PACKAGE LEAFLET: Information for the patient

LECORIN ACE

Film-coated tablets – (10 mg / 20 mg)

(Lercanidipine hydrochloride, Enalapril maleate)

Read all of this leaflet carefully before you start taking this medicine.

- 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 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.

In this leaflet:

1. WHAT LECORIN ACE IS AND WHAT IT IS USED FOR

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

Lecorin ACE is used for the treatment of hypertension in patients whose blood pressure is not adequately controlled by enalapril 20 mg alone. Lecorin ACE should not be used as first choice for initial treatment of hypertension.

2. BEFORE YOU TAKE LECORIN ACE

Do not take Lecorin ACE:

- if you are allergic to any of the active substances (lercanidipine, enalapril) or to any of the excipients of Lecorin ACE (see section 6);
- if you are allergic to medicines closely related to Lecorin ACE (e.g. amlodipine, felodipine, nifedipine, captopril, fosinopril, lisinopril, ramipril);
- if you are more than 3 months pregnant (it is also better to avoid Lecorin ACE in early pregnancy – see "Pregnancy" section);
- if you suffer from certain heart diseases:
  - untreated congestive heart failure;
  - obstruction to the flow of blood from the left ventricle of the heart, including a narrowing of the aorta (aortic stenosis);
  - unstable angina pectoris (angina at rest or progressively increasing angina);
  - or if less than one month has passed after a myocardial infarction;
- if you have severe liver or kidney problems, or if you are undergoing dialysis;
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren;
- if you use medicines such as:
  - antifungals (e.g. ketoconazole or itraconazole);
  - macrolide antibiotics (erythromycin, troleandomycin);
  - antivirals (e.g. ritonavir);
- if you are simultaneously using ciclosporin;
- simultaneously with grapefruit or grapefruit juice;
- if you have ever developed angioedema (oedema of the face, lips, tongue, and/or larynx, hands, and feet), either hereditary in type or after previous treatment with an ACE-inhibitor;
- if you have a hereditary tendency to tissue swelling or if you develop tissue swelling of unknown cause (hereditary or idiopathic angioedema).

Take special care with Lecorin ACE

Ask your doctor before you take Lecorin ACE:

- if you have low blood pressure (you may notice this as faintness or dizziness, specially 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 suffer from heart ischemic disease;
- if you suffer from a disturbance of blood flow in the brain (cerebrovascular disease);
- if you have any of the following heart diseases: heart failure, narrowing of the opening of the aortic or mitral valve or enlarged heart (hypertrophic cardiomyopathy);
- if you have renal problems;
- if your liver enzyme levels rise or if you develop jaundice;
- if your white blood cells are reduced (leucopenia, agranulocytosis), resulting in susceptibility to infection and severe general symptoms;
- if you suffer from certain diseases of the connective tissue with involvement of blood vessels (collagen vascular diseases);
- if you are simultaneously taking allopurinol (an anti-gout medicine), procainamide (a medicine used for treatment of irregular heartbeat), or lithium (a medicine used to combat certain types of depression);
- if you develop hypersensitivity reactions or tissue swelling (angioedema) during treatment with Lecorin ACE;
- if you suffer from diabetes mellitus;
- if you develop a persistent dry cough;
- if you are at risk of an elevation of the potassium level in your blood;
- if the reduction in blood pressure is inadequate because of your ethnic origin (especially in patients with black skin);
- if you think you are (or might become) pregnant; Lecorin ACE is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see “Pregnancy” section);
- if you are taking any of the following medicines used to treat high blood pressure:

- an angiotensin II receptor blocker (ARB) (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 Lecorin ACE”.

If you require desensitisation therapy for insect venom (e.g. from bees or wasps), Lecorin ACE should be temporarily replaced by a suitable medicine of a different type. Otherwise, life-threatening general symptoms may occur. Such reactions can also occur after insect bites (e.g. bee or wasp stings).

Use of Lecorin ACE while receiving dialysis or treatment for greatly elevated blood lipid levels can result in severe hypersensitivity reactions and even life-threatening shock.

Please inform your doctor that you are being treated with Lecorin ACE or that you require dialysis, so that the doctor can take this into account when prescribing treatment.

