Package leaflet: Information for the user

LERCARIL 10 mg/10 mg film-coated tablets
enalapril maleate/lercanidipine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Lercaril is and what it is used for

Lercaril is a fixed combination of an ACE-inhibitor (enalapril) and a calcium channel blocker (lercanidipine), two medicines that lower blood pressure.

Lercaril is used to treat high blood pressure (hypertension) in adult patients whose blood pressure is not adequately controlled by lercanidipine 10 mg alone. Lercaril should not be used for initial treatment of hypertension.

2. What you need to know before you take Lercaril

Do not take Lercaril:
- If you are allergic (hypersensitive) to enalapril maleate or lercanidipine hydrochloride or to any other ingredients of this medicine (listed in section 6).
- If you have ever had an allergic reaction to a type of medicine similar to those contained in Lercaril, i.e. medicines called ACE-inhibitors or calcium channel blockers.
- If you have ever had swelling of your face, lips, mouth, tongue or throat which caused difficulty in swallowing or breathing (angioedema) after taking a type of medicine called ACE-inhibitors, or when the reason why was not known or it was inherited.
- If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you are more than 3 months pregnant (it is also better to avoid Lercaril in early pregnancy – see pregnancy section).
- If you are suffering from certain heart diseases:

    - obstruction to the flow of blood from the heart
    - untreated heart failure
    - unstable angina (chest discomfort occurring at rest or progressively increasing)
    - within one month of a heart attack.
- If you have severe liver problems.
- If you have severe kidney problems, or if you are undergoing dialysis.
- If you are taking medicines that are inhibitors of the hepatic metabolism, such as:
    - antifungal medicines (such as ketoconazole or itraconazole).
    - macrolide antibiotics (such as erythromycin, troleandomycin, clarithromycin).
    - antivirals (such as ritonavir).
- If you are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).
- With grapefruit or grapefruit juice.

Warnings and precautions
Talk to your doctor or pharmacist before taking Lercaril:
- If you have low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- If you have been very sick (excessive vomiting) or have had diarrhoea recently.
- If you are on a salt restricted diet.
- If you have a heart problem.
- If you have a condition involving the blood vessels in the brain.
- If you have a kidney problem (including kidney transplantation). This may lead to higher levels of potassium in your blood which can be serious. Your doctor may need to adjust your dose of enalapril or monitor your blood level of potassium.
- If you have a liver problem.
- If you have a blood problem, such as low or lack of white blood cells (leucopenia, agranulocytosis), low platelet count (thrombocytopenia or a decreased number of red blood cells (anaemia).
- If you have a collagen vascular disease (e.g. lupus erythematosus, rheumatoid arthritis or scleroderma), you are on therapy that suppresses your immune system, you are taking the medicines allopurinol or procainamide, or any combinations of these.
- If you are a black patient you should be aware that black patients are at increased risk of allergic reactions with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing when taking ACE-inhibitors.
- If you have diabetes. You should monitor your blood for low blood glucose levels, especially during the first month of treatment. The level of potassium in your blood can also be higher.
- If you are taking potassium supplements, potassium-sparing agents, or potassium-containing salt substitutes.
- If you are over 70 years of age.
- If you have an intolerance to certain sugars (lactose).

If you are taking any of the following medicines, the risk of angioedema may be increased:
- Racecadotril, a medicine used to treat diarrhoea;
- Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus);
- Vildagliptin, a medicine used to treat diabetes.

If you are taking any of the following medicines used to treat high blood pressure:
- an angiotensin II receptor blocker (ARBs) (also known as sartans for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
- aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.
See also information under the heading "Do not take Lercaril".

If you are about to have a procedure
If you are about to have any of the following, tell your doctor that you are taking Lercaril:
- any surgery or receive anaesthetics (even at the dentist)
- a treatment to remove cholesterol from your blood called "LDL apheresis"
- a desensitisation treatment, to lower the effect of any allergy to bee or wasp stings.

You must tell your doctor if you think you are (or might become) pregnant or breast-feeding (see pregnancy, breast-feeding and fertility section).

Children and adolescents
The safety and efficacy of Lercaril in children aged up to 18 years have not been established.

Other medicines and Lercaril
Lercaril must not be taken with certain medications.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without prescription. This is because when Lercaril is taken with other medicines, the effect of Lercaril or of the other medicine may be changed, or certain side effects may occur more frequently.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- other medicines to lower blood pressure
- potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots). See "Do not take Lercaril"
- lithium (a medicine used to treat a certain kind of depression)
- medicines for depression called 'tricyclic antidepressants'
- medicines for mental problems called 'antipsychotics'
- non-steroidal anti-inflammatory medicines, including COX-2-inhibitors (medicines that reduce inflammation and can be used to help relieve pain)
- certain pain or arthritis medicines including gold therapy
- certain cough and cold medicines and weight reducing medicines which contain something called a 'sympathomimetic agent'
- medicines for diabetes (including oral antidiabetic medicines and insulin)
- astemizole or terfenadine (medicines for allergies)
- amiodarone, quinidine or sotalol (medicines to treat a fast heart beat)
- phenytoin, phenobarbital or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- digoxin (a medicine to treat heart problems)
- midazolam (a medicine that helps you to sleep)
- beta-blockers e.g. metoprolol (a medicine to treat high blood pressure, heart failure and abnormal heart rhythm)
- cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)

Do not take Lercaril if you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

If you are taking any of the following medicines, the risk of angioedema may be increased:
- Racecadotril, a medicine used to treat diarrhoea;
- Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus);
- Vildagliptin, a medicine used to treat diabetes.

