

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 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 (widen) the arteries, and the blood pressure is reduced.

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

2. What you need to know before you take Lecalpin

Do not take Lecalpin

- if you are allergic to lercanidipine or any of the other ingredients of this medicine (listed in section 6).
- if you have had allergic reactions to medicines that are closely related to Lecalpin tablets (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- if you are suffering from certain heart diseases:
 - uncontrolled cardiac failure
 - an obstruction to flow of blood from the heart
 - unstable angina (angina at rest or progressively increasing)
 - if you have had heart attack less than one month ago
- if you have severe liver or kidney problems
- If you are taking drugs that are inhibitors of CYP3A4 isoenzyme:
 - antifungal medicines (such as ketoconazole or itraconazole)
 - macrolide antibiotics (such as erythromycin or clarithromycin)
 - antivirals (such as ritonavir)

- at the same time as another drug called ciclosporin or cyclosporin
- 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 condition known as sick sinus syndrome, and do not have a pacemaker
- if you suffer from chest pain (angina pectoris), Lercandipine 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
- if you have problems with your liver or kidney, or you are on dialysis

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)
- 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 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/fainting, 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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not use if you are pregnant, or if you wish to become pregnant or if you are a woman in childbearing age and do not use any contraceptive method.

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 effect 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.

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.

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 you 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 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 below 18 years.

If you take more Lecalpin than you should

Immediately contact a doctor, the nearest hospital casualty department or the centre for poison information for advice.

Exceeding the correct dosage may cause blood pressure to become too low, and the heart to beat irregularly or faster. It may also lead to unconsciousness.

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

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people

not known:	frequency cannot be estimated from the available data
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Uncommon: Headache, dizziness, faster heartbeats, awareness of the beating of the heart, flushing (transient episodic redness of the face and neck), ankle swelling.

Rare: Sleepiness, weakness, tiredness, nausea, vomiting, diarrhoea, abdominal pain, indigestion, rash, muscle pain, passage of large amounts of urine, angina pectoris.

Very rare, not known: Decrease in blood pressure which may lead to fainting, allergic reaction, swelling of gums, increase in liver enzyme blood test values, fall in blood pressure which can cause dizziness, light-headedness or fainting, increase in the usual number of times one urinates, chest pain and heart attack.

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 6767836. 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 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 blister: Do not store above 25°C. Store in the original package to protect from moisture.

Al/PVDC blister: Do not store above 25°C. Store in the original package to protect from moisture.

HDPE bottles: Store in the original package. Keep the bottle tightly closed 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, round, biconvex 6.5 mm film-coated tablets, scored on one side, and marked 'L' on the other side.

Lecalpin 20 mg tablets are pink, round, biconvex 8.5 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, 98, 100 tablets

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

Blisters (Al/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

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,
Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland

Manufacturer

Actavis ehf.
Reykjavíkurvegi 78
IS-220 Hafnarfjörður
Iceland

Actavis Ltd.
BLB016 Bulebel Industrial Estate
Zejtun ZTN 3000
MALTA

Balkanpharma – Dupnitsa AD
3 Samokovsko Schosse Str.
Dupnitsa 2600
Bulgaria

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

Austria	Lercanidipin Actavis 10 mg Filmtabletten
	Lercanidipin Actavis 20 mg Filmtabletten
Belgium	Lercanidipine AB 10 mg filmomhulde tabletten

	Lercanidipine AB 20 mg filmomhulde tabletten
Denmark	Lercanidipinhydrochlorid Actavis
Finland	Lercanidipin Hydrochlorid Actavis 10 mg tabletti kalvopäällysteinen
	Lercanidipin Hydrochlorid Actavis 20 mg tabletti kalvopäällysteinen
Germany	Lercanidipin 1980 Puren 10 mg Filmtabletten,
	Lercanidipin 1980 Puren 20 mg Filmtabletten
Greece	Lercanidipin / Actavis
Iceland	Lerkanidipin Actavis
Ireland	Lecalpin 10mg Film-coated Tablets
	Lecalpin 20mg Film-coated Tablets
Italy	Lercanidipina Aurobindo
Netherlands	Lercanidipine HCL Aurobindo 10 mg, filmomhulde tabletten
	Lercanidipine HCL Aurobindo 20 mg, filmomhulde tabletten
Norway	Lerkanidipin Actavis
Portugal	Lercanidipina Aurovitas
Spain	Lercanidipino Aurovitas Spain 10 mg comprimidos recubiertos con película EFG
	Lercanidipino Aurovitas Spain 20 mg comprimidos recubiertos con película EFG
Sweden	Lerkanidipin Actavis
United Kingdom	Lercanidipine hydrochloride 10mg film-coated Tablets
	Lercanidipine hydrochloride 20mg film-coated Tablets

This leaflet was last revised in September 2017