Lercaril® 20 mg/10 mg film-coated tablets
(enalapril maleate/lercanidipine hydrochloride)

Package leaflet: Information for the user

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
2 What you need to know before you take Lercaril
3 How to take Lercaril
4 Possible side effects
5 How to store Lercaril
6 Contents of the pack and other information

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 enalapril 20 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 to enalapril or lercanidipine or any of the 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 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 suffer from certain heart diseases:
  - obstruction to the flow of blood out of the heart, including a narrowing of the aortic valve in your heart
  - untreated heart failure
  - chest discomfort occurring at rest or becoming worse or happening more often (unstable angina)
  - within one month of a heart attack.
* If you have severe kidney problems, or if you are undergoing dialysis.
* If you have severe liver problems.
* If you are taking drugs that are inhibitors of the hepatic metabolism, such as:
  - antifungals (e.g. ketoconazole, itraconazole).
  - macrolide antibiotics (e.g. erythromycin, troleandomycin).
  - antivirals (e.g. ritonavir).
* If you are taking another drug called cyclosporin or ciclosporin (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).
* 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 erithematosus, rheumatoid arthritis or scleroderma).
* 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.
* If you develop a persistent dry cough.
* If you are taking potassium supplements, potassium-sparing agents, or potassium-containing salt substitutes.
* If you have an intolerance to certain sugars (lactose)
* 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”.

<u>If you are about to have a procedure</u>
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 desensitization treatment, to lower the effect of any allergy to bee or wasp stings.

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

Children and adolescents
Do not give this medicine to children and adolescents under the age of 18 years as there is no information on if it works and if it is safe.

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 certain 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:
* medicines containing potassium (including dietary salt substitutes)
* other medicines that lower blood pressure, such as angiotensin II receptor-blockers, diuretics (water pills) or a medicine called aliskiren
* 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 drugs, 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 or quinidine (medicines to treat a fast heart beat)
* phenytoin or carbamazepine (medicines for epilepsy)
* rifampicin (a drug for the treatment of tuberculosis)
* digoxin (a medicine to treat heart problems)
* midazolam (a medicine that helps you to sleep)
* beta-blockers (medicines to treat high blood pressure and heart problems)
* a medicine for ulcers and heartburn called cimetidine at daily doses of more than 800 mg

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, drinks and alcohol
* Lercaril should be taken at least 15 minutes before a meal.
* Alcohol can increase the effect of Lercaril. You are therefore advised either to consume no alcohol or to strictly limit your alcohol intake.
* Lercaril should not be taken with grapefruit or grapefruit juice.

Pregnancy, breast-feeding and fertility

<u>Pregnancy and fertility</u>
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.

<u>Breast-feeding</u>
Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Lercaril. In the case of an older baby your doctor should advise you on the benefits and risks of taking Lercaril whilst breast-feeding, compared with other treatments.

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

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

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.

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
If you have taken more than you should, 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.

LERCARIL® 20 mg/10 mg film-coated tablets

(enalapril maleate/lercanidipine hydrochloride)

PATIENT INFORMATION LEAFLET (continued)

4 Possible side effects

Like all medicines, this medicine 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 1in 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 (affects more than 1 in 10 people)
Blurred vision.

Common (affects less than 1 in 10 people)
Depression, chest pain, changes in heart rhythm, angina, shortness of breath, change in sense of taste, increased levels of creatinine in your blood (usually detected by a test).

Uncommon (affects less than 1 in 100 people)
Anaemia (including aplastic and haemolytic), sudden fall in blood pressure, confusion, 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, slow movement of food through your intestine, inflammation of your pancreas, being sick, irritated stomach (gastric irritations), ulcer, anorexia, increased perspiration, itching or nettle rash, loss of hair, impaired kidney function, kidney failure, 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).

Rare (affects less than 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), pulmonary infiltrates, 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 bilirubin (measured in a blood test), erythema multiforme (red spots of different shapes on the skin), Stevens-Johnson syndrome (a serious skin condition where you have reddening and scaling of your skin, blistering or raw sores, or detachment of the top layer of skin from bottom layers), lower amount of urine produced, enlargement of the mammary glands in males.

Very Rare (affects less than 1 in 10,000 people)
Swelling in your intestine (intestinal angioedema).

Lercanidipine

Rare (affects less than 1 in 1,000 people)
Angina pectoris (chest pain due to lack of blood to your heart), vomiting, heartburn, muscle pain.

Very Rare (affects less than 1 in 10,000 people)
Chest pain.

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.

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 side effects
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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@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: 20 mg enalapril maleate (equivalent to 15.29 mg enalapril) and 10 mg lercanidipine hydrochloride (equivalent to 9.44 mg lercanidipine).

Core; lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (type A) , povidone K30, sodium bicarbonate, magnesium stearate.
Film-coating; 5 cp hypromellose, Titanium dioxide (E171), Macrogol 6000, Talc, Aluminium lake quinoline yellow (E104), Yellow Iron oxide (E172).

What Lercaril looks like and contents of the pack
Lercaril 20 mg/10 mg tablets are yellow, circular and biconvex film-coated tablets of 8.5 mm. Lercaril 20 mg/10 mg is available in packs of 28 tablets

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Manufactured by:
RECORDATI industria Chimica e Farmaceutica S.p.A. Via Matteo Civitali 1- I-20148 Milan, Italy

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Blind or partially sighted?
Is this leaflet hard to see or read?
Phone Lexon (UK) Limited,
Tel: +44 (0)1527 505414 for help.

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria Zanipril 20 mg/10 mg Filmtabletten
Belgium Zanicombo
Bulgaria Lercapril
Cyprus Zaneril
Czech Rep. Lercaprel 20 mg/10 mg
Denmark Zanipress
Estonia Lercaril
Finland Zanipress
France Zanextra
Germany Zanipress
Greece Lercaprel
Hungary Coripren
Iceland Zanipress
Ireland Lercaril
Italy Zanipril
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