If you are shortly to undergo an operation or anaesthesia (including dental anaesthesia), please inform your doctor that you are taking Lecorin ACE, since an abrupt fall in blood pressure could occur during anaesthesia.

Since there is no clinical experience in patients under 18 years of age, use in children and adolescents is not currently recommended.

Use of this medicine requires regular medical monitoring. Therefore, please be absolutely sure to undergo whatever laboratory tests and examinations your doctor orders.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

When Lecorin ACE is taken simultaneously with certain other medicines, the effect of Lecorin ACE or of the other medicine may be intensified or weakened, or certain side effects may occur more frequently.

The blood pressure-lowering effect can be intensified if you use any of the following medicines together with Lecorin ACE:

- ciclosporin (a medicine that suppresses the immune system);

- oral antifungal drugs such as ketoconazole and itraconazole;
- antiviral agents such as ritonavir;
- macrolide antibiotics such as erythromycin or troleandomycin;
- the anti-ulcer drug cimetidine at daily doses of more than 800 mg;
- diuretics such as hydrochlorothiazide, chlorthalidone, furosemide, triamterene, amiloride, indapamide, spironolactone, or other blood pressure-lowering medicines;
- certain vasodilating agents such as glyceryl trinitrate and organic nitrates (isosorbide) or anaesthetic agents;
- certain antidepressant and antipsychotic medicines;
- baclofene.

The blood pressure-lowering effect can be weakened if you use any of the following medicines together with Lecorin ACE:

- certain painkillers (e.g. paracetamol, ibuprofen, naproxen, indomethacin, or aspirin unless used at low dosage);
- drugs acting on blood vessels (e.g. noradrenaline, isoprenaline, dopamine, salbutamol);
- anticonvulsants such as phenytoin and carbamazepine;
- rifampicin (a drug for the treatment of tuberculosis).

If you use digoxin, please ask your doctor what signs you should look out for.
If you use potassium-sparing diuretics (spironolactone) or potassium supplements, the level of potassium in your blood may increase.
Simultaneous use of lithium carbonate and Lecorin ACE can lead to lithium toxicity.
If you use immunosuppressant or anti-gout medicines, you may in very rare cases be susceptible to severe infections.
If you suffer from diabetes, please note that simultaneous use of Lecorin ACE and either insulin or oral antidiabetic agents such as sulfonylureas and biguanides can result in hypoglycaemia (excessive reduction of blood sugar level) during the first month of treatment.
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 Lecorin ACE and “Take special care with Lecorin ACE”).
Please inform your doctor if you are using antihistamines such as terfenadine or astemizole or

anti-arrhythmic agents such as amiodarone or quinidine, or estramustine or amifostine or gold salts, since during simultaneous use of Lecorin ACE and these drugs certain drug interactions can occur.

Taking Lecorin ACE with food and drinks

Alcohol can increase the effect of Lecorin ACE. You are therefore recommended not to consume alcohol.

The tablets should not be taken with grapefruit or grapefruit juice.

Pregnancy

Tell your doctor or pharmacist before taking this medicine if you are pregnant, think you might be pregnant or are planning to have a baby.

Your doctor will normally advise you to stop taking Lecorin ACE before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Lecorin ACE. Lecorin ACE is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breastfeeding

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

Ask your doctor or pharmacist for advice before taking any medicines.

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.

Important information about some of the excipients of Lecorin ACE

Lecorin ACE 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 LECORIN ACE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
Unless otherwise prescribed by your doctor, the usual 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.
If you have the impression that the effect of Lecorin ACE is too strong or too weak, please talk to your doctor.

If you take more Lecorin ACE than you should

If you take more Lecorin ACE than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.
Taking more than the dose prescribed by your doctor, can cause severe fall of blood pressure and irregular and faster heart beat. This can result in loss of consciousness.
In addition, a severe fall in blood pressure can result in reduced blood flow to important organs, cardiovascular failure, and renal failure.

If you forget to take Lecorin ACE

If you forget to take one dose, take it as soon as you remember, except when it is almost time for the next dose. In this case take the next dose when it is the usual time to take it. Do not take a double dose to make up a forgotten dose.

