

Package leaflet: Information for the user

Lecalpin 10 mg film-coated tablets

Lecalpin 20 mg film-coated tablets

Lercanidipine hydrochloride

Read all of this leaflet carefully before you start using 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 Lecalpin is and what it is used for
2. What you need to know before you take Lecalpin
3. How to take Lecalpin
4. Possible side effects
5. How to store Lecalpin
6. Contents of the pack and other information

1. What Lecalpin is and what it is used for

Lecalpin belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives) that lower blood pressure.

Lecalpin is used to treat your high blood pressure also known as hypertension in adults over the age of 18 years (it is not recommended for children under 18 years old).

2. What you need to know before you take Lecalpin

Do not take Lecalpin

- if you are allergic (hypersensitive) to lercanidipine or any of the other ingredients of this medicine (listed in section 6).
- if you are suffering from certain heart diseases:
 - untreated heart failure
 - an obstruction to flow of blood from the heart
 - unstable angina (chest discomfort occurring at rest or progressively increasing)
 - within one month of heart attack
- if you have severe liver problems
- if you have severe kidney problems or 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 or 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
- if you are pregnant, or if you wish to become pregnant or if you are a woman in child-bearing age and do not use any contraceptive method.
- if you are breast-feeding

Warnings and precautions

Talk to your doctor before taking Lecalpin

- if you have a heart problem
- if you have liver or kidney problems

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 Lecalpin in children aged up to 18 years have not been established.

Other medicines and Lecalpin

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

Taking Lecalpin with certain other medicines (see below), may alter the effect of these medicines or of Lecalpin or certain side effects may occur more frequently (see also section 2 “Do not take Lecalpin”).

It is especially important for your doctor to know if you are already being treated with any of the following medicines:

- phenytoin, phenobarbital or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- midazolam (a medicine that helps you sleep)
- cimetidine (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- digoxin (a medicine to treat a heart problem)
- terfenadine or astemizole (medicines for allergies)
- amiodarone, quinidine or sotalol (medicines to treat a fast heart beat)
- beta-blockers e.g. metoprolol (a medicine to treat high blood pressure, heart failure and abnormal heart rhythm)
- simvastatin (a medicine to lower cholesterol in your blood)
- Other medicines to treat high blood pressure

Lecalpin with food, drink and alcohol

A high fat meal significantly increases blood levels of the medicine (see section 3)

Lecalpin must not be taken with grapefruit or grapefruit juice (they can increase its hypotensive effect). See section 2 “Do not take Lecalpin”.

Alcohol can increase the effect of Lecalpin. Do not consume alcohol during treatment with Lecalpin.

Pregnancy, breast-feeding and fertility

Lecalpin is not recommended if you are pregnant, it should not be used during breast-feeding. There are no data from the use of Lecalpin in pregnant women and in nursing mothers. If you are pregnant or breast-feeding, if you are not using any contraceptive method, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

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

Lecalpin contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Lecalpin

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

Adults

The recommended dose is one Lecalpin 10 mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast. Your doctor may decide you to increase your dose to one Lecalpin 20 mg film-coated tablet daily, if needed. (see Section 2 “Lecalpin with food, drink and alcohol”)

The tablets should preferably be swallowed whole with 1/2 glass of water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in children and adolescents

Lecalpin is not recommended for use in children and adolescents under 18 years.

Elderly patients

No adjustment of the daily dose is required. However, special care should be exercised in starting treatment.

Patients with liver or kidney problems

Special care is needed in starting treatment in these patients and an increase in daily dose to 20 mg should be approached with caution

If you have any further questions on the use of this medicine as your doctor or pharmacist.

If you take more Lecalpin 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 Lecalpin

If you forget to take your tablet, take it as soon as you remember, unless it is almost time for your next dose. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lecalpin

If you stop taking Lecalpin your blood pressure may increase again. Please consult your doctor before stopping the treatment.

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

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:

Rare (may affect up to 1 in 1,000 people):

angina pectoris (e.g. chest tightness 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 these attacks with the group of medicines to which Lecalpin 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.

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 HPRC 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 Lecalpin

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 label, carton or bottle after EXP. The expiry date refers to the last day of that month.

Storage conditions:

Al/PVC/PVDC blister: Do not store above 30°C. Store in the original package to protect from moisture.

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 Lecalpin contains

- The active substance is lercanidipine hydrochloride.
One 10 mg film-coated tablet contains 10 mg lercanidipine hydrochloride, equivalent to 9.4 mg lercanidipine.
One 20 mg film-coated tablet contains 20 mg lercanidipine hydrochloride, equivalent to 18.8 mg lercanidipine.
- The other ingredients are:
Tablet core: Magnesium stearate, povidone, sodium starch glycolate (Type A), lactose monohydrate, microcrystalline cellulose.
Film-coating 10 mg tablets: Macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172).
Film-coating 20 mg tablets: Macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E172).

What Lecalpin looks like and contents of the pack

Lecalpin 10 mg tablets are yellow colored, round shaped, biconvex, coated tablets debossed with “LT1” one one side and breakline on the other side. The diameter of the tablet is approximately 6.5mm.

Lecalpin 20 mg tablets are pink colored, round shaped, biconvex, coated tablets debossed with “LT2” on one side and breakline on the other side. The diameter of tablet is approximately 8.5mm.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Pack sizes:

Blisters (Al/PVC/PVDC):

Lecalpin 10 mg film-coated tablets: 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 tablets

Lecalpin 20 mg film-coated tablets: 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Ireland	Lecalpin 10mg Film-coated Tablets
	Lecalpin 20mg Film-coated Tablets
United Kingdom	Lercanidipine hydrochloride 10mg film-coated Tablets
	Lercanidipine hydrochloride 20mg film-coated Tablets

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