

Package leaflet: Information for the patient

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 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.

What is in this leaflet:

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

1. What Lercanidipine Hydrochloride is and what it is used for

Lercanidipine Hydrochloride 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. It is not recommended for children under 18 years old.

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

2. What you need to know before you take Lercanidipine Hydrochloride

Do not take Lercanidipine Hydrochloride

- if you are allergic to Lercanidipine Hydrochloride or to any other ingredients in this medicine (listed in section 6)
- if you are suffering from certain heart diseases:
 - untreated 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 problems
- if you have severe kidney problems or you are undergoing dialysis.
- if you are taking drugs that are inhibitors of 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

Warning and precautions

Talk to your doctor or pharmacist before taking Lercanidipine Hydrochloride tablets:

- if you have a heart problem,
- if you have problems with your liver or kidney

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 Hydrochloride in children aged up to 18 years have not been established.

Other medicines and Lercanidipine Hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Lercanidipine Hydrochloride with certain other medicines, may alter the effect of these medicines or of Lercanidipine Hydrochloride. 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 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 or sotalol (medicines to treat a fast heart beat)
- medicines known as beta-blockers e.g. metoprolol (medicines to treat high blood pressure)
- simvastatin (a medicine to lower cholesterol in your blood)
- other medicines to treat high blood pressure

Lercanidipine Hydrochloride with food, drink and alcohol

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

- You must **not** consume alcohol during treatment with this medicine since it may increase the effect of Lercanidipine Hydrochloride.

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

Pregnancy and breast-feeding

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

Lercanidipine Hydrochloride has a negligible influence on the ability to drive or use machines. However, side effects such as dizziness, weakness, tiredness and rarely sleepiness may occur. You should be careful until you know how you react to Lercanidipine Hydrochloride

Lercanidipine Hydrochloride contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lercanidipine Hydrochloride

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

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, because a high fat meal significantly increases your blood levels of the medicine. Your doctor may advise you to increase your dose to one Lercanidipine Hydrochloride 20 mg film-coated tablet daily, if needed.

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

Elderly people

No adjustment of the daily dose is required. However, special care should be taken when starting treatment.

Patients with liver or kidney problems

Special care is needed when starting treatment. Your doctor may decide to adjust your dose.

Use in children and adolescents

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

If you take more Lercanidipine Hydrochloride 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 Hydrochloride

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 the forgotten tablet.

If you stop taking Lercanidipine Hydrochloride

If you stop taking this medicine 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.

Some side effects can be serious. If you experience any of the following, tell your doctor immediately or go to your nearest hospital casualty department:

Rare (may affect up to 1 in 1,000 people)

- allergic reactions (symptoms include itching, rash, urticaria),
- chest pain often spreading to the arms or neck and sometimes to the shoulders and back due to a lack of blood to your heart (angina pectoris),
- fainting.

If you have angina pectoris, Lercanidipine Hydrochloride may very rarely cause increased frequency of attacks that may last longer and become more severe. Isolated cases of heart attack may be observed.

Other side effects:

Common (may affect up to up to 1 in 10 people)

- Headache,
- Fast heart rate,
- Awareness of the beating of the heart (palpitations),
- Flushing (transient episodic redness of the face, neck or upper chest),
- Ankle swelling.

Uncommon (may affect up to 1 in 100 people)

- Dizziness,
- Feeling weak or feeling tired, Fall in blood pressure,
- Heartburn
- Stomach pain,
- Feeling sick,
- Skin rash,
- Itching,
- Muscle pain,
- Passage of large amounts of urine.

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

- Increase in liver enzyme blood test values,
- Swelling of the gums
- 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 or pharmacist. 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lercanidipine Hydrochloride

Keep 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.

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

Bottles: Keep the bottle tightly closed 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 contains

The active substance is Lercanidipine Hydrochloride.

Each 10 mg film-coated tablet contains 10 mg Lercanidipine Hydrochloride, equivalent to 9.4 mg Lercanidipine.

Each 20 mg film-coated tablet contains 20 mg Lercanidipine Hydrochloride, equivalent to 18.8 mg Lercanidipine.

The other ingredients are: magnesium stearate, povidone, sodium starch glycolate (type A), lactose monohydrate, see section 'Lercanidipine Hydrochloride, microcrystalline cellulose.

The film-coating of 10 mg tablets also contains macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172).

The film-coating of 20 mg tablets also contains macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide (E172).

What Lercanidipine Hydrochloride looks like and contents of the pack

Lercanidipine Hydrochloride 10 mg 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 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.

Lercanidipine Hydrochloride 10 mg film-coated tablets are available in blister packs containing 14, 20, 28, 30, 50, 56, 98, 100 tablets or in bottles containing 14, 25, 28, 30, 50, 56, 84, 90, 98, 100, 112 tablets

Lercanidipine Hydrochloride 20 mg film-coated tablets are available in blister packs containing 28, 30, 50, 56, 98, 100 tablets or in bottles containing 28, 30, 50, 90, 98, 100, 105 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan
Potters Bar,
EN6 1TL,
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Manufacturer

Actavis Ltd. BLB015-016 Bulebel Industrial Estate, Zejtun ZTN3000, Malta

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