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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 Lecalpin 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. 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 vessels that carry blood away from the heart (the arteries). It is the entry of calcium into the muscle cells of the heart and blood vessels that causes the heart to contract and the blood vessels to narrow.

Lecalpin has been prescribed to you to treat hypertension.

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 calcium channel blockers.
• If you have had an obstruction to flow of blood from the heart (uncontrolled cardiac failure).
• If you have a heart condition known as sick sinus syndrome, and do not have a pacemaker.
• If you have a heart attack less than one month ago.
• If you have a breathing or liver problems.
• If you are taking drugs that are inhibitors of CYP3A4 or CYP2C19.
• If you are taking antifungal medicines (such as ketoconazole or itraconazole).
• If you have an intolerance to some sugars, contact your doctor before taking this medicine.
• If you have an allergy to some sugars, contact your doctor before taking this medicine.

• If you are pregnant, or if you wish to become pregnant. If you are pregnant or breast-feeding, ask your doctor for advice before taking this medicine.
• If you have diabetes, or if you wish to become pregnant or if you are a woman in childbearing age, do not use any contraceptive method.

Driving and using machines
Lecalpin has not been shown to impair your ability to drive or use machines. However, side effects (dizziness, confusion, drowsiness, and rarely sleepiness) may occur. You should be careful if you know how you react to Lecalpin.

Lecalpin contains lactose monohydrate which may cause life-threatening allergic reactions (see below), and may alter the effect of these medicines:
• Common LOW Dose: Neutrophils, eosinophils, lymphocytes, monocytes, platelets and reticulocytes.
• Not common LOW Dose: Neutrophils, eosinophils, lymphocytes, monocytes, platelets and reticulocytes.
• Rare LOW Dose: Neutrophils, eosinophils, lymphocytes, monocytes, platelets and reticulocytes.

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 advice.

Exceeding the correct dosage may cause:
• Severe headaches.
• Rapid heart rate.
• Excessive sweating.
• Tachycardia (abnormally fast heart rate).
• An obstruction to flow of blood from the heart (uncontrolled cardiac failure).
• Hypertension.

If you forget to take Lecalpin
If you forget to take your tablets, take it as soon as you remember, unless it is almost time for your next dose. Then you 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, it is important to continue taking your other medicines. Ask your doctor or pharmacist before stopping the treatment.

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 using the following definitions:

- very common: affects more than 1 in 10 people
- common: affects up to 1 in 10 people
- uncommon: affects up to 1 in 100 people
- rare: affects up to 1 in 1,000 people
- very rare: affects up to 1 in 10,000 people
- frequency cannot be estimated

Some side effects may affect more than one in 10 people
- May affect more than 1 in 10 people
- May affect up to 1 in 100 people
- May affect up to 1 in 1,000 people
- May affect up to 1 in 10,000 people
- May affect up to 1 in 10 people

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPR A Pharmacovigilance, Earlfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

How to store Lecalpin
Keep this medicine out of the sight and reach of children.

Do not use the 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
ADVICE: Do not store above 30°C. Store in the original package to protect from moisture.

Do not store away medicines as waste material or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

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: APL2, polyvinyl alcohol (partly hydrolysed), talc, magnesium silicate, black titanium dioxide (E 172), yellow iron oxide (E 177), polyvinyl alcohol (partly hydrolysed), talc, magnesium stearate, povidone, black titanium dioxide (E 172), yellow iron oxide (E 177), red iron oxide (E 172).

What Lecalpin looks like and contents of the leaflet
- 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 size
Blisters (AL/PVC/PVDC):
- Lecalpin 10 mg film-coated tablets: 14, 20, 30, 50, 60, 90, 100 tablets.
- Lecalpin 20 mg film-coated tablets: 14, 20, 30, 50, 60, 90, 100 tablets.

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

All not pack sizes may be marketed.

Marketing Authorisation Holder

Manufacturer
Actavis IRL
Repleikvenyqur 78, 220 Hafnarfjörður, Iceland.

And/or
Actavis Ltd.
88 B.016 Bubbel Industrial Estate, Zupenh T.N.
3000, Malta.

And/or
Balkarparkarna – Dupixten Ltd.
3 Samokovsko Schosse St., Dupixten, Bulgaria.

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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Lercanidipine 10 mg & 20 mg Film-coated Tablets PIL - IRELAND

Lercanidipine hydrochloride 10 mg & 20 mg Film-coated Tablets PIL - IRELAND

Less than 0.01%