Package leaflet: Information for the user

Lercanidipine Hydrochloride 10 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 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 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 (of the dihydropyridine derivative). Lercanidipine hydrochloride 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).

Lercanidipine hydrochloride is used for the treatment of mild to moderate **high blood pressure**.

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

Do not take Lercanidipine hydrochloride if
- You are **allergic** to Lercanidipine hydrochloride or **any of the other ingredients** of this medicine (listed in section 6).
- You have had **allergic reactions** to medicinal products closely related to Lercanidipine hydrochloride (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
  - 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
- You have **severe liver or kidney problems**
- You are taking one of the following **medicinal products /food**:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin or troleandomycin)
  - antivirals (such as ritonavir)
  - are taking another medicinal product called ciclosporin or cyclosporin (used after transplants to prevent organ rejection)
  - with grapefruit or grapefruit juice.

You must tell your doctor if you think you are (or might become) pregnant or breast-feeding (see pregnancy, breast-feeding and fertility section)

Do not use if you are **pregnant, breast-feeding**, or you wish to become pregnant (see section Pregnancy and breast-feeding for more information).

Warnings and precautions
Talk to your doctor or pharmacist before taking Lercanidipine hydrochloride if
- You have certain other heart conditions and do not have a pacemaker, or you have pre-existing angina
- You have problem with your liver or kidney or you are on dialysis.

Children and adolescents
Lercanidipine hydrochloride should not be used for children and adolescents under 18 years.

Other medicines and Lercanidipine Hydrochloride
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Especially if you are taking:
- **beta-blockers** e.g. metoprolol, diuretics (water tablets) or ACE-inhibitors (medicines to treat high blood pressure).
- **cimetidine** (more than 800 mg per day, a medicine for ulcers, indigestion, or heartburn)
- **digoxin** (a medicine to treat a heart problem)
- **midazolam** (a medicine that helps you sleep)
- **rifampicin** (a medicine to treat tuberculosis)
- **astemizole or terfenadine** (medicines for allergies)
- **simvastatin** (a medicine for high cholesterol value)
- **fluoxetine** (a medicine to treat major depressive disorder)
- **amiodarone or quinidine** (medicines to treat a fast heart beat)
- **phenytoin or carbamazepine** (medicines for epilepsy). Your doctor will want to monitor your blood pressure more frequently than usual.

Lercanidipine hydrochloride with food, drink and alcohol
- A high fat meal significantly increases blood levels of the medicine (see section 3).
- Patients should **not consume alcohol** during treatment with Lercanidipine hydrochloride since it may increase the effect of Lercanidipine hydrochloride.
- Patients should **not take grapefruit or grapefruit juice** (they can increase its hypotensive effect), see section 2.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Lercanidipine hydrochloride if you are pregnant or breast-feeding, you wish to become pregnant or if you are not using any contraceptive method.

Driving and using machines
Caution should be exercised because of the possibility of dizziness, weakness, tiredness and rarely sleepiness.

Do not drive or use machines until you know how Lercanidipine hydrochloride affects you.

Lercanidipine Hydrochloride Tablets contain Lactose
Lercanidipine Hydrochloride Tablets contain 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.

Lercanidipine Hydrochloride Tablets contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per daily dose of 10 mg, 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 tablet of Lercanidipine Hydrochloride 10 mg (corresponding to 10 mg lercanidipine hydrochloride) daily at the same time each day, **preferably in the morning at least 15 minutes before breakfast**, because a high fat meal significantly increases blood levels of

the active substance. Your doctor may advise you to increase the dose to two tablets Lercanidipine hydrochloride (corresponding to 20 mg Lercanidipine hydrochloride) daily, if needed.

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

The tablet should preferably be swallowed with some water.

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

Elderly:
No adjustment of the daily dose is required. However, special care should be exercised when 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 take more Lercanidipine hydrochloride than you should
Do not exceed the prescribed dose.
If you take more than the prescribed dose or in the event of overdose, seek medical advice immediately and, if possible, take your tablets and/or the container with you.

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 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.

Some side effects can be serious:
If you experience any of these side effects 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.

If you suffer from pre-existing angina pectoris, with the group of medicines to which lercanidipine hydrochloride belongs, you may experience increased frequency, duration or severity of these attacks. 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):
- Fall in blood pressure
- Dizziness
- Heartburn
- Feeling sick
- Stomach pain
- Skin rash
- Itching
- Passage of large amount of urine (polyuria)
- Feeling weak or tired
- Muscle pain (myalgia)

Rare (may affect up to 1 in 1,000 people):
- sleepiness (somnolence)
- feeling sick (nausea)
- extraordinary daytime urinary frequency (pollakiuria)
- vomiting
- diarrhoea
- skin rash with red, raised, itchy bumps
- chest pain

Not known (frequency cannot be estimated from the available data):
- swelling of gums (gingival hypertrophy)
- changes in liver function (detected by blood tests) (reversible increases in serum levels of hepatic transaminases)
- 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. The expiry date refers to the last day of that month.

Store in the original carton in order to protect from light.

Do not store above 25°C

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

The active substance is lercanidipine hydrochloride. One film-coated tablet contains 10 mg lercanidipine hydrochloride, which is equivalent to 9.4 mg lercanidipine.

The other ingredients are
Core:
sodium starch glycolate (type A), cellulose microcrystalline (Flocel 101), lactose monohydrate, povidone K30, magnesium stearate.

Film-coating:
Hypromellose, macrogol 6000, ferric oxide yellow (E 172), titanium dioxide (E 171).

What Lercanidipine hydrochloride 10 mg looks like and contents of the pack
Lercanidipine hydrochloride 10 mg are yellow, round (diameter 6.5 mm), biconvex, film-coated tablets with score line on one side and plain on the other side.

Lercanidipine hydrochloride 10 mg is available in blister packs of 28 Film-coated Tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (UK) Ltd.
3rd Floor, Nexus Building,
4 Gatwick Road,
Crawley,
West Sussex,
RH10 9BG,
United Kingdom

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LOCATION : Baddi	**COUNTRY : UK**		**Supersedes A/W No.:**	
SIZE : 150 x 300 mm			**CODE : 8109811-7803**	**DATE : 19-08-2026**
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	**Department**	**Name**	**Signature**	**Date**
Prepared By	**Pkg.Dev**			
Reviewed By	**Pkg.Dev**			
Approved By	**Quality**			
This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.				

