

PACKAGE LEAFLET: Information for the patient

LECORIN

Film-coated tablets – 10 mg

(Lercanidipine hydrochloride)

Read 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. 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.

In this leaflet:

1. What Lecorin is and what it is used for
2. Before you take Lecorin
3. How to take Lecorin
4. Possible side effects
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6. Other information

1. WHAT LECORIN IS AND WHAT IT IS USED FOR

Lecorin contains the active substance lercanidipine hydrochloride, that is a dihydropyridine calcium-channel blocker with actions similar to those of nifedipine.

Lecorin influences the myocardial cells, the cells within the specialised conducting system of the heart, and the cells of vascular smooth muscle. Thus, myocardial contractility, the formation and propagation of the electrical impulse and coronary or systemic vascular tone may be diminished.

Lecorin is indicated for the treatment of mild to moderate essential hypertension.

2. BEFORE YOU TAKE LECORIN

Do not take Lecorin if you:

- are hypersensitive to the active substance lercanidipine hydrochloride or to any other dihydropyridine or to any of the excipients of the Lecorin tablets;
- are in pregnancy or lactation period;
- have aortic stenosis;
- suffer from cardiac diseases such as: unstable angina, you are within 1 month from the myocardial infarction, congestive uncontrolled heart failure;
- have severe hepatic impairment;
- have severe renal impairment;
- have acute porphyria;
- are taking strong inhibitors of CYP3A4;
- are taking cyclosporin.

Take special care with Lecorin

Ask your doctor before taking Lecorin:

- if you have cardiac disorders like sick sinus syndrome (if pacemaker is not in situ);
- if you have left ventricular dysfunction or ischaemic heart disease.

The co-administration with grapefruit juice increases the plasmatic concentration of Lecorin, so do not consume it during the period you are being treated with Lecorin.

Alcohol should be avoided since it may potentiate the effect of vasodilating antihypertensive drugs.

Other medicines and Lecorin

Concomitant treatment with other medicines may affect or be affected by Lecorin. Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without prescription. Do not forget to inform your doctor for the treatment with Lecorin, if you are being given any other drug during treatment, especially these below:

- antibacterials: avoid concomitant use with erythromycin;
- antifungals: itraconazole and ketoconazole can possibly inhibit the metabolism of lercanidipine – avoid concomitant use;

- antihypertensives: enhance the hypotensive effect; the first dose of post-synaptic alpha-blockers increases the risk of hypotensive effect;
- antivirals: ritonavir, cobicistat increase the concentration of Lecorin – avoid concomitant use;
- cardiac glycosides: digoxin concentration is increased by Lecorin;
- ciclosporin: concomitant treatment with Lecorin can increase the concentration of both drugs;
- benzodiazepines: midazolam increases the absorption of Lecorin;
- idelalisib: increases the plasma concentration of Lecorin – avoid concomitant use;
- cimetidine (more than 800 mg daily): increases the plasma concentration of Lecorin;
- anticonvulsants (CYP3A4 inducers e.g. phenytoin, phenobarbital, carbamazepine) and rifampicin: reduce the antihypertensive effect.

The co-administration with grapefruit juice increases the plasmatic concentration of Lecorin.

Pregnancy and breastfeeding

It is advised that Lecorin should not be administered during pregnancy or breastfeeding.

Women of childbearing-potential not using contraception should not take Lecorin.

Consult your doctor if you are taking Lecorin and if you think you are pregnant.

Driving and using machines

Clinical experience with lercanidipine hydrochloride indicates that it is unlikely to impair the patient ability to drive or use machinery. However, caution should be exercised because lercanidipine hydrochloride can cause: dizziness, asthenia, fatigue and rarely somnolence.

Important information about some of the excipients of Lecorin

This drug 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

Always, take Lecorin exactly as your doctor has told you. You should consult your doctor or your pharmacist if you are not sure.

The tablet is given by mouth. Swallow each tablet with water.

Adults: the usual dose is one tablet 10 mg daily, at the same time every day (preferably in the morning 15 minutes before breakfast). After at least two weeks of use, your doctor may advise you to increase the dose to 20 mg daily if necessary.

Patients with hepatic or renal impairment

Special attention is needed at the beginning of the therapy in these patients and during the increase of the dose to 20 mg.

If you take more Lecorin

If you take more Lecorin than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Lecorin

If you forget a dose (or more doses), take the following dose when it is time to take it usually. Do not take a double dose (or higher) to make up for a forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor for the below side effects that may appear to you:

- less commonly: flushing, peripheral oedema, palpitations, tachycardia, headache, dizziness;
- rarely: gastro-intestinal disturbances, angina, asthenia, drowsiness, polyuria, myalgia, rash;
- very rarely: gingival hyperplasia, myocardial infarction, hypotension.

If any of the side effects worsens, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LECORIN

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

Do not use Lecorin after the expiry date, which is stated on the carton.

Keep in the original packaging to protect it from light and moisture, at a temperature not higher than 30°C.

6. OTHER INFORMATION

What Lecorin 10 mg film-coated tablets contain

The **active substance** is lercanidipine hydrochloride.

Each film-coated tablet contains 10 mg lercanidipine hydrochloride.

The **excipients** are:

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

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

Content of the pack:

Carton box with 30 film-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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