If you stop taking Lecorin ACE

If you stop taking Lecorin ACE your blood pressure may rise again. Please talk to your doctor before you stop taking Lecorin ACE.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Lecorin ACE can cause side effects, although not everybody gets them.

Please inform your doctor immediately if you develop any of the following signs or symptoms:

- swelling of the face, limbs, lips, mucous membranes, tongue, and/or larynx, or shortness of breath;
- yellow colouration of the skin and mucous membranes;
- fever, swelling of the lymph nodes, and/or inflammation of the throat.

In such cases you must stop taking Lecorin ACE while your doctor will take appropriate measures.

The most frequent side effects are cough, headache, dizziness, peripheral oedema and rash. The adverse effects observed either with enalapril 20 mg / lercanidipine 10 mg or with enalapril or lercanidipine alone are listed below.

Blood and lymphatic system disordes

Anaemia, reduction in the number of certain blood cells, reduction of haemoglobin and haematocrit, reduced bone marrow function, lymph node swelling, autoimmune diseases.

Metabolism and nutrition disorders

Reduction of blood sugar levels (hypoglycemia).

Eye disorders

Blurred vision.

Nervous system disorders

Dizziness, headache, depression, confusion, drowsiness, sleeplessness, nervousness, abnormal sensations (e.g. pins and needles), altered dreams, sleep disturbances.

Cardiovascular disorders

Swelling of the ankles, excessive fall in blood pressure including excessive fall in blood pressure when standing up (orthostatic hypotension), brief loss of consciousness (fainting), heart attack or

stroke, chest pain, a feeling of tightness in the chest, abnormal heart rhythm, increased heart rate, heart pounding, coldness of the hands and feet.

Respiratory, thoracic and mediastinal disorders

Cough, shortness of breath, nasal discharge, sore throat and hoarseness, wheezing, asthma, abnormalities in the lung tissue, sniffling, inflammation of the lung.

Gastrointestinal disorders

Nausea, diarrhoea, abdominal pain, altered taste, intestinal obstruction, inflammation of the pancreas, vomiting, digestive disturbances, constipation, loss of appetite, gastric irritation, mouth dryness, gastric ulcer, inflammation and ulceration of the mucous membrane of the mouth, inflammation of the tongue, gum hyperplasia, intestinal swelling.

Hepatobiliary disorders

Liver failure, inflammation of the liver, jaundice (yellowing of the skin and/or the whites of the eyes).

Skin and subcutaneous tissue disorders

Flushing of the face, reddening and warm sensation in the skin, swelling of the face, lips, tongue, throat, hands, increased sweating, itch, urticaria, hair loss, severe skin reactions.
A symptom complex has been described that can be associated with some or all of the following side effects: fever, inflammation of serous surfaces, inflammation of blood vessels, muscle and joint pain / inflammation and certain changes in laboratory values, skin rash, light sensitivity and other skin reactions can occur.

Renal and urinary disorders

Kidney problems, reduced urine output, increased urine output.

Reproductive system and breast disorders

Impotence, breast enlargement in men.

General disorders and administration site conditions

Feeling of weakness, tiredness, facial reddening, muscle cramps, ringing in the ears, malaise, fever.

Investigations

Increased potassium level in blood, increased creatinine level in blood, increased urea level in blood, reduced sodium level in blood, increased level of liver enzymes and serum bilirubin.

Talk to your doctor or pharmacist if you get any of these side effects or any of side effects not listed in this leaflet.

5. HOW TO STORE LECORIN ACE

Keep out of the sight and reach of children!

Do not use Lecorin ACE after the expiry date which is stated on the package.

Store below 25°C!

Keep in the original package to protect it from light and humidity.

6. FURTHER INFORMATION

What Lecorin ACE film coated tablets contain

The active substances are lercanidipine hydrochloride and enalapril maleate.

Each film-coated tablet contains 10 mg lercanidipine hydrochloride and 20 mg enalapril maleate.

The excipients are:

tablet core: lactose monohydrate, sodium starch glycolate, microcrystalline cellulose, povidone, sodium hydrogen carbonate, magnesium stearate

film coat: polyvinyl alcohol, titanium dioxide, macrogol, talc, yellow iron oxide, red iron oxide, black iron oxide.

Contents of the pack

Box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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