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

The medicine is dispensed with a doctor's prescription only

Ramipril Teva 5 mg

Tablets

Composition:

Each Ramipril Teva 5 mg tablet contains: Ramipril 5 mg

For information regarding inactive ingredients, see section 2 "Important information about some ingredients of the medicine" and section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for 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 to treat hypertension, to reduce the risk of a heart attack or stroke, to reduce the risk or delay a worsening of kidney problems (in patients with or without diabetes), to treat heart failure, to treat after a heart attack combined with heart failure.

Therapeutic class: Antihypertensive agent of the ACE inhibitors group.

2. Before using the medicine

☒ Do not use this medicine if:

- You are sensitive (allergic) to ramipril, to other medicines of the ACE inhibitors group, or to any of the other ingredients the medicine contains (see section 6 - "Additional information"). Signs of allergic reaction may include: rash, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.
- You have suffered in the past from a severe allergic reaction called angioedema, whose signs include: itching, urticaria, red blotches on the hands, legs and neck, swelling of the throat and tongue, swelling around the eyes and lips, breathing and swallowing difficulties.
- You have taken in the past or are currently taking sacubitril/valsartan, a medicine that is used for treatment of a certain type of chronic heart failure in adults.
- You are undergoing dialysis treatments or another type of blood filtration. Depending on the type of machine used, Rampiril Teva may not be suitable for you.
- You have a kidney problem in which the blood supply to the kidney is reduced – renal artery stenosis.
- You are in the last six months of pregnancy (see section "Pregnancy and breastfeeding").
- You have low or unstable blood pressure. This evaluation will be performed by the doctor.
- You have diabetes or renal impairment and are treated with an antihypertensive medicine containing aliskiren.

Do not take Ramipril Teva if the above apply to you. In case of doubt, consult the doctor before taking Ramipril Teva.

Special warnings regarding the 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 a significant loss of salts or fluids (due to vomiting, diarrhea, increased sweating, a low-salt diet, taking diuretics for a prolonged period of time or if you have undergone dialysis).
- You are due to undergo treatment to reduce your allergy to bee or wasp stings (desensitization).
- You are about to receive anesthetics during a surgery or dental treatment. You may need to discontinue treatment with Ramipril Teva one day before; consult the doctor.
- Your potassium blood level is high (per blood test results).
- You are taking medicines that may lower your blood sodium level or are suffering from a medical condition that may lower your blood sodium level. Your doctor may refer you to periodical tests of your blood sodium levels, especially if you are an elderly patient.
- You are taking medicines that may increase the risk for a severe allergic reaction calles angioedema, such as mTOR inhibitors (e.g. temsirolimus, everolimus, sirolimus), vildagliptin, Neprilysin inhibitors (NEP inhibitors, e.g. racecadotril) or sacubitril/valsartan. For sacubitril/valsartan, see also section: "Do not use this medicine if".
- You are suffering from connective tissue diseases, such as scleroderma or lupus (systemic lupus erythematosus).
- You should inform your doctor if you think you are pregnant or that you might be pregnant. Ramipril Teva is not recommended during the first 3 months of pregnancy and may cause serious harm to the fetus after the third month (see section "Pregnancy and breastfeeding").
- You are taking any of the following medicines used for lowering blood pressure:
  - Angiotensin II Receptor Blockers (ARBs), known also as sartans (e.g. valsartan, telmisartan, irbesartan), especially if you are suffering from kidney problems related to diabetes.
  - Aliskiren.

Your doctor may order periodical tests of your renal function, blood pressure and blood salts levels (e.g. potassium) (see also section "Do not use this medicine if").

❗ Children and adolescents

Ramipril Teva is not recommended for use in children and adolescents under the age of 18, since the efficacy and safety of Ramipril Teva in children have not yet been determined.

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

❗ Drug-drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the doctor or the pharmacist. That is because Ramipril Teva may affect the activity of other medicines and other medicines may affect the activity of Ramipril Teva.

Especially inform the doctor or pharmacist if you are taking:

Combination with the following medicines may cause reduced efficacy of Ramipril Teva:

- 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, noradrenaline or adrenaline. The doctor must closely monitor your blood pressure.

Combination with the following medicines may lead to an increased chance for side effects:

- Sacubitril/valsartan - a medicine used to treat a type of chronic heart failure in adults (see also section "Do not use this medicine if").
- 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 (given to reduce the level of uric acid in the blood).
- Procainamide (given for treatment of heart rhythm problems).
- Temsirolimus (for treatment of cancer).
- Sirolimus, everolimus (to prevent rejection of transplants).
- Vildagliptin (for treatment of type 2 diabetes).
- Racecadotril (for treatment of diarrhea).
- The doctor may need to change your dosage or take other precautions if you are taking Angiotensin II receptor blockers or aliskiren (see also section "special warnings regarding the use of the medicine" and for aliskiren, also section "Do not use this medicine if").

