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, 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 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 children and adolescents under the age of 18.

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 this medicine if:
- You are sensitive (allergic) to the active ingredients (enalapril and/or lercanidipine) or to any of the other ingredients this medicine contains (see section 6 – "Additional information"), or to other medicines of those therapeutic groups (see above).
- You are pregnant, over 3 months (it is also better to avoid using Lercanapril Teva during the first months of pregnancy - see section "Pregnancy and breastfeeding").
- You have diabetes or renal impairment and are treated with an antihypertensive medicine containing aliskiren.
- You have the following cardiac diseases: untreated heart failure, blocked blood flow from the left ventricle including aortic stenosis, unstable angina (at rest or worsening or frequent), a heart attack that occurred over the last month.
- You have a severe liver or kidney impairment, or you are undergoing dialysis.
- You are taking antifungal medicines (e.g., ketoconazole, itraconazole), macrolide antibiotics (e.g., erythromycin, troleandomycin), antiviral medicines (e.g., ritonavir), ciclosporin.
- You had angioedema (edema of the face, mouth, lips, tongue and/or throat, which causes swallowing or breathing difficulties) due to a hereditary reason or due to use of a medicine of the angiotensin-converting enzyme inhibitors (ACE inhibitors) group, or due to an unknown reason.
- You eat grapefruits or drink 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 had vomiting or diarrhea.
- You are on a low-salt diet.
- You have a heart disease or a condition that involves blood vessels in the brain, kidney problems (including kidney transplant), liver problems, diabetes, connective tissue diseases with blood vessels involvement (e.g., lupus, rheumatoid arthritis or scleroderma (systemic sclerosis)).
- You have blood problems, such as: low white blood cells count or lack of white blood cells (leukopenia, agranulocytosis), low platelet levels (thrombocytopenia) or a decrease in red blood cells count (anemia).
- If you have a dark skin, you should be aware that dark-skinned patients are at a higher risk for developing an allergic reaction that includes swelling of the face, lips, tongue or throat along with swallowing or breathing difficulties when taking an angiotensin-converting enzyme inhibitor (ACE inhibitor).
- You are developing a persistent dry cough.
- You are taking potassium supplements or potassium-containing salts or potassium-sparing medicines.
- You think you are pregnant or might become pregnant or are breastfeeding (see section "Pregnancy and breastfeeding").
- If you are taking any of the following medicines for lowering your blood pressure:
  - Angiotensin II receptor blockers (e.g., valsartan, telmisartan, irbesartan), especially if you have kidney problems due to diabetes.
  - Aliskiren.

The treating doctor should be informed about taking this medicine before: a surgery or sedation (including dental), a mechanical treatment for removing cholesterol from the blood (LDL apheresis) or a treatment for alleviating an allergic reaction to insect venom (such as bees or wasps).

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. Especially if you are taking:
- Ciclosporin (for suppression of the immune system), oral antifungal medicines (e.g., ketoconazole and itraconazole), antiviral medicines (e.g., ritonavir), macrolide antibiotics (e.g., erythromycin, troleandomycin). See section 2: "Do not use this medicine if".
- Cimetidine (for peptic ulcer, in dosage higher than 800 mg/day).
- Other medicines for lowering blood pressure, such as: Angiotensin II receptor blockers, diuretics or aliskiren; vasodilators (e.g., nitroglycerin or other organic nitrates, anesthetics).
- Digoxin (for treatment of certain cardiac problems), antiarrhythmic medicines (e.g., amiodarone, quinidine).
- Antidepressants (e.g., tricyclic antidepressants, lithium), anti-psychotics.
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines for pain relief or rheumatoid arthritis, including treatment with gold.
- Antiepileptics (e.g., phenytoin, carbamazepine), rifampicin (for treatment of tuberculosis).
- Medicines containing potassium or potassium supplements.
- Cough and cold medicines, medicines for weight loss containing a sympathomimetic component.
- Medicines for treatment of diabetes (orally administered medicines, insulin).
- Astemizole or terfenadine (medicines for allergies).
- Midazolam (a medicine for sleep disturbances).
- Beta blockers (medicines for treatment of hypertension and cardiac problems).

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

Use of the medicine and food
- Do not take the medicine together with grapefruit or grapefruit juice.
- Lercanapril Teva should be taken at least 15 minutes before a meal.

Use of the medicine and alcohol consumption
Alcohol can increase the effect of Lercanapril Teva. Therefore, it is recommended not to consume alcohol or to strictly limit your alcohol consumption.

Pregnancy and breastfeeding
Pregnancy
Tell your doctor if you think you are pregnant or might become pregnant. Usually, the doctor will advise you to stop using Lercanapril Teva before you become pregnant or as soon as you find out you are pregnant, and will advise you to take another medicine instead of Lercanapril Teva.
Lercanapril Teva is not recommended during pregnancy and you should not take it if your pregnancy is advanced (beyond 3 months), as it may cause severe harm to the fetus.
Breastfeeding
Tell your doctor if you are breastfeeding or are about to start breastfeeding. Breastfeeding neonates (during the first few weeks after birth), and especially preterm babies, is not recommended during treatment with Lercanapril Teva. Regarding a mature baby, your doctor will advise you about the benefits and risks of taking Lercanapril Teva during breastfeeding, compared to other treatments.

