Package leaflet: Information for the user

Lerkanidipin Actavis 10 mg film-coated tablets
Lerkanidipin Actavis 20 mg film-coated tablets

Lercanidipine hydrochloride

Read all of this leaflet carefully before you start using 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 /.../ is and what it is used for

/.../ 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.

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

2. What you need to know before you take /.../

Do not take /.../
- if you are allergic to lercanidipine or any of the other ingredients of this medicine (listed in section 6).
- 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 problem
- if you have severe kidney problems or you are undergoing dialysis
- if you are taking drugs that are inhibitors of CYP3A4 isoenzyme:
  - antifungal medicines (such as ketoconazole or intraconazole)
  - macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
  - antivirals (such as ritonavir)
- at the same time as another drug called ciclosporin or cyclosporin
- with grapefruit or grapefruit juice

Warnings and precautions
Talk to your doctor before taking /…/

- if you have a heart condition known as sick sinus syndrome, and do not have a pacemaker
- if you have other heart problems or suffer from chest pain (angina pectoris)
- if you have problems with your liver or kidney, or you are on dialysis

Other medicines and /…/
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Taking **/.../** with certain other medicines (see below), may alter the effect of these medicines or of /.../.

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/day (a medicine for ulcers, indigestion, or heartburn)
- digoxin (a medicine to treat a heart problem)
- terfenadine or astemizole (medicines for allergies)
- amiodarone, quinidine or sotalol (medicines to treat a fast heart beat)
- metoprolol (a medicine to treat high blood pressure)
- simvastatin (a medicine for high cholesterol value)
- other medicines to treat high blood pressure

/.../ with food, drink and alcohol
You must not eat grapefruit or drink grapefruit juice as this may increase the effect of /.../.

Do not consume alcohol during treatment with /.../. If you use alcohol together with **/.../** you may experience dizziness/fainting, tiredness or weakness because alcohol may increase the effect of /…/.

Pregnancy and breast-feeding
/.../ is not recommended if you are pregnant and should not be used during breast-feeding.
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 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.

/.../ 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 medicinal product.
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 /.../

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 /.../ 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 /.../ 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 there to help you break the tablet if you have difficulty swallowing it whole.

Use in children and adolescents
/.../ is not recommended for use in children and adolescents below 18 years.

If you take more /.../ 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 headache and unconsciousness.

If you forget to take /.../
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 a forgotten dose.

If you stop taking /.../
If you stop taking /.../ 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 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 /.../ belongs. Isolated cases of heart attack may be observed,

Other possible side effects:

Common (may affect up to 1 in 10 people):
Headache, faster heartbeats, awareness of the beating of the heart, flushing (transient episodic redness of the face and neck), ankle swelling.

Uncommon (may affect up to 1 in 100 people)
Dizziness, decrease in blood pressure which may lead to fainting, indigestion, nausea, abdominal pain, rash, itching, muscle pain, passage of large amounts of urine, weakness, tiredness.

Rare (may affect up to 1 in 1,000 people)
Sleepiness, vomiting, diarrhoea, increase in the usual number of times one urinates, chest pain.

Not known (frequency cannot be estimated from the available data)
Swelling of gums, increase in liver enzyme blood test values, 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. 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:
Al/PVC/PVDC blister: Do not store above 30°C. Store in the original package to protect from moisture.
HDPE bottles: 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.

6. Contents of the pack and other information

What /.../ 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 /.../ looks like and contents of the pack

/.../ 10 mg tablets are yellow, round, biconvex 6.5 mm film-coated tablets, scored on one side, and marked 'L' on the other side.

/.../ 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 (Al/PVC/PVDC):
/.../ 10 mg film-coated tablets: 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 tablets
/.../ 20 mg film-coated tablets: 14, 20, 28, 30, 50, 56, 60, 90, 98, 100 tablets

Bottles:

/.../ 10 mg film-coated tablets: 100 tablets
/.../ 20 mg film-coated tablets: 100 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Actavis Ltd.
BLB015-016 Bulebel Industrial Estate
Zejtun ZTN 3000
MALTA

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

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	Lercanidipin Actavis 10 mg Filmtabletten
	Lercanidipin Actavis 20 mg Filmtabletten
Finland	Lercanidipin Hydrochlorid Actavis 10 mg tabletti kalvopäällysteinen
	Lercanidipin Hydrochlorid Actavis 20 mg tabletti kalvopäällysteinen
Iceland	Lerkanidipin Actavis
Norway	Lerkanidipin Actavis
Sweden	Lerkanidipin Actavis

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