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

Active ingredient:

Each **Ramipril Teva 5 mg** tablet contains:

Ramipril 5 mg

Inactive ingredients and allergens in the preparation: see section 2 and section 6.

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, for treatment 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 to the active ingredient, ramipril, to another preparation from the ACE inhibitors group or to any of the other ingredients the medicine contains (see section 6). Signs of allergic reaction may include: rash, swallowing or breathing difficulties, 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 spots on the hands, feet and neck, swelling of the throat and tongue, swelling around the eyes and lips, breathing and swallowing difficulties.
- If 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.
- If you are undergoing dialysis treatments or another type of blood filtration. Depending on the type of machine used, Ramipril Teva may not be suitable for you.
- If you have a kidney problem in which the blood supply to the kidney is reduced (renal artery stenosis).
- In the last six months of pregnancy (see under section 2 – "Pregnancy, breastfeeding and fertility").
- If you have low or unstable blood pressure. This evaluation will be performed by the doctor.
- If you have diabetes or renal impairment and are treated with an antihypertensive medicine containing aliskiren.

Do not take Ramipril Teva if the above applies 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 stop the treatment with Ramipril Teva one day before; consult the doctor.
- Your blood potassium 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 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. racecadotril) or sacubitril/valsartan. For sacubitril/valsartan, see also section: "Do not use this medicine".
- 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 under section 2 – "Pregnancy, breastfeeding and fertility").
- You are taking any of the following medicines used for lowering blood pressure:
  - 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 order periodical tests of your renal function, blood pressure and blood salts levels (e.g. potassium). See also under section 2 – "Do not use this medicine".

Children and adolescents

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

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

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. That is because Ramipril Teva may affect the activity of other medicines and other medicines may also 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").
- 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 (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 and/or take other precautions if you are taking angiotensin-II receptor blockers (ARBs) or aliskiren (see also sections "Do not use this medicine" and "Special warnings regarding the use of the medicine").

Combination 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 above 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 also have an additional effect on lowering blood pressure.

Pregnancy, breastfeeding and fertility

Pregnancy

You should tell your doctor if you think you are pregnant or might become pregnant.

Ramipril Teva is not recommended in the first 12 weeks of pregnancy and must not be used at all from the 13th week, since using it during pregnancy may harm the baby.

If you become pregnant while being treated with Ramipril Teva, tell your doctor immediately. The doctor may decide on an alternative treatment that is safe for use in pregnancy. If necessary, switching to a suitable alternative treatment should be done before a planned pregnancy.

Breastfeeding

Before receiving Ramipril Teva, tell your doctor if you are breastfeeding or planning to breastfeed, since there is limited information regarding the use of Ramipril Teva during breastfeeding. Ramipril Teva is not recommended for use during 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 and do not operate machinery.

Important information about some of the ingredients of the medicine

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

Each tablet of Ramipril Teva 5 mg contains 92 mg lactose (as lactose monohydrate). If you suffer from sugar intolerance, contact the treating doctor before starting treatment with Ramipril Teva.

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 only by the doctor.

Elderly patients

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

Do not exceed the recommended dose.

How to take the medicine

- The medicine should be taken at the same time each day.
- The tablet should be swallowed whole with liquids.
- Do not chew or crush the tablet.
- It is possible to halve Ramipril Teva 5 mg tablets into equal halves according to the score line marked on the tablet, and to take half a dose when necessary.

If you accidentally took a higher dosage or if a child accidentally swallowed this medicine:

Immediately refer to a doctor or to a hospital emergency room and bring the package of the medicine with you, so the doctor knows 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 the medicine:

If you forgot to take this medicine at the scheduled time, take the next dose at the next scheduled time and consult the 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 a 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 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 may be signs of a severe allergic reaction to Ramipril Teva.
- 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 spots, blotches on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, fainting, dizziness 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 the eyes (jaundice) – these can be signs of liver problems, such as inflammation of the liver or liver damage.

Other side effects include:

Inform the treating doctor if any of the effects listed below worsens or lasts longer than a few days.

Common side effects (occur in up to 1 user out of 10)

- Headache or feeling tired
- Feeling dizzy – likely to occur in the beginning of treatment with Ramipril Teva or when the dosage of Ramipril Teva is increased
- Fainting, unusually 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 tests showing a higher potassium level than usual

Uncommon side effects (occur in up to 1 user out of 100)

- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, prickling, burning or sensation of creeping on the skin (paresthesia)
- 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 pain
- 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 (occur in up to 1 user out of 1,000)

- Feeling unstable or confusion
- Redness and swelling of the tongue
- Severe peeling of the skin, tingling, 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 (occur in up to 1 user out of 10,000)

- Increased sensitivity to sunlight

Other side effects reported:

Tell the treating 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 the 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://sideeffects.health.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/blister. The expiry date refers to the last day of that month.

Storage conditions:

Store in the original package at a temperature not exceeding 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, Ramipril Teva 5 mg also contains:

Lactose monohydrate, pregelatinized maize starch, sodium hydrogen carbonate, croscarmellose sodium, sodium stearyl fumarate, Iron oxide red, Iron oxide yellow.

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

Ramipril Teva 5 mg: a pink, oblong, flat tablet with a score line on one side, debossed with "R" on one side of the score line and with "3" on the other side. The tablet may be divided into equal halves.

The tablets are packed in a blister tray. Each package contains 20, 28, 30, 50, 56 or 60 tablets. Not all package sizes are marketed.

This leaflet does not contain all of the information about the preparation. If you have any question or if you are unsure about something, please contact the doctor.

License holder and manufacturer and the address: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Revised in August 2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

Ramipril Teva 5 mg: 176-76-37218-99

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