

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lercanidipine Hydrochloride 10 mg Film-coated Tablets

Lercanidipine Hydrochloride 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 of the 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 Lercanidipine Hydrochloride Film-coated Tablets is and what it is used for
2. What you need to know before you take Lercanidipine Hydrochloride Film-coated Tablets
3. How to take Lercanidipine Hydrochloride Film-coated Tablets
4. Possible side effects
5. How to store Lercanidipine Hydrochloride Film-coated Tablets
6. Contents of the pack and other information

1. WHAT LERCANIDIPINE HYDROCHLORIDE FILM-COATED TABLETS IS AND WHAT IT IS USED FOR

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

Lercanidipine is used to treat 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 LERCANIDIPINE HYDROCHLORIDE FILM-COATED TABLETS

Do not take Lercanidipine Hydrochloride Film-coated Tablets if you:

- are allergic to lercanidipine hydrochloride or to any of the ingredients in Lercanidipine Hydrochloride Film-coated Tablets
- are suffering from certain heart diseases:
 - o untreated heart failure
 - o an obstruction to flow of blood from the heart
 - o unstable angina (chest discomfort occurring at rest or progressively increasing)

- within one month of heart attack
- have severe liver problems
- have severe kidney problems or you are undergoing dialysis.
- are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).
- are taking medicines that are inhibitors of hepatic metabolism, such as,
 - antifungal medicines (such as ketoconazole or itraconazole)
 - are taking macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
 - are taking antivirals (such as ritonavir)
- with grapefruit or grapefruit juice.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lercanidipine Hydrochloride Film-coated Tablets if you:

- have a heart problem
- 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 Lercanidipine in children aged up to 18 years have not been established.

Other medicines and Lercanidipine Hydrochloride Film-coated Tablets

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because when lercanidipine is taken with other medicines the effect of lercanidipine or of the other medicine may be changed or certain side effects may occur more frequently (see also section 2 “Do not take Lercanidipine Hydrochloride Film-coated Tablets if you”).

In particular, tell your doctor if you are taking 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 rhythms)
- simvastatin (a medicine to lower cholesterol in your body)
- other medicines to treat high blood pressure

Lercanidipine Hydrochloride Film-coated Tablets with food, drink and alcohol

- A high fat meal significantly increases blood levels of the medicine (see section 3).
- Alcohol can increase the effect of lercanidipine. Do not consume alcohol during treatment with lercanidipine
- Lercanidipine must not be taken with grapefruit or grapefruit juice (they can increase its hypotensive effect). See section 2 – Do not take lercanidipine.

Pregnancy, breast-feeding and fertility

Lercanidipine HCl is not recommended if you are pregnant, it should not be used during breast-feeding. There are no data from the use of lercanidipine HCl 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.

Lercanidipine Hydrochloride Film-coated Tablets contains lactose

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

3. HOW TO TAKE LERCANIDIPINE HYDROCHLORIDE FILM-COATED TABLETS

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 10 mg once daily, at the same time each day, preferably in the morning at least 15 minutes before breakfast. Your doctor may advise you to increase the dose to one Lercanidipine Hydrochloride 20 mg film-coated tablet daily, if needed (see section 2 “Lercanidipine Hydrochloride Film-coated Tablets with food, drink and alcohol”).

The tablets should preferably be swallowed whole with some water.

The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Use in children

This medicine should not be used in children under 18 years of age.

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 ask your doctor or pharmacist.

If you take more lercanidipine than you should

Do not exceed the prescribed dose. If you take 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 your Lercanidipine Hydrochloride Film-coated Tablets

If you forget to take your tablet simply miss that dose and then go on as before. Do not take a double dose to make up for a forgotten 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, 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 lercanidipine 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App

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

5. HOW TO STORE LERCANIDIPINE HYDROCHLORIDE FILM-COATED TABLETS

Keep this medicine out of the sight and reach of children.

Do not use Lercanidipine Hydrochloride Film-coated Tablets after the expiry date, which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 25°C. Store in the original package in order 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 Lercanidipine Hydrochloride Film-coated Tablets contain

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, talc, titanium dioxide (E 171), yellow iron oxide (E 172).

Film-coating 20 mg tablets: Macrogol, polyvinyl alcohol, talc, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E172).

What Lercanidipine Hydrochloride Film-coated Tablets look like and contents of the pack

Lercanidipine Hydrochloride 10 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.

Lercanidipine Hydrochloride 20 mg Film-coated 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:

Blister packs containing:

Lercanidipine Hydrochloride 10 mg Film-coated Tablets: 7, 10, 14, 20, 28, 30, 35, 50, 56, 60, 98, 100 tablets

Lercanidipine Hydrochloride 20 mg Film-coated Tablets: 7, 10, 14, 20, 28, 30, 35, 42, 50, 56, 60, 98, 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Glenmark Pharmaceuticals Europe Limited
Laxmi House, 2 B Draycott Avenue,
Kenton, Middlesex,
HA3 0BU
United Kingdom

Manufacturer
Glenmark Pharmaceuticals Europe Limited
Building 2, Croxley Green Business Park, Croxley Green, Hertfordshire, WD18 8YA, United Kingdom

Glenmark Pharmaceuticals s.r.o.
Fibíchova 143,566 17 Vysoké Mýto, Czech Republic

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