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

The medicine is dispensed with a doctor's prescription only

Lercanapril Teva 10/10 Film-coated tablets

Lercanapril Teva 10/20 Film-coated tablets

Composition:

Each tablet of **Lercanapril Teva 10/10** contains:

Lercanidipine hydrochloride 10 mg and Enalapril maleate 10 mg.

Each tablet of **Lercanapril Teva 10/20** contains:

Lercanidipine hydrochloride 10 mg and Enalapril maleate 20 mg.

For information regarding inactive ingredients and allergens, see section 2 – "Important information about some of the 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 treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Lercanapril Teva is not intended for primary treatment of hypertension.

1. WHAT IS THE MEDICINE INTENDED FOR?

- **Lercanapril Teva 10/10** is used for treatment of hypertension in patients whose blood pressure cannot be adequately controlled through treatment with lercanidipine alone.
- **Lercanapril Teva 10/20** is used for treatment of hypertension in patients whose blood pressure cannot be adequately controlled through treatment with enalapril alone.

Therapeutic class:

- Enalapril belongs to the angiotensin-converting enzyme inhibitors (ACE inhibitors) group.
- Lercanidipine belongs to the calcium channel blockers group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients (enalapril maleate and/or lercanidipine hydrochloride) or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You have previously had an allergic reaction to a type of medicine similar to those in **Lercanapril Teva**, i.e. medicines called ACE inhibitors or calcium channel blockers.
- You have ever suffered from swelling of the face, mouth, lips, tongue or throat, which caused swallowing or breathing difficulties (angioedema), due to the use of a medicine of the ACE inhibitors group, due to an unknown reason or due to a hereditary reason.
- You are taking sacubitril/valsartan, a medicine used for treatment of a type of chronic heart failure in adults, as the risk of angioedema (rapid swelling under the skin in areas such as the throat) increases.
- You have diabetes or kidney impairment and are treated with an antihypertensive medicine containing aliskiren.
- You are over 3 months pregnant (it is also better to avoid using **Lercanapril Teva** in the beginning of pregnancy – see section "Pregnancy and breastfeeding").
- You suffer from certain heart diseases: blocked blood flow from the heart, untreated heart failure, unstable angina (chest discomfort at rest, or chest discomfort that gradually worsens), within a month after a heart attack.
- You have severe liver problems.
- You suffer from severe kidney problems, or you are treated with dialysis.
- You are taking medicines that inhibit liver metabolism, such as: antifungals (such as ketoconazole, itraconazole), antibiotics from the macrolide family (such as erythromycin, troleandomycin, clarithromycin), antiviral medicines (such as ritonavir).
- You are taking a medicine called cyclosporine (used after transplantations, to prevent organ rejection).
- You consume grapefruits or grapefruit juice.

Special warnings regarding the use of the medicine

Before treatment with Lercanapril Teva, inform the doctor if:

- You have low blood pressure (manifest as fainting or dizziness, especially when standing up).
- You have recently suffered from severe vomiting or from diarrhea.
- You are on a limited salt diet.
- You suffer from a heart problem.
- You suffer from a condition that involves blood vessels in the brain.
- You suffer from kidney problems (including kidney transplant). These problems may lead to high levels of potassium in the blood which may be severe. The doctor may need to adjust the enalapril dosage or monitor the blood potassium level.
- You suffer from a liver problem.
- You suffer from a blood problem such as: low level or lack of white blood cells (leukopenia, agranulocytosis), low platelet levels (thrombocytopenia) or a decrease in red blood cell count (anemia).
- You suffer from connective tissue disease with blood vessels involvement (such as lupus erythematosus, rheumatoid arthritis or systemic sclerosis [scleroderma]). You are receiving immunosuppressive treatment, you are taking the medicines allopurinol or procainamide or any combination of these.
- You are a black-skinned patient. You should be aware that black-skinned patients are at a high risk of developing an allergic reaction that includes swelling of the face, lips, tongue or throat along with swallowing or breathing difficulties, upon taking ACE inhibitors.
- You have diabetes. You should monitor your blood sugar level for low glucose levels, especially during the first month of treatment. Your blood potassium level may also be high.
- You are taking potassium supplements or potassium-sparing medicines or potassium-containing salts.
- You are over 70 years old.

