is because Ramipril Inovamed may affect the activity of other medicines and other medicines may affect the activity of Ramipril Inovamed. In particular, inform the doctor or pharmacist if you are taking:
Combination with the following medicines can cause reduced efficacy of Ramipril Inovamed:

- medicines to relieve pain and inflammation (for example, NSAIDs such as ibuprofen or indomethacin and aspirin).
 - medicines to treat low blood pressure, shock, heart failure, asthma or allergies, such as ephedrine, noradrenalin or adrenalin. The doctor must closely monitor your blood pressure.
- Combination with the following medicines can lead to an increased chance of side effects:
- sacubitril/valsartan – a medicine for treating a type of chronic heart failure in adults (also see “Do not use the medicine” section)
 - medicines to relieve pain and inflammation (for example, NSAIDs such as ibuprofen or indomethacin and aspirin)
 - medicines to treat cancer (chemotherapy)
 - medicines to prevent rejection of transplants, such as cyclosporine
 - diuretics, such as furosemide
 - medicines that can raise the blood potassium level, such as spironolactone, triamterene, amiloride, potassium salts, trimethoprim alone or in combination with sulfamethoxazole (for infections) and heparin (to thin the blood)
 - steroids for treatment of inflammation, such as prednisolone
 - allopurinol (to reduce the level of uric acid in the blood)
 - procainamide (for treatment of heart rhythm problems)
 - temsirolimus (to treat cancer)
 - sirolimus, everolimus (for prevention of graft rejection)
 - vildagliptin (to treat type 2 diabetes)
 - racecadotril (against diarrhea)
- The doctor may need to change your dosage and/or to take other precautions if you are taking angiotensin-II receptor blockers (ARB) or aliskiren (also see “Do not use the medicine” and “Special warnings regarding use of the medicine” sections).

Combination with the following medicines can affect their action:

- medicines for diabetes, such as oral medicines to lower sugar, and insulin. Ramipril Inovamed may reduce your blood sugar level; strictly monitor blood sugar levels when taking Ramipril Inovamed.
- lithium (given for treatment of mental problems). Ramipril Inovamed may cause an increase in the level of lithium in the blood; the doctor must strictly monitor lithium level while you are taking Ramipril Inovamed.

If the aforementioned affect you (or in case of doubt), please consult the doctor before taking Ramipril Inovamed.

Use of the medicine and food:

The medicine can be taken with or without food.

Use of the medicine and alcohol consumption:

Drinking alcohol during the course of treatment with Ramipril Inovamed can cause dizziness. Consult your doctor regarding the possibility of drinking alcohol during the course of treatment with Ramipril Inovamed, since alcohol can have an additional effect on lowering blood pressure.

Pregnancy, breastfeeding and fertility:

Pregnancy

Tell your doctor if you think you are pregnant or might become pregnant. Ramipril Inovamed is not recommended during the first 12 weeks of pregnancy and must not be used at all from week 13, as its use during pregnancy may be harmful to the baby.

If you become pregnant while you are being treated with Ramipril Inovamed, tell your doctor immediately. Your doctor may decide on an alternative treatment that is safe for use in pregnancy. If required, switching to an appropriate alternative treatment should be performed before a planned pregnancy.

Breastfeeding

Before you receive Ramipril Inovamed, tell your doctor if you are breastfeeding or planning to breastfeed as there is limited information on the use of Ramipril Inovamed during breastfeeding. Ramipril Inovamed is not recommended for use during breastfeeding.

Driving and operating machinery:

You may feel dizzy while taking Ramipril Inovamed. It is more likely to occur at the beginning of treatment or when increasing the dosage. If this happens, do not drive or operate machinery.

Important information about some of the ingredients of the medicine:
The tablets contain lactose monohydrate. If you suffer from an intolerance to certain sugars, consult your doctor before starting to use the medicine. In addition,

the tablets contain sodium as follows: 2.5 mg tablets – 1.49 mg sodium, 5 mg tablets – 2.92 mg sodium, 10 mg tablets – 5.94 mg sodium.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation.

The dosage and treatment regimen will be determined by the doctor only.

Elderly patients

Your doctor may lower the starting dosage and adjust the dosage more slowly.

Do not exceed the recommended dose.

Method of administration

- Take the medicine at a set time every day.
- Swallow the tablet whole with liquid.
- Do not chew or crush the tablet.
- Ramipril Inovamed 2.5 mg, Ramipril Inovamed 5 mg and Ramipril Inovamed 10 mg tablets can be halved on the score line, into equal halves, and half a dose taken as necessary.

If you accidentally took a higher dosage, or if a child has accidentally swallowed the medicine:

Refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you, so the doctor will know what you took. Do not drive by yourself; ask someone else to monitor you or call for an ambulance.

If you forget to take the medicine:

If you forgot to take this medicine at the required time, take the next dose at the regular time and consult the doctor. Do not take a double dose to compensate for the forgotten dose!

Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ramipril Inovamed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Discontinue treatment with Ramipril Inovamed and refer to a doctor immediately if you experience any of the following serious side effects – you may need urgent medical treatment:

- swelling of the face, lips or throat, which causes swallowing or breathing difficulties, as well as tingling and rash – these can be signs of a severe allergic reaction to Ramipril Inovamed.
- a severe skin reaction which includes rash, mouth ulcers, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme).

