

Lercanidipine hydrochloride 10mg and 20mg film-coated tablets

Read all of this leaflet carefully before you start using 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- antivirals (such as ritonavir)
- at the same time as another drug called ciclosporin or cyclosporin
- with grapefruit or grapefruit juice
- 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**

Take special care with Lercanidipine

You should consult your doctor before taking Lercanidipine hydrochloride tablets if you:

- have certain other **heart conditions**, or if you have a pacemaker
- have **angina pectoris**, Lercanidipine may very rarely cause increased frequency of attacks that may last longer and become more severe. Myocardial infarction has been reported in isolated cases.
- have problems with your **liver** or **kidney**, or you are on **dialysis**

Using other medicines

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

Taking Lercanidipine with certain other medicines (see below), may alter the effect of these medicines or of Lercanidipine.

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 800mg (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)

Using Lercanidipine with food and drink

You must not eat grapefruit or drink grapefruit juice as this may increase the effect of Lercanidipine.

If you use alcohol together with Lercanidipine 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 taking Lercanidipine and think that you may be pregnant, consult your doctor.

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.

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- 2 Before you take**
- 3 How to take**
- 4 Possible side effects**
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1 What Lercanidipine hydrochloride tablets are and what they are used for

Lercanidipine 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.

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

2 Before you take

Do not take Lercanidipine if you:

- are **allergic** (hypersensitive) to lercanidipine or to any of the ingredients in Lercanidipine hydrochloride tablets
- have **had an allergic reaction** to medicines that are closely related to Lercanidipine hydrochloride tablets (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- 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)
 - have had a heart attack less than one month ago
- have **severe liver** or **kidney** problems
- are **taking drugs** that are inhibitors of CYP3A4 isoenzyme:
 - antifungal medicines (such as ketoconazole or itraconazole)
 - macrolide antibiotics (such as erythromycin or troleandomycin)

Driving and using machines

Lercanidipine 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 Lercanidipine.

Important information about some of the ingredients of Lercanidipine

Lercanidipine 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

Always take Lercanidipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one Lercanidipine hydrochloride 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 Lercanidipine hydrochloride 20mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with 1/2 glass of water. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Lercanidipine is not recommended for use in children and adolescents below 18 years.

If you take more Lercanidipine 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 Lercanidipine

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.

If you stop taking Lercanidipine

If you stop taking Lercanidipine 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 product, ask your doctor or pharmacist.

4 Possible side effects

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

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

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare, not known:	affects less than 1 user in 10,000, frequency cannot be estimated from the available data

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.

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

5 How to store

Keep out of the reach and sight of children.

Do not use Lercanidipine 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.

HDPE bottles: Do not store above 25°C. Store in the original package. Keep the bottle tightly closed to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What Lercanidipine hydrochloride tablets contains

- The active substance is lercanidipine hydrochloride.

One 10mg film-coated tablet contains 10mg lercanidipine hydrochloride, equivalent to 9.4mg lercanidipine.

One 20mg film-coated tablet contains 20mg lercanidipine hydrochloride, equivalent to 18.8mg lercanidipine.

The other ingredients are: Tablet core: Magnesium stearate, povidone, sodium starch glycolate (Type A), lactose monohydrate, microcrystalline cellulose.

Film-coating 10mg tablets: Macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172).

Film-coating 20mg tablets: Macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E 172).

What Lercanidipine hydrochloride tablets looks like and contents of the pack

Lercanidipine hydrochloride 10mg tablets are yellow, round, biconvex 6.5mm film-coated tablets, scored on one side, and marked 'L' on the other side.

Lercanidipine hydrochloride 20mg tablets are pink, round, biconvex 8.5mm 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
28 tablets

Marketing Authorisation Holder

Actavis Group PTC ehf
Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Iceland

Manufacturers

Balkanpharma – Dupnitsa AD
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