Driving and operating machinery
Using the medicine may cause dizziness, weakness, fatigue or drowsiness. If you experience these effects, avoid driving a vehicle, operating dangerous machinery or any other activity that requires alertness.

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 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.
Lercanapril Teva is not intended for children and adolescents under the age of 18. The dosage and treatment regimen will be determined only by the doctor.
The generally accepted dosage is one tablet per day, at the same time each day.

Do not exceed the recommended dose.
The tablet should be swallowed whole with a glass of water.
Lercanapril Teva should be taken at least 15 minutes before a meal, preferably before breakfast.
The tablets should not be halved, no information is available regarding crushing/chewing.

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

Tests and follow-up
The doctor may check your kidney function, blood pressure and the amount of electrolytes (e.g., potassium) in the blood at regular intervals.

If you forgot to take this medicine at the required time, skip the missed dose and take the next dose at the regular time. Never take two doses on the same day!

If you have accidentally taken a higher dosage, blood pressure may decrease excessively and heart rate may become fast or irregular. If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
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 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 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.
Upon beginning treatment with Lercanapril Teva, you may feel weak or 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 still concerned, inform your doctor.

Common side effects (side effects that occur in 1-10 out of 100 users): Headache, dizziness, cough.

Uncommon side effects (side effects that occur in 1-10 out of 1,000 users): Changes in blood indices, such as decrease in platelet level, increase in blood potassium level, nervousness (anxiety), sensation of dizziness when standing up, vertigo, fast or irregular heartbeat (palpitations), sudden redness in the face, neck or chest (flushing), low blood pressure, abdominal pain, constipation, nausea, elevated liver enzymes levels, redness in the skin, joint pain, increased urinary frequency, weakness, tiredness, sensation of heat, swelling of the ankle.

Rare side effects (side effects that occur in 1-10 out of 10,000 users): Anemia, an allergic reaction, ringing in the ears (tinnitus), fainting, dry throat, sore throat, digestive difficulties, salty sensation in the tongue, diarrhea, dry mouth, gum swelling, 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, producing large amounts of urine, impotence.

Other side effects due to taking only enalapril or lercanidipine:
Enalapril
Very common side effects (side effects that occur in more than one out of ten users):
Blurred vision.

Common side effects (side effects that occur in 1-10 out of 100 users):
Depression, chest pain, changes in the heart rhythm, angina pectoris, shortness of breath, altered sense of taste, increased blood creatinine level (usually may be diagnosed through laboratory testing).

Uncommon side effects (side effects that occur in 1-10 out of 1,000 users):
Anemia (including aplastic and hemolytic anemia), a sudden drop in blood pressure, confusion, sleeplessness or drowsiness, 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, asthma, slow movement of food through the bowels, inflammation of the pancreas (pancreatitis), vomiting, stomach irritation, an ulcer, lack of appetite (anorexia), increased sweating, itching or rash, hair loss, impaired kidney function, kidney failure, elevated protein levels 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).

Rare side effects (side effects that occur in 1-10 out of 10,000 users): 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), lung infiltrates, nose inflammation, pneumonia, liver problems, such as impaired liver function, hepatitis, jaundice (yellowing of the skin or eyes), high levels of bilirubin (measured in blood tests), erythema multiforme (red dots in various shapes on the skin), Stevens-Johnson syndrome (a severe skin condition with redness and skin exfoliation, blisters or wounds or separation of the upper layer of the skin from the lower layers), producing small amounts of urine, mammary glands enlargement in men.

Very rare side effects (side effects that occur in less than 1 out of 10,000 patients): Intestinal swelling (intestinal angioedema).

Lercanidipine
Rare side effects (side effects that occur in 1-10 out of 1,000 users): angina pectoris (chest pain due to insufficient blood in the heart), vomiting, heartburn, muscle pain.

Very rare side effects (side effects that occur in 1-10 out of 10,000 users): Chest pain.
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.

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.
Different medicines should not be stored in the same package.

6. Additional information

In addition to the active ingredients, Lercanapril Teva 10/10 also contains:
Microcrystalline cellulose, Pregelatinised starch,Sodium starch glycolate (type A), Hypromellose, Sodium hydrogen carbonate, Anhydrous colloidal silica, Titanium dioxide (E171), Talc, Macrogol 6000, Magnesium stearate

In addition to the active ingredients, Lercanapril Teva 10/20 also contains:
Microcrystalline cellulose, Pregelatinised starch, Sodium starch glycolate (type A), Sodium hydrogen carbonate, Hypromellose, Anhydrous colloidal silica, 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, 30 tablets.
Not all package sizes may be marketed.

License holder and its address:
Abic Marketing Ltd. (a Teva subsidiary)
P.O. box 8077, Netanya.

Name and address of the manufacturer:
Teva Pharmaceutical Industries Ltd.
P.O. box 3190, Petah Tikva.
Revised in May 2020.

Registration number 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

LERCANAPRIL PL MW0520

teva