Read all of this leaflet carefully before you start using this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Lercanidipine is and what it is used for
2. Before you take Lercanidipine
3. How to take Lercanidipine
4. Possible side effects
5. How to store Lercanidipine
6. Further information

1. WHAT LERCANIDIPINE IS AND WHAT IT IS USED FOR

Lercanidipine 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.

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

2. BEFORE YOU TAKE LERCANIDIPINE

Do not take Lercanidipine
- if you are allergic (hypersensitive) to lercanidipine or to any of the ingredients in Lercanidipine tablets
- if you have had allergic reactions to medicines that are closely related to Lercanidipine tablets (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- if you are suffering from certain heart diseases:
  - uncontrolled 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 or kidney problems
- If you are taking drugs that are inhibitors of CYP3A4 isoenzyme:
  -- antifungal medicines (such as ketoconazole or intracnazole)
  -- macrolide antibiotics (such as erythromycin or troleandomycin)
  -- antivirals (such as ritonavir)
  -- at the same time as another drug called ciclosporin or cyclosporin
  -- with grapefruit or grapefruit juice
- if you are pregnant, or if you wish to become pregnant or if you are a woman in child-bearing age and do not use any contraceptive method
- if you are breast-feeding

- Take special care with Lercanidipine - You should consult your doctor before taking

Lercanidipine tablets:
- if you have certain other heart conditions, or if you have a pacemaker
- if you have angina pectoris, Lercanidipine may in very rare cause increased frequency of attacks that may last longer and become more severe. Myocardial infarction has been reported in isolated cases.
- if you have problems with your liver or kidney, or you are on dialysis

Using other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken 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.

It is especially important for your doctor to know if you are already being treated with any of the following medicines:
- phenytoin 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 (medicines to treat a fast heart beat)
- metoprolol (a medicine to treat high blood pressure)
- simvastatin (a medicine for high cholesterol value)

Using Lercanidipine with food and drink
You must not eat grapefruit or drink grapefruit juice as this may increase the effect of Lercanidipine.

If you use alcohol together with Lercanidipine you may experience dizziness/fainting, tiredness or weakness. This is because the medicine may lower your blood pressure considerably together with alcohol.

Pregnancy and breast-feeding
Ask your doctor for advice before taking any medicine. If you are taking Lercanidipine and think that you may be pregnant, consult your doctor. **Do not** use Lercanidipine if you are pregnant, or if you wish to become pregnant or if you are a woman in childbearing age and do not use any contraceptive method. **Do not** use Lercanidipine if you are breast-feeding.

**Driving and using machines**
Lercanidipine 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.

**Important information about some of the ingredients of Lercanidipine**
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 Lercanidipine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is one Lercanidipine 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 decide you to increase your dose to one Lercanidipine 20 mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with 1/2 glass of water. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

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

**If you take more Lercanidipine 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**
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.

**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, Lercanidipine can cause side effects, although not everybody gets them.

The frequencies of side effect have been listed below according to the following definitions:

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common:</td>
<td>affects more than 1 user in 10</td>
</tr>
<tr>
<td>Common:</td>
<td>affects 1 to 10 users in 100</td>
</tr>
<tr>
<td>Uncommon:</td>
<td>affects 1 to 10 users in 1,000</td>
</tr>
<tr>
<td>Rare:</td>
<td>affects 1 to 10 users in 10,000</td>
</tr>
<tr>
<td>Very rare, not known:</td>
<td>affects less than 1 user in 10,000, frequency cannot be estimated from the available data</td>
</tr>
</tbody>
</table>

**Uncommon:** Headache, dizziness, faster heartbeats, awareness of the beating of the heart, flushing (transient episodic redness of the face and neck), ankle swelling.

**Rare:** Sleepiness, weakness, tiredness, nausea, vomiting, diarrhoea, abdominal pain, indigestion, rash, muscle pain, passage of large amounts of urine, angina pectoris.

**Very rare, not known:** Decrease in blood pressure which may lead to fainting, allergic reaction, swelling of gums, increase in liver enzyme blood test values, fall in blood pressure which can cause dizziness, light-headedness or fainting, increase in the usual number of times one urinates, chest pain and heart attack.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE LERCANIDIPINE**

Keep out of the reach and sight of children.

Do not use Lercanidipine 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:**
AI/PVC blister and Al/PVdC blister: Do not store above 25°C. Store in the original package to protect from moisture.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
6. FURTHER INFORMATION

What Lercanidipine contains

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

What Lercanidipine looks like and contents of the pack

Lercanidipine 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 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.

Pack sizes:
Blisters:
Lercanidipine 10 mg film-coated tablets: 28, 50, 56, 98, 100 tablets
Lercanidipine 20 mg film-coated tablets: 28, 50, 56, 98, 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan
Station Close, Potters Bar, Hertfordshire, EN6 1TL

Manufacturer

Actavis hf. Reykjavikurvegur 76-78, IS 220 Hafnarfjörður Iceland

Actavis Ltd. BL16 Bulebel Industrial Estate, Zejtun ZTN3000, Malta

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