

Lercanidipine Hydrochloride 10 mg
Film-coated Tablets
Lercanidipine Hydrochloride 20 mg
Film-coated Tablets
lercanidipine hydrochloride

**Package leaflet: Information
for the user**

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 (dihydropyridine derivatives) that lower blood pressure.

Lercanidipine is used to treat mild to moderate **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

Do not take Lercanidipine Hydrochloride:

- If you are **allergic** to lercanidipine hydrochloride, to medicines closely related to Lercanidipine Hydrochloride (such as amlodipine, nifedipine or lacidipine) or **any of the other ingredients** of this medicine (listed in section 6).
- If you are suffering from **certain heart diseases**:
 - untreated heart failure
 - obstruction to flow of blood from the heart
 - unstable angina (chest discomfort occurring at rest or progressively increasing)
 - within one month of heart attack
- If you have **severe liver problems**
- If you have **severe kidney problems or you are undergoing dialysis**
- If you 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.

Warnings and precautions

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

- you have a heart problem
- you have liver or kidneys problems. You must tell your doctor if you think you are (or might become) **pregnant or breast-feeding** (see section "Pregnancy, breast-feeding and fertility").

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. This is because when Lercanidipine Hydrochloride is taken with other medicines the effect of Lercanidipine Hydrochloride 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").

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- **phenytoin, phenobarbital or carbamazepine** (medicines for epilepsy)
- **rifampicin** (a medicine to treat tuberculosis)
- **astemizole or terfenadine** (medicines for allergies)
- **amiodarone, quinidine or sotalol** (medicines to treat a fast heart beat)
- **midazolam** (a medicine that helps you sleep)
- **digoxin** (a medicine to treat a heart problem)
- **beta-blockers** e.g. **metoprolol** (a medicine to treat high blood pressure, heart failure and abnormal heart rhythm)
- **cimetidine** (more than 800 mg, a medicine for ulcers, indigestion, or heartburn)
- **simvastatin** (a medicine to lower cholesterol in your blood)
- other medicines to treat high blood pressure
- **ketoconazole or itraconazole** (antifungal medicines)
- **erythromycin or troleandomycin or clarithromycin** (macrolide antibiotics)
- **ritonavir** (antivirals)
- **ciclosporin** (a medicine which lowers the body's resistance to disease)

Lercanidipine Hydrochloride with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

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

If you develop dizziness, weakness or drowsiness with this medicine, do not drive a vehicle or operate machines.

Lercanidipine Hydrochloride contains sodium

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

3 How to take Lercanidipine Hydrochloride

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

[10 mg]

Adults: The recommended dose is 10 mg lercanidipine hydrochloride 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 20 mg daily, if needed (see section 2 "Lercanidipine Hydrochloride with food, drink and alcohol").

The tablet should preferably be swallowed whole with some water.

[20 mg]

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**. The dose of 10 mg is not possible

with the tablets in this leaflet. Your doctor may advise you to increase the dose to 20 mg daily, if needed (see section 2 "Lercanidipine Hydrochloride with food, drink and alcohol"). The tablet should be preferably swallowed whole with some water).

Elderly: 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.

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

If you take more Lercanidipine Hydrochloride 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 corrected dose can cause an excessive drop in blood pressure and your heart can beat irregularly or faster.

If you forget to take Lercanidipine Hydrochloride

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 Hydrochloride

If you stop taking Lercanidipine Hydrochloride 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 Hydrochloride 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 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 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 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

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

Do not use this medicine after the expiry date which is stated on each blister strip and on the outer carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original package in order to protect from light.

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 to protect the environment.

6 Contents of the pack and other information

What Lercanidipine Hydrochloride contains

[10 mg]

The active substance is lercanidipine hydrochloride. Each 10 mg Lercanidipine Hydrochloride Film-Coated Tablet contains 10 mg lercanidipine hydrochloride, equivalent to 9.4 mg lercanidipine.

The other ingredients are:

Core:

Maize starch, sodium starch glycolate (type A), silica, colloidal anhydrous, cellulose, microcrystalline, poloxamer 188, sodium stearyl fumarate, macrogol 6000.

Film-coating:

Hypromellose (E464), macrogol 6000, iron oxide yellow (E 172), titanium dioxide (E 171).

[20 mg]

Each 20 mg Lercanidipine Hydrochloride Film-Coated Tablet contains 20 mg lercanidipine hydrochloride, equivalent to 18.8 mg lercanidipine.

The other ingredients are:

Core:

Cellulose, microcrystalline, maize starch, sodium starch glycolate (type A), silica, colloidal anhydrous, povidone K 30, sodium stearyl fumarate.

Film-coating:

Hypromellose (E464), macrogol 6000, iron oxide red (E 172), titanium dioxide (E 171).

What Lercanidipine Hydrochloride look like and contents of the pack

[10 mg]

Lercanidipine Hydrochloride 10 mg Film-Coated Tablets are yellow, round shaped biconvex, film-coated tablet of 6.5 mm diameter, with score line on one side and plain on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

[20 mg]

Lercanidipine Hydrochloride 20 mg Film-Coated Tablets are pink, round shaped biconvex, film-coated tablet of 8.5 mm diameter, with score line on one side and plain on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Available in pack sizes of: 14, 28, 30, 50 x1, 56, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom..

Manufacturer

Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany

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