If you are taking any of the following medicines, the risk of angioedema may be higher:

- Racecadotril, a medicine for treatment of diarrhea.
- Medicines used for the prevention of transplanted organ rejection and for cancer (such as temsirolimus, sirolimus, everolimus).
- Vildagliptin, a medicine used for treatment of diabetes.

If you are taking any of the following medicines used for treatment of high blood pressure:

- Angiotensin II receptor blockers (such as: valsartan, telmisartan, irbesartan), especially if you have kidney problems due to diabetes.
- Aliskiren.

Tests and follow-up

The doctor may check your kidney function, blood pressure and the amount of electrolytes (such as potassium) in the blood at regular intervals. In addition, see section "Do not use the medicine if".

If you are about to undergo a medical procedure

If you are about to undergo any of the following, tell the doctor that you are taking **Lercanapril Teva**:

- Surgery or receiving sedatives (including at the dentist).
- Treatment for removing cholesterol from the blood called LDL apheresis.
- Treatment for reducing an allergic reaction to bee or wasp stings.

You must tell the doctor if you think you are pregnant, might become pregnant or are breastfeeding (see section "Pregnancy and breastfeeding").

Children and adolescents

There is no information regarding the safety and efficacy of the medicine in children and adolescents under the age of 18 years.

Drug interactions

Do not take **Lercanapril Teva** in combination with certain medicines.

If you are taking, have recently taken, or if you may take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

This is because taking **Lercanapril Teva** in combination with other medicines may change the effect of **Lercanapril Teva** or the effect of the other medicines, or certain side effects may occur more frequently.

Especially inform the doctor or pharmacist if you are taking:

- Other medicines for lowering blood pressure.
- Potassium supplements (including salt substitutes), potassium-sparing diuretics, other medicines that may increase blood potassium level (such as: trimethoprim and co-trimoxazole for treatment of infections caused by bacteria; cyclosporine [immunosuppressant, to prevent the rejection of a transplanted organ]; heparin, a medicine used for blood thinning to prevent clots). See section 2 "Do not use the medicine if".
- Lithium (a medicine for treatment of a certain type of depression).
- Antidepressant medicines called tricyclic antidepressants.
- Medicines for mental problems called antipsychotics.
- Non-steroidal anti-inflammatory medicines, including COX-2 inhibitors (medicines for reducing inflammation and pain relief).
- Certain medicines for pain relief or rheumatoid arthritis, including treatment with gold.
- Certain medicines for treatment of cough and cold and medicines for weight loss containing a sympathomimetic component.
- Medicines for treatment of diabetes (including oral medicines and insulin).
- Astemizole or terfenadine (medicines for treatment of allergies).
- Amiodarone, quinidine or sotalol (medicines for treatment of fast heartbeat).
- Phenytoin, phenobarbital or carbamazepine (medicines for treatment of epilepsy).
- Rifampicin (a medicine for treatment of tuberculosis).
- Digoxin (a medicine for treatment of heart problems).
- Midazolam (a medicine for sleep disturbances).
- Beta blockers such as metoprolol (a medicine for treatment of hypertension, heart failure and irregular heart rate).
- Cimetidine (in a dosage higher than 800 mg per day. A medicine for stomach ulcer, digestion problems or heartburn).

Do not take **Lercanapril Teva** if you are taking sacubitril/valsartan, a medicine used for treatment of a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in areas such as the throat) increases.

If you are taking any of the following medicines, the risk of angioedema may be higher:

- Racecadotril, a medicine for treatment of diarrhea.
- Medicines used for the prevention of transplanted organ rejection and for cancer (such as temsirolimus, sirolimus, everolimus).
- Vildagliptin, a medicine used for treatment of diabetes.

Your doctor may need to adjust your dosage and/or take other precautions if you are taking angiotensin II receptor blockers or aliskiren (see section "Do not use the medicine if" and section "Special warnings regarding the use of the medicine").

Use of the medicine and food

- Take **Lercanapril Teva** at least 15 minutes before a meal.
- A high-fat meal significantly increases the level of the medicine in the blood.
- Do not take **Lercanapril Teva** when consuming grapefruits or grapefruit juice, as they may increase the effect of the medicine on lowering blood pressure (see section "Do not use the medicine if").

Use of the medicine and alcohol consumption

Alcohol may increase the effect of **Lercanapril Teva**. Do not consume alcohol during treatment with **Lercanapril Teva**.