Your doctor may need to change your dose and/or to take other precautions:
- If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings "Do not take Lercaril" and "Warnings and precautions").

Lercaril with food, drink and alcohol
- Lercaril should be taken at least 15 minutes before a meal.
- A high fat meal significantly increases blood levels of the medicine.
- Alcohol can increase the effect of Lercaril. Do not consume alcohol during treatment with Lercaril.
- Lercaril must not be taken with grapefruit or grapefruit juice as they can increase its hypotensive effect (see "Do not take Lercaril").

Pregnancy, breast-feeding and fertility
Pregnancy and fertility
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Lercaril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lercaril. Lercaril is not recommended during pregnancy and must not be taken when you are more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding
Lercaril should not be used during breast-feeding.

Driving and using machines
If you develop dizziness, weakness or drowsiness with this medicine, do not drive a vehicle or operate machines.

Lercaril contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Lercaril

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults: unless otherwise prescribed by your doctor, the recommended dose is one tablet once daily at the same time each day. The tablet should preferably be taken in the morning at least 15 minutes before breakfast. The tablets should be swallowed whole with water. See "Lercaril with food, drink and alcohol".

Patients with kidney problems/elderly: your dose of medicine will be decided by your doctor and will be based on how well your kidneys are working.

If you take more Lercaril than you should
Do not exceed the prescribed dose. If you have taken more than the prescribed dose, talk to your doctor or go to the hospital straight away. Take the medicine pack with you. Taking more than the correct dose can cause an excessive drop in blood pressure and your heart can beat irregularly or faster.

If you forget to take Lercaril
- If you forget to take your tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Lercaril
- Do not stop taking your medicine unless your doctor tells you to.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Lercaril can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Some side effects can be serious.
If any of the following happen, tell your doctor straight away:
Allergic reaction with swelling of your face, lips, tongue or throat which may cause difficulty in breathing or swallowing.

When you start taking Lercaril you might feel faint or dizzy or have blurred vision; this is caused by a sudden fall in blood pressure and if this happens, it will help to lie down. If you are worried, please talk to your doctor.

Side effects observed with Lercaril

Common (may affect up to 1 in 10 people)
- Cough;
- Feeling dizzy, headache.

Uncommon (may affect up to 1 in 100 people)
- Changes in blood values such as a lower number of blood platelets;
- Increased blood potassium level;
- Nervousness (anxiety);
- Feeling dizzy when standing up, vertigo;
- Fast heartbeat, fast or uneven heartbeat (palpitations);
- Sudden reddening of your face, neck or upper chest (flushing), low blood pressure;
- Abdominal pain, constipation, feeling sick (nausea);
- Higher levels of liver enzymes;
- Redness of the skin;
- Joint pain;
- Increased number of times one urinates;
- Feeling weak, tiredness, feeling hot, ankle swelling.

Rare (may affect up to 1 in 1,000 people)
- Anaemia;
- Allergic reactions;

- Ringing in your ears (tinnitus);
- Fainting;
- Dry throat, sore throat;
- Indigestion, salty sensation on the tongue, diarrhoea, dry mouth, swelling of gums;
- Allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing, skin rash, hives;
- Getting up at night to urinate, producing large amounts of urine;
- Impotence.

Additional side effects observed with enalapril or lercanidipine alone

Enalapril

Very Common (may affect more than 1 in 10 people)
Blurred vision, feeling dizzy, weak or sick and cough.

Common (may affect up to 1 in 10 people)
Depression, headache, fainting (syncope), chest pain, light-headedness due to low blood pressure, changes in heart rhythm, fast heartbeat, angina, shortness of breath, change in sense of taste, increased levels of creatinine in your blood (usually detected by a test), high levels of potassium in the blood, diarrhoea, abdominal pain, tiredness (fatigue), rash, allergic reaction with swelling of the face, lips, tongue or throat with difficulty in swallowing or breathing.

Uncommon (may affect up to 1 in 100 people)
Anaemia (including aplastic and haemolytic), sudden fall in blood pressure, confusion, nervousness, sleeplessness or sleepiness, feeling your skin prickling or being numb, heart attack (possibly due to very low blood pressure in certain high-risk patients, including those with blood flow problems of the heart or brain), stroke (possibly due to very low blood pressure in high-risk patients), runny nose, sore throat and hoarseness, asthma-associated tightness in chest, slow movement of food through your intestine (ileus), inflammation of your pancreas, being sick (vomiting), indigestion, constipation irritated stomach (gastric irritations), dry mouth, ulcer, anorexia, itching or nettle rash, loss of hair, impaired kidney function, kidney failure, increased sweating, high level of proteins in your urine (measured in a test), muscle cramps, generally feeling unwell (malaise), high temperature (fever), low level of blood sugar or sodium, high level of blood urea (all measured in a blood test), flushing, fast or uneven heartbeat (palpitations), vertigo (spinning sensation), ringing in your ears (tinnitus), impotence.