Combining ramipril with the following medicines can affect their action:

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

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

❗ Use of the medicine and food

The medicine may be taken with or without food.

❗ Use of the medicine and alcohol consumption

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

❗ Pregnancy and breastfeeding

Pregnancy

You should tell your doctor if you think you are pregnant or might become pregnant. Usually, the doctor will advise you to stop taking Ramipril Teva before you become pregnant or when you find out you are pregnant, and will advise you to take another medicine instead of ramipril.

Ramipril Teva is not recommended during the first 12 weeks of pregnancy and must not be used at all starting from week 13, since it may cause serious harm to the fetus.

Breastfeeding

Ramipril Teva should not be taken while breastfeeding.

Consult with the doctor or pharmacist before taking any medicine during pregnancy and when breastfeeding.

❗ Driving and operating machinery

You may feel dizzy while taking Ramipril Teva. 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 ingredients of the medicine

This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

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 how to use 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

- The medicine should be taken at the same time each day.
- The tablet should be swallowed whole with liquids.
- The tablet should not be chewed or crushed.
- The tablets may be halved according to the score line on the tablet.

If you accidentally took a higher dose or if a child accidentally swallowed the medicine, immediately contact 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 have taken. Do not drive on your own, ask someone else to take you or call for an ambulance.

If you forgot to take this medicine at the required time, take the next dose at the regular time and consult a doctor. Do not take a double dose in order to compensate for the forgotten dose! Follow the treatment as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Ramipril Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Discontinue treatment with Ramipril Teva and refer to a doctor immediately if you experience any of the following severe 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 may be signs of a severe allergic reaction to ramipril.
- A severe skin reaction which includes rash, mouth ulcers, worsening of a pre-existing skin disease, redness, blisters or detachment of the 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 a 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 marks, blotches on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin – these may 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 worsens or lasts longer than a few days.

Common side effects - occurring in 1-10 out of 100 users

- Headache or feeling tired
- Feeling dizzy – likely to occur in the beginning of treatment with ramipril or when the dosage of ramipril is increased
- Fainting, abnormally low blood pressure, especially when standing up or sitting down 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 tests showing a higher potassium level than usual

Uncommon side effects - occurring in 1-10 out of 1,000 users

- Balance problems (vertigo)
- Itching and unusual skin sensations, such as numbness, tingling, pricking, burning or paresthesia in the skin
- Loss of or change in the sense of taste
- Sleeping problems
- Feeling depressed, anxious, more nervous than usual or restlessness
- Blocked nose, breathing difficulties or worsening of asthma
- Swelling in the intestines (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 rate
- Swelling of the arms and legs – may be a sign of the body retaining more fluids than usual
- Flushing
- Blurred vision
- Joint pains
- Fever
- Impotence in men, reduced sexual desire in men or women
- A rise in certain white blood cells (eosinophilia) seen in blood tests
- Blood test results indicating a change in liver, pancreas or kidney function

Rare side effects - side effects that occur in 1-10 out of 10,000 users

- Feeling unstable or confused
- Redness and swelling of the tongue
- Severe peeling of the skin, stinging, lumpy rash
- Nail problems (e.g., loosening or separation of the nail from its base)
- Skin rash or bruises
- Blotches on the skin and sensation of cold in the extremities
- In the eyes – redness, tingling, swelling or tearing
- Hearing disturbances and ringing in the ears
- Feeling weak
- Blood test results showing a decrease in the number of red blood cells, white blood cells or platelets, or in the amount of hemoglobin.

Very rare side effects - occurring in less than 1 in 10,000 users

- Increased sensitivity to sunlight

Other side effects reported:

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

- Difficulty concentrating
- Swelling of the mouth
- Blood test results indicating too few blood cells in your blood
- Blood test results indicating lower than usual blood sodium level
- Concentrated urine (dark-colored), nausea or vomiting, muscle cramps, confusion and convulsions, which may occur due to interruption in the release of the hormone that regulates the secretion of urine (ADH). If you experience these effects, contact the doctor as soon as possible
- A change in the color of your fingers and toes when you are cold, followed by a feeling of tingling or pain when you warm up (Raynaud's phenomenon)
- Enlarged breasts 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 suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Store below 25°C.

6. Additional information

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

Microcrystalline cellulose, magnesium hydroxide, sodium stearyl fumarate, ferric oxide yellow

What does the medicine look like and what are the contents of the package:

Ramipril Teva 5 mg: Yellow, round tablet with a score line on both sides; on one side of the tablet "5" is debossed on one side of the score line and "RL" on the other side of the score line.

The package of the medicine contains 28 or 30 tablets in a tray (blister).

Not all package sizes may be marketed.

Name and address of the Manufacturer and Marketing Authorization Holder:

Teva Pharmaceutical Industries Ltd., P.O. box 3190, Petah Tikva.

This leaflet was reviewed and approved by the Ministry of Health in June 2015 and has been updated in accordance with the Ministry of Health instructions in January 2019.

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

Ramipril Teva 5 mg: 132.90.31076

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