Pregnancy and breastfeeding

Pregnancy

You should inform your doctor if you think you are pregnant or might become pregnant. Usually, the doctor will recommend you to stop using **Lercanapril Teva** before you become pregnant or as soon as you find out you are pregnant, and advise you to take another medicine instead of **Lercanapril Teva**.

Lercanapril Teva is not recommended during pregnancy and you must not take it if you are more than 3 months pregnant, as it may cause severe harm to the fetus if used beyond the third month of pregnancy.

Breastfeeding

Do not use **Lercanapril Teva** during breastfeeding.

Driving and operating machinery

If you feel dizziness, weakness or drowsiness while using this medicine, do not drive a vehicle 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.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

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

Adults: the generally accepted dosage is one tablet per day, at the same time.

Swallow the tablet whole with a glass of water.

Take **Lercanapril Teva** at least 15 minutes before a meal, preferably before breakfast. See section 2 "Use of the medicine and food".

Children and adolescents: the medicine is not intended for treatment of children and adolescents under the age of 18 years.

Patients with kidney problems/the elderly: the dosage of the medicine will be determined by the doctor according to your kidney function.

Do not exceed the recommended dose.

Do not halve the tablets, as there is no score line. No information is available regarding crushing/chewing.

If you accidentally took a higher dosage, there may be an excessive decrease in blood pressure and irregular or fast heart rate. If you took an overdose or if a child accidentally swallowed this medicine, refer to the doctor or a hospital emergency room immediately and take the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the scheduled time, skip the forgotten dose. Take the next dose as usual. Do not take a double dose in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting a 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 **Lercanapril 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.

Some side effects may be severe.

Refer to the doctor immediately if you experience an allergic reaction with swelling of the face, lips, tongue or throat, which may cause difficulty breathing or swallowing.

At the beginning of treatment with **Lercanapril Teva**, you may feel weak, dizzy or have blurry vision. This happens due to a sudden drop in your blood pressure. If this happens, you should lie down. If you are concerned, tell your doctor.

Side effects that have been observed with Lercanapril Teva

Common side effects (effects that occur in 1-10 users out of 100):

Headache, dizziness, cough.

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

- Changes in blood indices such as decrease in blood platelet level.
- Increase in blood potassium level.
- Nervousness (anxiety).
- Sensation of dizziness when standing up, vertigo.
- Rapid heartbeat, awareness of the heartbeats (palpitations).
- Sudden redness of the face, neck or upper part of the chest (flushing), low blood pressure.
- Abdominal pain, constipation, nausea.
- Elevated liver enzyme levels.
- Redness of the skin.
- Joint pain.
- Increase in the number of times passing urine.
- Feeling of weakness, tiredness, heat sensation, swelling of the ankles.

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

- Anemia.
- Allergic reactions.
- Ringing in the ears (tinnitus).
- Fainting.
- Dry throat, sore throat.
- Digestive difficulties, salty sensation in the tongue, diarrhea, dry mouth, swelling of the gums.
- An allergic reaction accompanied by swelling of the face, lips, tongue or throat along with swallowing or breathing difficulties, skin rash, hives.
- Getting up at night to urinate, production of large amounts of urine.
- Impotence.

Additional side effects observed with enalapril or lercanidipine alone:

Enalapril

Very common side effects (effects that occur in more than one user out of ten):

Blurred vision, dizziness, weakness, nausea and cough.

Common side effects (effects that occur in 1-10 users out of 100):

Depression, headache, fainting, chest pain, dizziness due to low blood pressure, changes in the heart rhythm, rapid heartbeat, angina pectoris, shortness of breath, altered sense of taste, increased blood creatinine level (usually detectable through testing), high potassium level in the blood, diarrhea, abdominal pain, tiredness, rash, an allergic reaction with swelling of the face, lips, tongue or throat along with swallowing or breathing difficulties.

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

Anemia (including aplastic and hemolytic anemia), a sudden drop in blood pressure, confusion, irritability, insomnia or sleepiness, tingling sensation in the skin or numbness in the skin, a heart attack (probably due to very low blood pressure in patients at risk, including those with blood flow issues in the heart or the brain), a stroke (probably due to very low blood pressure in patients at risk), rhinitis, sore throat and hoarseness, chest pressure related to asthma, slow movement of food through the bowels, inflammation of the pancreas (pancreatitis), vomiting, digestive difficulties, constipation, stomach irritation, dry mouth, an ulcer, anorexia, itching or rash (hives), hair loss, impaired kidney function, kidney failure, increased sweating, elevated levels of protein in the urine (measured in a test), muscle cramps, general malaise, high fever, low levels of sugar or sodium in the blood, high levels of urea in the blood (measured in blood tests), flushing, awareness of the heartbeats (palpitations), vertigo (spinning sensation), ringing in the ears (tinnitus), impotence.