Rare (may affect up to 1 in 1,000 people)
Changes in blood values such as a lower number of white blood cells, bone marrow depression, autoimmune diseases, strange dreams or sleep problems, 'Raynaud's phenomenon' (where your hands and feet may become very cold and white due to low blood flow), inflammation of your nose, pneumonia, liver problems such as lower liver function, inflammation of your liver, jaundice (yellowing of the skin or eyes), higher levels of liver enzyme or bilirubin (measured in a blood test), erythema multiforme (red spots of different shapes on the skin), Stevens-Johnson syndrome and toxic epidermal necrolysis (a serious skin condition where you have reddening and scaling of your skin, blistering or raw sores), exfoliative dermatitis /erythroderma (severe skin rash with flaking or peeling the skin), or pemphigus (small fluid-filled bumps on the skin), lower amount of urine produced, enlargement of the mammary glands in males (gynaecomastia), swollen glands in neck, armpit or groin, accumulation of fluid or other substances in the lungs (as seen on X-rays), inflammation of the cheeks, gums, tongue, lips, throat.

Very Rare (may affect up to 1 in 10,000 people)
Swelling in your intestine (intestinal angioedema).

Not known (frequency cannot be estimated from the available data)
Over production of antidiuretic hormone, which causes fluid retention, resulting in weakness, tiredness or confusion.
A symptom complex has been reported which may include some or all of the following: fever, inflammation of blood vessels (serositis/vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, photosensitivity or other skin manifestations may occur.

Lercanidipine

Some side effects can be serious.
If any of the following happen, tell your doctor straight away:

Rare (may affect up to 1 in 1,000 people)
Angina pectoris (chest pain due to lack of blood to your heart), allergic reactions (symptoms include itching, rash, urticaria), fainting.

Patients with pre-existing angina pectoris may experience increased frequency, duration or severity of the attacks with the group of medicines to which lercanidipine belongs. Isolated cases of heart attack may be observed.

Other possible side effects:
Common (may affect up to 1 in 10 people): headache, fast heart rate, feeling of fast or uneven heart beat (palpitations), sudden reddening of your face, neck or upper chest (flushing), ankle swelling.

Uncommon (may affect up to 1 in 100 people): dizziness, fall in blood pressure, heartburn, feeling sick, stomach pain, skin rash, itching, muscle pain, passage of large amounts of urine, feeling weak or feeling tired.

Rare (may affect up to 1 in 1,000 people): sleepiness, vomiting, diarrhoea, hives, increase in the usual number of times one urinates, chest pain.

Not known (frequency cannot be estimated from the available data): swelling of gums, changes in liver function (detected by blood tests), cloudy fluid (when performing dialysis through a tube into your abdomen), swelling of your face, lip, tongue or throat which may cause difficulty in breathing or swallowing.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. You can ask your doctor or pharmacist for more information about side effects. Both have a more complete list of side effects.

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lercaril

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and the carton after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lercaril contains

The active substances are enalapril maleate and lercanidipine hydrochloride.
Each film-coated tablet contains: 10 mg enalapril maleate (equivalent to 7.64 mg enalapril) and 10 mg lercanidipine hydrochloride (equivalent to 9.44 mg lercanidipine).

The other ingredients are:
Core: lactose monohydrate, cellulose microcrystalline, sodium starch glycolate type A, povidone K30, sodium hydrogen carbonate, magnesium stearate.
Film-coating: hypromellose 5 cP, titanium dioxide (E171), talc, macrogol 6000.

What Lercaril looks like and contents of the pack
Lercaril 10 mg/10 mg tablets are white, circular and biconvex film-coated tablets of 8.5 mm.

Lercaril 10 mg/10 mg is available in packs of 7, 14, 28, 30, 35, 42, 50, 56, 90, 98 and 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
RECORDATI IRELAND Ltd., Raheens East, Ringaskiddy, Co. Cork, Ireland.

Manufacturers
RECORDATI Industria Chimica e Farmaceutica S.p.A. – Via Matteo Civitali 1 – I-20148 Milan, Italy
Doppel Farmaceutici S.r.l., Via Volturno 48, Quinto de'Stampi, 20089 Rozzano (MI), Italy

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Zanipril 10 mg/10 mg Filmtabletten
Belgium, Luxembourg	Zanicombo
Bulgaria	Lercapril
Cyprus, United Kingdom (NI)	Zaneril
Denmark, Finland, Germany, Iceland, Malta, Norway, Portugal, Spain	Zanipress
France	Zanextra
Greece, Latvia, Poland	Lercaprel
Hungary	Coripren
Ireland, Estonia	Lercaril
Italy	Zanipril
Lithuania	Lercaprel 10 mg/10 mg plėvele dengtos tabletės
The Netherlands	Lertec
Romania	Lercaril 10 mg/10 mg
Slovenia	Lercaprel 10 mg/10 mg
Sweden	Zanitek

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