Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

1. Keep this leaflet. You may need to read it again.
2. If you have any further questions, ask your doctor or pharmacist.
3. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs or symptoms are the same as yours.
4. 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

What Lecalpin is and what it is used for
Lecalpin belongs to a group of medicines called calcium channel blockers that block the entry of calcium into the muscle cells of the heart and the blood vessels that carry blood away from the heart (the arteries). It is the entry of calcium into these cells that causes the heart to contract and arteries to narrow. By blocking the entry of calcium, calcium channel blockers decrease contraction of the heart and dilate (widens) the arteries, and the blood pressure is reduced.

Lecalpin has been prescribed to you to treat your high blood pressure, also known as hypertension.

What you need to know before you take Lecalpin
Do not take Lecalpin:
1. If you are allergic to lercanidipine or any of the other ingredients of this medicine (listed in section 6).
2. If you have had allergic reactions to medicines that are closely related to Lecalpin tablets (such as amiodipine, nicardipine, felodipine, isradipine, nifedipine or laadiipine).
3. If you are suffering from certain heart diseases:
   - uncontrolled cardiac failure
   - an abnormal flow of blood from the heart
   - unstable angina (angina at rest or progressively increasing)
4. If you have had a heart attack less than one month ago
5. If you have severe liver or kidney problems
6. If you are taking drugs that are inhibitors of CYP3A4 isoenzyme:
   - antifungal medicines (such as ketoconazole or itraconazole)
   - macrolide antibiotics (such as erythromycin or troleandomycin)
   - antiviral (such as zidovudine)
   - at the same time as another drug called ciclosporin or cyclosporine
   - with grapefruit or grapefruit juice
7. If you are pregnant, or you wish to become pregnant or if you are a woman in child-bearing age and do not use any contraceptive method.
8. If you are breast-feeding

Warnings and precautions
Talk to your doctor before taking Lecalpin
1. If you have a heart condition known as sick sinus syndrome, and do not have a pacemaker
2. If you suffer from chest pain (angina pectoris), Lercanidipine may in very rare cases cause increased frequency of attacks that may last longer and become more severe. Heart attacks have been reported in isolated cases.
3. If you have problems with your liver or kidney, or you are on dialysis.
4. If you are experiencing chest pain, also known as hypertension.

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.

It is especially important for your doctor to know if you are already being treated with any of the following medicines:
- phenytoin or carbamazepine (medicines for epilepsy)
- rifampin (a medicine to treat tuberculosis)
- midazolam (a medicine that helps you sleep)
- cimetidine, more than 800 mg (a medicine for ulcers, stomach irritation, or heartburn)
- digoxin (a medicine to treat a heart problem)
- terfenadine or astemizole (medicines for allergies)
- anxiolytic or quinidine (medicines to treat a fast heart beat)
- metoprolol (a medicine to treat high blood pressure)
- simvastatin (a medicine for high cholesterol value)

Lecalpin with food, drink and alcohol
You must not eat grapefruit or drink grapefruit juice as this may increase the effect of Lecalpin.

If you use alcohol together with Lecalpin you may experience dizziness/flattening, tiredness or weakness. This is because the medicine may lower your blood pressure considerably together with alcohol.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine.

1. If you are pregnant or if you are a woman in child-bearing age do not use any contraceptive method.
2. Do not use 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.
3. Do not use if you are breast-feeding.

Driving and using machines
Lecalpin has a negligible influence on the ability to drive or use machines. However, side effects such as dizziness, weakness, tiredness and rarely sleepiness may occur. You should be careful until you know how you react to Lecalpin.

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.

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.

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, because a high fat meal significantly increases your blood levels of the medicine.

Your doctor may decide to increase your dose to one Lecalpin 20 mg film-coated tablet daily, if needed. The tablets should preferably be swallowed whole with 1/2 glass of water. The capsule is only there to help you break the tablet if you have difficulty swallowing it whole.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequencies of side effects have been listed below according to the following definitions:

- **Common:** may affect more than 1 in 10 people
- **Uncommon:** may affect up to 1 in 10 people
- **Rare:** may affect up to 1 in 100 people
- **Very rare:** may affect up to 1 in 1,000 people
- **Not known:** frequency cannot be estimated from the available data

**What Lecalpin contains**

- **What Lecalpin looks like and contents of the pack**

   **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.

   **What Lecalpin looks like and contents of the pack**

   Lecalpin 20 mg film-coated tablets are yellow, round, biconvex 6.5 mm film-coated tablets, scored on one side, and marked ‘L’ on the other side.

   - Lecalpin 10 mg tablets are pink, round, biconvex 4.5 mm film-coated tablets, scored on one side, and marked ‘L’ on the other side.

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

   **Pack sizes**

   - Blisters (Al/PVC):
     - Lecalpin 10 mg film-coated tablets: 14, 20, 28, 30, 50, 56, 60, 90, 96, 100 tablets
     - Lecalpin 20 mg film-coated tablets: 14, 20, 28, 30, 50, 56, 60, 90, 96, 100 tablets

   - Bottles:
     - Lecalpin 10 mg film-coated tablets: 100 tablets
     - Lecalpin 20 mg film-coated tablets: 100 tablets

   **Not all pack sizes may be marketed.**

**Marketing Authorisation Holder**

Actavis Group PTC ehf, Reykjavikurvegur 77-78, 220 Hafnarfjörður, Iceland

**Manufacturer**

Actavis ehf, BLR-016 Bulebel Industrial Estate, Zejtun ZTN 3000, Malta

**And/or**

Balkangarna – Dupigna AD, 3 Samiekosko Shrstei Dr, Dupigna 3060, Bulgaria

---

**Contents of the pack and other information**

**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/PVDC blister: Do not store above 25°C. Store in the dark.

Al/PVC blister: Do not store above 25°C. Store in the environment.

Do not throw away medicines via wastewater or household waste. 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 1 676 4971; Fax: +353 1 6762157.

Please report side effects. For help provide more information on the safety of this medicine.

---

**Lercanidipine (Lecalpin)**

10 mg & 20 mg Tablets PIL - IE

**This leaflet was last revised in September 2017**

---

* Please note that only Artwork Studio is permitted to make changes to the above artwork. No changes are permitted by any 3rd party other than added notes and marks up for required changes.