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

Changes in blood indices such as decrease in the number of white blood cells, bone marrow suppression, autoimmune diseases, strange dreams or sleeping problems, Raynaud's phenomenon (cold and pallor in the hands and feet due to low blood flow), nose inflammation, pneumonia, liver problems such as decrease in liver function, inflammation of the liver, jaundice (yellowing of the skin or of the eyes), high levels of liver enzymes or bilirubin (measured in blood tests), erythema multiforme (red dots in various shapes on the skin), Stevens-Johnson syndrome and toxic epidermal necrolysis (severe skin conditions with redness and peeling of the skin, blisters or open wounds), exfoliative dermatitis/erythroderma (severe rash in the skin with peeling of the skin), pemphigus (small bumps in the skin filled with liquid), decrease in the production of urine, mammary gland enlargement in men, swollen glands in the neck, underarm or groin, accumulation of fluids or other substances in the lungs (seen on X-rays), inflammation of the cheeks, gums, tongue, lips, throat.

Very rare side effects (effects that occur in less than 1 user out of 10,000):

Intestinal swelling (intestinal angioedema).

Side effects with unknown frequency (effects whose frequency has not yet been determined):

Excessive production of anti-diuretic hormone which causes fluid retention, resulting in weakness, tiredness or confusion. A complex of symptoms that may include some or all of the following effects has been reported: fever, inflammation of blood vessels (serositis/vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, sensitivity to light or other skin effects may occur.

Lercanidipine

Some side effects may be severe.

Refer to the doctor immediately if any of the following effects occur:

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

Angina pectoris (chest pain due to lack of blood supply to the heart), allergic reactions (symptoms include itch, rash and hives), fainting.

Patients with existing angina pectoris can experience an increase in the frequency, duration or severity of the attacks due to use of medicines from the group to which lercanidipine belongs. Isolated cases of heart attack may occur.

Additional side effects

Common side effects (effects that occur in 1-10 users out of 100):

Headache, rapid heartbeat, awareness of the heartbeats (palpitations), sudden redness of the face, neck or upper part of the chest (flushing), swelling of the ankles.

Uncommon side effects (effects that occur in 1-10 users out of 1,000):

Dizziness, drop in blood pressure, heartburn, nausea, abdominal pain, skin rash, itch, muscle pain, passing urine in large amounts, feeling weak or tired.

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

Sleepiness, vomiting, diarrhea, hives, increase in the number of times passing urine, chest pain.

Side effects with unknown frequency (effects whose frequency has not yet been determined):

Swelling of the gums, changes in liver function (seen in blood tests), turbid liquid (when performing dialysis through an abdominal tube), swelling of the face, lips, tongue or throat, which may cause difficulties in breathing or swallowing.

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://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. The expiry date refers to the last day of that month.

Store below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, Lercanapril Teva 10/10 also contains:

Cellulose microcrystalline, Starch pregelatinised, Sodium starch glycolate (type A), Hypromellose, Sodium hydrogen carbonate, Silica colloidal anhydrous, Titanium dioxide (E171), Talc, Macrogol 6000, Magnesium stearate.

In addition to the active ingredients, Lercanapril Teva 10/20 also contains:

Cellulose microcrystalline, Starch pregelatinised, Sodium starch glycolate (type A), Sodium hydrogen carbonate, Hypromellose, Silica colloidal anhydrous, Titanium dioxide (E171), Talc, Macrogol 6000, Magnesium stearate, Iron oxide yellow (E172).

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

Lercanapril Teva 10/10: white to off white, round, biconvex film-coated tablets.

Lercanapril Teva 10/20: light yellow to yellowish, round, biconvex film-coated tablets.

The tablets are packed in blisters.

Package sizes: 7, 10, 14, 15, 28 or 30 tablets.

Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

Teva Israel Ltd.

124 Dvora HaNevi'a St., Tel Aviv

The leaflet was revised in July 2023 in accordance with the Ministry of Health guidelines.

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

Lercanapril Teva 10/10: 164.44.35533

Lercanapril Teva 10/20: 164.45.35534

teva