

Lercanidipine hydrochloride 10mg and 20mg film-coated tablets

Read all of this leaflet carefully before you start taking 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.
- The full name of this medicine is Lercanidipine hydrochloride 10mg and 20mg film-coated tablets, but within this leaflet it will be referred to as Lercanidipine.

What is in this leaflet:

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

1. What Lercanidipine 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

Do not take Lercanidipine if you:

- are **allergic** (hypersensitive) to lercanidipine or any of the other ingredients of this medicine (listed in section 6).
- are suffering from certain **heart** diseases:
 - untreated heart failure
 - an obstruction to flow of blood from the heart
 - unstable angina (chest discomfort occurring at rest or progressively increasing)
 - have had a heart attack less than one month ago
- have **severe liver** problems
- have **severe kidney** problems or you are undergoing dialysis
- are **taking medicines** that are inhibitors of the hepatic metabolism, such as:
 - antifungal medicines (such as ketoconazole or itraconazole)
 - macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
 - antivirals (such as ritonavir)
 - if you are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection)
 - with grapefruit or grapefruit juice

- are **pregnant**, or if you wish to become pregnant or if you are a woman of child-bearing age and do not **use any contraceptive method**
- if you are **breast-feeding**

Warnings and precautions

Talk to your doctor before taking Lercanidipine hydrochloride 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 if you are breast-feeding (see 'Pregnancy, Breast-feeding and Fertility')

Children and adolescents

The safety and efficacy of lercanidipine in children aged up to 18 years have not been established.

Other medicines and Lercanidipine

Please 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 Lercanidipine with certain other medicines (see below) may alter the effect of these medicines or of Lercanidipine or certain side effects may occur more frequently (see also 'Do not take Lercanidipine').

It is especially important for your doctor to know if you are already being treated with 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 800mg (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 heartbeat)
- beta-blockers e.g. metoprolol (a medicine to treat high blood pressure, heart failure and abnormal heart rhythm)
- simvastatin (a medicine to lower cholesterol in your blood)

Lercanidipine with food, drink and alcohol

A high fat meal significantly increases blood levels of the medicine (see section 3)

Lercanidipine must not be taken with grapefruit or grapefruit juice as these can increase the medicine's hypotensive effect. See 'Do not take Lercanidipine'.

Alcohol can increase the effect of Lercanidipine. Do not consume alcohol during treatment with Lercanidipine.

Pregnancy, breast-feeding and fertility

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

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults

The recommended 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. Your doctor may advise you to increase your dose to one Lercanidipine hydrochloride 20mg film-coated tablet daily, if needed (see section 2 'Lercanidipine with food, drink and alcohol').

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

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

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 20mg should be approached with caution.

If you take more Lercanidipine than you should

Do not exceed the prescribed dose. If you have taken 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 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 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 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 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 heartbeat (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 Website: 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

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

Do not take 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/PVDC blister: Do not store above 30°C.

Store in the original package 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 tablets contain

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.

10mg tablets: Macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172). 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 look like and contents of the pack

Lercanidipine hydrochloride 10mg tablets are yellow coloured, round shaped, biconvex, coated tablets debossed with “LT1” on one side and breakline on the other side. The diameter of tablet is approximately 6.5 mm.

Lercanidipine hydrochloride 20mg tablets are pink coloured, round shaped, biconvex coated tablets debossed with “LT2” on one side and breakline on the other side. The diameter of tablet is approximately 8.5 mm.

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

Pack sizes:

Blisters

28 tablets

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