Report to the doctor immediately if you experience any of the following side effects:

- increased heart rate, strong or irregular heartbeat (palpitations), chest pain, tightness in the chest or a more serious problem such as heart attack or stroke.
- shortness of breath or coughing – these could be signs of a lung problem.
- bruising more easily, bleeding for longer than usual, any sign of bleeding (e.g., bleeding from the gums), purple spots, patches on the skin or getting infections more easily than usual. sore throat and fever, feeling tired, fainting, dizzy or pale skin – these can be signs of blood or bone marrow problems.
- severe abdominal pain which can radiate to the back – could be a sign of pancreatitis.
- fever, chills, tiredness, loss of appetite, abdominal pain, nausea, yellowing of the skin or eyes (jaundice) – these can be signs of liver problems, such as inflammation of the liver or liver damage.

Other side effects include:

Please tell your doctor if any of the effects listed below worsen or last longer than a few days.

Common effects (occur in up to 1 in 10 users)

- headache or feeling tired
- feeling dizzy – likely to occur at the beginning of treatment with Ramipril Inovamed or when the Ramipril Inovamed dosage is raised
- fainting, abnormally low blood pressure, especially when standing up or sitting up quickly
- dry cough, sinusitis or bronchitis, shortness of breath
- stomach or intestinal pain, diarrhea, indigestion, nausea and vomiting
- skin rash, with or without raised areas
- chest pain
- muscle cramps or pain
- blood test results showing a higher potassium level than usual.

Uncommon effects (occur in up to 1 in 100 users)

- balance problems (vertigo)
- itching and unusual skin sensations, such as numbness, stinging, tingling, or burning of the skin (paresthesia)
- loss of or change in the sense of taste
- sleep problems
- feeling depressed, anxious, more nervous than usual or restless
- blocked nose, breathing difficulties or worsening of asthma
- intestinal angioedema, manifested by abdominal pain, vomiting or diarrhea
- heartburn, constipation or dry mouth
- urinating more than usual
- sweating more than usual
- reduction or loss of appetite
- increase or change in heart rhythm
- swelling of the arms and legs – can be a sign of more

fluid retention than usual in the body

- flushing
- blurred vision
- joint pains
- fever
- impotence in men, reduced libido in men and women
- a rise in certain white blood cells (eosinophilia) that is seen in blood tests
- blood test results that indicate a change in liver, pancreas or kidney function.

Rare effects (occur in up to 1 in 1,000 users)

- feeling of instability or confusion
- redness and swelling of the tongue
- severe peeling of the skin, itching, blotchy rash
- nail problems (e.g., loosening or separation of the nail from its base)
- skin rash or bruises
- patches on the skin and cold sensation in the extremities
- in the eyes – redness, tingling, swelling or tearing
- hearing disturbances and ringing in the ears
- sensation of weakness
- blood test results that show a drop in red blood cell, white blood cell or platelet counts, or in the amount of hemoglobin.

Extremely rare effects (occur in up to 1 in 10,000 users)

- increased sensitivity to sunlight.

Other reported side effects:

Please tell your doctor if any of the effects listed below worsen or last longer than a few days:

- difficulty concentrating
- swelling of the mouth
- blood test results showing too few blood cells in your blood
- blood test results showing lower than normal sodium levels in your blood
- concentrated urine (dark in color), nausea or vomiting, muscle cramps, confusion and fits, which may be a result of a disturbance in secretion of the hormone which regulates secretion of urine (ADH). If you experience these effects, refer to the doctor as soon as possible
- a change in the color of the fingers and toes when you are cold, followed by a tingling feeling or pain when they warm up (an effect called Raynaud's phenomenon)
- breast enlargement in men
- slowed or changed reactions
- burning sensation
- change in the way things smell
- hair loss.

If a side effect occurs, if one of the side effects worsens, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: <http://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Do not dispose of medicines in a sewer or waste bin. Ask your pharmacist how to dispose of unused medicines. These measures will help preserve the environment.

Storage conditions:

Store below 25°C.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Starch pregelatinized, Lactose monohydrate, Sodium hydrogen carbonate, Croscarmellose sodium, Sodium stearyl fumarate. (Ramipril 2.5 mg – Ferric oxide yellow), (Ramipril 5 mg – Ferric oxide red).

What the medicine looks like and the contents of the package:

Tray (blister) package of tablets in a carton box.

Tablet appearance:

Ramipril Inovamed 2.5 mg – Light yellow to yellow colored flat faced bevel edged, round uncoated tablet debossed with “H” and “18” separated by score line on one side and plain on other side.

Ramipril Inovamed 5 mg – Light pink colored mottled, flat faced bevel edged round uncoated tablet debossed with “H” and “19” separated by score line on one side and plain on other side.

Ramipril Inovamed 10 mg – White to off-white-colored, flat faced bevel edged round uncoated tablet debossed with “H” and “20” separated by score line on one side and plain on other side.

Manufacturer: Aurobindo Pharma Ltd., Plot #2, Maitrivihar, Ameerpet, Hyderabad, 500038, India.

License holder and importer: Inovamed Ltd., 55 Beer Ganim Street, P.O.B. 62, Even Yehuda, 40500.

This leaflet does not contain all the information about the preparation. If you have any question or if you are uncertain about something, please refer to the doctor.

Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:

Ramipril Inovamed 2.5 mg: 166-47-35580

Ramipril Inovamed 5 mg: 166-48-35581

Ramipril Inovamed 10 mg: 166-49-35582

Revised in July 2021 according to MOH guidelines.