**What in this leaflet**
- If you get any side effects, talk to your doctor or pharmacist.
- This medicine has been prescribed for you.
- Keep this leaflet. You may need to read it again.
- 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.

**How to take**

**Possible side effects**

**How to store**

**Contents of the pack and other information**

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**What Lercanidipine hydrochloride tablets are and what they are 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 blood vessels. This reduces the ability of the blood vessels to contract, which reduces the need for the heart to pump so hard to push blood around the body. This reduces the amount of blood that your heart needs to pump and lowers your blood pressure.

**Lercanidipine**

**Contents of the pack and other information**

**Possible side effects**

**How to take**

**What you need to know before you take**

Do not take Lercanidipine if you: 

- are allergic to lercanidipine or any of the other ingredients of this medicine (listed in section 4).
- have had allergic reactions to medicines that are closely related to Lercanidipine hydrochloride tablets (such as nifedipine, isradipine, felodipine, nicardipine).
- are suffering from certain heart diseases:
  - uncontrolled cardiac failure
  - an obstruction to flow of blood from the heart
  - unstable angina (angina at rest or at night)
  - uncontrolled cardiac failure
- have a history of liver problems.
- believe that you may be pregnant.
- have any heart disease or heart problems.
- are taking any other medicines that are closely related to LXP 134 (a group of medicines called calcium channel blockers). If you are not sure if you are taking any other medicines that are close related to LXP 134, please ask your doctor or pharmacist.
- have suffered from chest pain (angina pectoris).
- are taking any other medicines that are closely related to LXP 134.
- have had a heart attack less than one month ago.
- have severe liver or kidney problems.
- are taking medicines that may affect the entry of calcium into the muscle cells of the heart (for example, medicines that are inhibitors of the cytochrome P450 enzyme system).
- are taking any other medicines that may affect the entry of calcium into the muscle cells of the heart.
- are pregnant.
- are breastfeeding.
- are taking any other medicines, including those obtained without a prescription.
- have recently had a liver or kidney illness.
- have any heart condition known as sick sinus syndrome, and do not have a pacemaker.
- have suffered from chest pain (angina pectoris). Lercanidipine may in very rare cases cause increased symptoms of angina that may last longer and become more severe. Heart problems have occurred in isolated cases. You should consult your doctor or pharmacist if you:
- have heart burn, sore throat or a hoarse voice.
- are pregnant or if you are breastfeeding.
- are taking any other medicines, including those obtained without a prescription.
- have recently had a liver or kidney illness.

**Warnings and precautions**

**Talking to your doctor before taking**

Lercanidipine hydrochloride tablets are for adults 18 years and older. You may take this medicine with or without food. Do not exceed the correct dosage.

**Driving and using machines**

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

**Pregnancy and breast-feeding**

Do not use if you are pregnant, or if you wish to become pregnant or if you are a woman in the childbearing age until you have taken advice from your doctor or pharmacist.

**Other medicines and Lercanidipine**

Tell your doctor or pharmacist if you are taking any other medicine, or are taking or have taken any medicine that might take any other medicines, including medicines obtained without a prescription. Taking Lercanidipine with certain other medicines (see below), may alter the effect of either of these medicines or 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 a tubercular problem)
- itraconazole or ketoconazole (antiviral medicines)
- simvastatin (a medicine for high cholesterol value)
- metoprolol (a medicine to treat high blood pressure)
- digoxin (a medicine to treat a fast heart beat)
- cimetidine, more than 800mg (a medicine for ulcers, indigestion or heartburn)
- antivirals (such as ritonavir)
- macrolide antibiotics (such as ketoconazole or Itraconazole)

**How to take**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is one 10mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before a meal, because high fat meal significantly increases your blood levels of the medicine.

Your doctor may decide to increase your dose up to one Lercanidipine hydrochloride 20mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with 11 oz (300 ml) of water. The core line is only there to help you break the tablet if you have difficulty swallowing.

Use in children and adolescents

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

If you take more Lercanidipine than you should

In the event of an overdose (accidental or deliberate), ask your doctor for advice. Lercanidipine may in very rare cases cause increased symptoms of angina that may last longer and become more severe. Heart problems have occurred in isolated cases. Consult your doctor or pharmacist if you:

- have any heart condition known as sick sinus syndrome, and do not have a pacemaker.
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- have heart burn, sore throat or a hoarse voice.
- are pregnant or if you are breastfeeding.
- are taking any other medicines, including those obtained without a prescription.
- have recently had a liver or kidney illness.

**How to store**

**Contents of the pack and other information**

**Possible side effects**

**How to take**

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  - uncontrolled cardiac failure
  - an obstruction to flow of blood from the heart
  - unstable angina (angina at rest or at night)
  - uncontrolled cardiac failure
- have a history of liver problems.
- believe that you may be pregnant.
- have any heart disease or heart problems.
- are taking any other medicines that are closely related to LXP 134 (a group of medicines called calcium channel blockers). If you are not sure if you are taking any other medicines that are close related to LXP 134, please ask your doctor or pharmacist.
- have suffered from chest pain (angina pectoris).
- are taking any other medicines that are closely related to LXP 134.
- have had a heart attack less than one month ago.
- have severe liver or kidney problems.
- are taking medicines that may affect the entry of calcium into the muscle cells of the heart (for example, medicines that are inhibitors of the cytochrome P450 enzyme system).
- are taking any other medicines that may affect the entry of calcium into the muscle cells of the heart.
- are pregnant.
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- itraconazole or ketoconazole (antiviral medicines)
- simvastatin (a medicine for high cholesterol value)
- metoprolol (a medicine to treat high blood pressure)
- digoxin (a medicine for high (cholesterol) value)

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- have heart burn, sore throat or a hoarse voice.
- are pregnant or if you are breastfeeding.
- are taking any other medicines, including those obtained without a prescription.
- have recently had a liver or kidney illness.
If you forget to take Lercanidipine

If you forget to take your tablets, take it as soon as you remember. If 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 need to 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.

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Very common: affects more than 1 in 10 people
Common: affects up to 1 in 10 people
Uncommon: affects up to 1 in 100 people
Rare: affects up to 1 in 1,000 people
Very rare, not known: frequency cannot be estimated

What Lercanidipine hydrochloride tablets looks like and contains of the pack

Lercanidipine hydrochloride 10mg tablets are yellow, round, bisect 8.5mm film-coated tablets, scored on one side, and marked ‘L’ on the other side.

Lercanidipine hydrochloride 20mg tablets are pink, round, bisect 8.5mm 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 pieces.

Pack sizes

28 tablets

Marketing Authorisation Holder

Accord, Barnstaple, EX32 8NS, UK

Manufacturers

Balkanpharma – Dupnitsa AD
3 Samokovsko Shosse Str
Dupnitsa 2600, Bulgaria

This leaflet was last revised in May 2019.

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, anorgasmia.
- Very rare, not known:
  - Decrease in blood pressure which may lead to fainting, arrhythmia, sweating, loss of balance or vision, 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.

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 at: www.mhra.gov.uk/yellowcard

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What Lercanidipine hydrochloride contains

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. Film-coating 20mg tablets: Macrogol, polyvinyl alcohol (partly hydrolysed), talc, titanium dioxide (E 172), yellow iron oxide (E 172), red iron oxide (E 172) coated tablets, scored on one side, and marked ‘L’ on the other side.

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

How to store

Keep this medicine 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.

Storage conditions

• Temperature: Store in the original package to protect from moisture.
• Container: Store in the original package. Keep the bottle tightly closed 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.

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