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

This medicine is dispensed with a doctor's prescription only.

LERCAPRESS 10
LERCAPRESS 20

Film-coated Tablets

Composition:

Each **Lercapress 10** tablet contains:

Lercanidipine hydrochloride 10 mg

Each **Lercapress 20** tablet contains:

Lercanidipine hydrochloride 20 mg

For the list of inactive ingredients, please see section 6: "Further information".

Read this 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 for the treatment of your ailment. Do not pass it on to others. It may harm them even if is seems to you that their medical condition is similar.

This medicine is not usually intended for use in children and adolescents under 18 years of age.

1. WHAT IS THIS MEDICINE INTENDED FOR?

This medicine is used to treat hypertension.

Therapeutic group: A dihydropyridine derivative calcium channel blocker.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine if:

- You are sensitive (allergic) to lercanidipine, to any of the other ingredients contained in the medicine (see section 6 "Further Information") or to other medicines from this group, such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine.
- Do not use this medicine if you are pregnant, planning to become pregnant, are of child-bearing age and are not using reliable contraception, or are breastfeeding.
- You are suffering from certain heart diseases: uncontrolled heart failure, blockage of blood flow from the heart, unstable angina pectoris (angina pectoris at rest or that is gradually increasing) and are within one month of heart attack.
- You are suffering from a severe liver or kidney disease.
- You are concomitantly taking: cyclosporine, antifungals such as ketoconazole or itraconazole, macrolide antibiotics such as erythromycin or troleandomycin, antivirals such as ritonavir.
- You consume grapefruits or grapefruit juice.

Special warnings regarding use of the medicine:

Before treatment with Lercapress, inform the doctor if:

- you are suffering from liver or kidney problems or are undergoing dialysis.
- you suffer from certain other heart conditions (such as sick sinus syndrome), that were not treated by insertion of a pacemaker.
- you suffer from angina pectoris.
- you have been told in the past by a doctor that you have an intolerance to certain sugars.
- you are sensitive to any type of food or medicine.

❗ If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, inform the doctor or pharmacist. It is particularly important to inform the doctor or pharmacist if you are taking:

- other antihypertensives such as beta-blockers, diuretics or ACE-inhibitors, quinidine or amiodarone (for rapid pulse), phenytoin, carbamazepine (for seizures) – the doctor may monitor blood pressure more frequently than usual.
- rifampicin (for tuberculosis), cimetidine (for peptic ulcer, indigestion and heartburn) – more than 800 mg per day, midazolam (sleep aid), astemizole or terfenadine (for allergies), digoxin, simvastatin (to lower cholesterol).
- medicines listed in section "Do not use this medicine if".

❗ Use of the medicine and food

Consumption of grapefruits or grapefruit juice may increase the effect of **Lercapress**; therefore, avoid their consumption during the course of treatment.

It is preferable to take the medicine in the morning, at least 15 minutes before breakfast, since high-fat meals may significantly increase the level of the medicine in the blood.

❗ Use of the medicine and alcohol consumption

Abstain from consuming alcoholic beverages during the course of treatment with **Lercapress** since alcohol may increase the effect of the medicine.

❗ Pregnancy and breastfeeding

Do not use this medicine if you are pregnant, planning to become pregnant, or if you are of child-bearing age and are not using reliable contraception. Consult a doctor if you are taking **Lercapress** and think you may be pregnant.

Do not use the medicine if you are breastfeeding.

❗ Driving and operating machinery

Use of this medicine may cause dizziness, weakness and tiredness; therefore, confirm that it does not have such an effect on you before performing activities such as driving or operating machines.

❗ Important information regarding some of the ingredients of the medicine

This medicine contains lactose. If you have been told in the past by a doctor that you have an intolerance to certain sugars, consult a doctor before starting treatment with this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

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

The recommended dosage is usually: one **Lercapress 10** tablet per day.

If necessary, the doctor may increase the dosage to one **Lercapress 20** tablet per day.

Do not exceed the recommended dose.

Take the medicine at the same time every day. Swallow the tablet with a little water, preferably in the morning at least 15 minutes before breakfast. The tablet can be halved or crushed for immediate use.

This medicine is not usually intended for children and adolescents under 18 years of age.

Tests and follow up

During the course of treatment with this medicine, the following tests should be performed: blood pressure, ECG and heart rate.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. If you accidentally took a higher dosage, the following signs may develop: too great a drop in blood pressure, irregular or rapid heart rate, loss of consciousness.

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

If you forgot to take this medicine at the scheduled time, take a dose as soon as you remember, but if it is almost time for taking the next dose, skip the forgotten dose and take the next dose on time. Never take two doses together.

Even if there is an improvement in your health, do not stop treatment abruptly without consulting with the doctor. If you stop using this medicine, your blood pressure may rise again.

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 a doctor or a pharmacist.

4. SIDE EFFECTS

As with any medicine, use of **Lercapress** 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 use and refer to a doctor immediately upon occurrence of:

swelling of the ankles or legs, palpitations, muscle pains, angina pectoris, increase in volume of urine or frequency of urination (rare); thickening of the gums, drop in blood pressure, chest pain (very rare); fainting and allergic reaction (symptoms such as itching, rash, urticaria may occur).

Other medicines from this group have been reported in rare cases to cause thickening of the gums. In patients with angina, other medicines from this group may increase the frequency, duration or severity of the attacks. Isolated incidents of myocardial infarction have been observed. If you experience any of these problems with **Lercapress**, inform the doctor immediately.

Additional side effects:

Uncommon side effects (effects that occur in 1-10 in 1,000 users): headache; dizziness; rapid pulse; palpitations; sudden reddening of the face, neck or chest.

Rare side effects (effects that occur in 1-10 in 10,000 users): digestive system disturbances including dyspepsia, heartburn, diarrhea, nausea, vomiting and abdominal pain; sleepiness; weakness; tiredness; rash; frequent urination; muscle pains.

Very rare side effects (effects that occur in less than one in 10,000 users) or side effects whose frequency is unknown: thickening of the gums; changes in liver function (detected in lab tests); increased frequency of urination; drop in blood pressure that can cause dizziness and fainting; allergic reaction; chest pain and heart attack.

If a side effect occurs, if one of the side effects worsens, if you suffer from a side effect not mentioned in the leaflet, or if there is a change in your general feeling, consult the doctor immediately.

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 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.
- Store the medicine at a temperature below 25°C and in a place protected from light.

6. FURTHER INFORMATION

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

Microcrystalline cellulose, Lactose, Sodium starch glycollate, Povidone, Magnesium stearate, Opadry white Y-1-7000, Opadry yellow OY-6478.

Each **Lercapress 10** tablet contains:
approximately 39 mg lactose and approximately 0.5 mg sodium.

Each **Lercapress 20** tablet contains:
approximately 78 mg lactose and approximately 1 mg sodium.

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

Lercapress is packaged in trays (blister) that are inserted into a carton box. Each package of **Lercapress** contains 30 tablets.

Lercapress are yellow, round, biconvex coated tablets with a score line on one side.

Registration holder and address: Unipharm Ltd., P.O.B. 21429, Tel-Aviv 6121301.

Manufacturer and address: Trima Ltd.,
Kibbutz Maabarot.

This leaflet was checked and approved by the Ministry of Health in August 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Lercapress 10: 141 51 31848 00
Lercapress 20: 143 67 32975 00

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