Package leaflet: Information for the patient

[Nationally completed name] 10 mg film-coated tablets
[Nationally completed name] 20 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 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 [Nationally completed name] is and what it is used for

[Nationally completed name], lercanidipine hydrochloride, belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives) that lower blood pressure. [Nationally completed name] 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 and adolescents under 18 years old).

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]:
- 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:
  - Untreated heart failure
  - Obstruction to flow of blood from the heart
  - Unstable angina (crushing chest pain at rest or progressively increasing)
  - Heart attack less than a month ago
- 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 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 (used after transplants to prevent organ rejection)
- With grapefruit or grapefruit juice.

Do not take this medicine if you are pregnant or breast-feeding, or if you wish to become pregnant or if you are a woman in child-bearing age and do not use any contraceptive method (see section Pregnancy, breast-feeding and fertility for more information).

Warnings and precautions
Talk to your doctor or pharmacist before taking [Nationally completed name]:
- If you have certain other heart conditions which have not been treated by insertion of pacemaker or have pre-existing angina (crushing chest pain)
- If you have problems with your liver or kidneys.

Children and adolescents
The safety and efficacy of [Nationally completed name] in children and adolescents aged up to 18 years have not been established.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

It is especially important for your doctor to know if you are already being treated with any of the following medicines:
- beta-blockers e.g. metoprolol (a medicine to treat high blood pressure, heart failure and abnormal heart rhythms)
- other medicines that affect blood pressure (alpha blockers for the treatment of high blood pressure or prostate enlargement, tricyclic antidepressants and neuroleptics for treating mental disorders)
- cimetidine, more than 800 mg (a medicine for ulcers, indigestion, or heartburn)
- simvastatin (a medicine to lower cholesterol in your blood)
- 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)
- amiodarone, quinidine, or sotalol (medicines to treat a fast heart beat)
- phenytoin, phenobarbital or carbamazepine (medicines for epilepsy).

[Nationally completed name] with food, drink and alcohol
- A high fat meal significantly increases blood levels of the medicine (see section 3).
- Alcohol can increase the effect of this medicine. Do not consume alcohol during treatment with this medicine.
- Do not take this medicine with grapefruit or grapefruit juice (this can increase its blood pressure lowering effect). See section "Do not take [Nationally completed name]".

Pregnancy, breast-feeding and fertility
[Nationally completed name] should not be used 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
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 [Nationally completed name] affects you**.**

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

3. How to take [Nationally completed name]

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

Adults
The recommended dose is one [Nationally completed name] 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 blood levels of the medicine.
Your doctor may advise you to increase the dose to one [Nationally completed name] 20 mg film-coated tablet daily, if needed.

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

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 and adolescents
This medicine should not be used in children and adolescents under 18 years of age.

If you take more [Nationally completed name] 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 dose may cause blood pressure to become too low and the heart to beat irregularly or faster, you may feel dizzy or have a headache.

If you forget to take [Nationally completed name]
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 [Nationally completed name]
If you stop taking [Nationally completed name] 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):
Crushing chest pain (angina pectoris), fainting and allergic reactions (symptoms include itching, rash, hives, difficulty breathing or swallowing, dizziness).
If you suffer from pre-existing angina pectoris, with the group of medicines to which [Nationally completed name] belongs, you may experience increased frequency, duration or severity of these attacks. Isolated cases of heart attack may be observed.

Not known (frequency cannot be estimated from the available data):
Swelling of your face, lip, tongue or throat which may cause difficulty in breathing or swallowing.

Other possible side effects:

Common (may affect up to 1 in 10 people):
Headache, faster heart beats, palpitations (heart pounding or racing), flushing (e.g. in the face), ankle swelling.

Uncommon (may affect up to 1 in 100 people):
Dizziness, fall in blood pressure, indigestion, feeling sick, stomach pain, skin rash, itching, muscle pain, passage of large amounts of urine, feeling weak or feeling tired.

Rare (may affect up to 1 in 1,000 people):
Sleepiness, being sick, 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).

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 [Nationally completed name]

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 blister and carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.
Store in original packaging in order 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. Content of the pack and other information

What [Nationally completed name] contains

- The active substance is lercanidipine hydrochloride. Each film-coated tablet contains 10 mg of lercanidipine hydrochloride.
  Each film-coated tablet contains 20 mg of lercanidipine hydrochloride.

10 mg film-coated tablets:
- The other excipients are magnesium stearate (E 572), povidone K-30 (E 1201), sodium starch glycolate Type A, lactose monohydrate, microcrystalline cellulose (E 460) in tablet core and macrogol 3350 (E 1521), partly hydrolysed polyvinyl alcohol, talc (E 553b), titanium dioxide (E 171), yellow iron oxide (E 172) in film coating.

20 mg film-coated tablets:
- The other excipients are magnesium stearate (E 572), povidone K-30 (E 1201), sodium starch glycolate type A, lactose monohydrate, microcrystalline cellulose (E 460) in tablet core and macrogol 3350 (E 1521), partly hydrolysed polyvinyl alcohol, talc (E 553b), titanium dioxide (E 171), yellow iron oxide (E 172), red iron oxide in film coating.

What [Nationally completed name] looks like and content of the pack

10 mg film-coated tablets:
Yellow film-coated tablet of round biconvex shape (diameter 6.5 mm), scored on one side, marked 'L' on the other side.

20 mg film-coated tablets:
Pink film-coated tablet of round biconvex shape (diameter 8.5 mm), scored on one side, marked 'L' on the other side.

The film-coated tablets are packed in PVDC/PVC//Aluminium blisters and inserted in a carton.

Pack sizes:
10 mg film-coated tablets:
7, 10, 14, 20, 28, 30, 35, 50, 56, 60, 98, or 100 film-coated tablets

20 mg film-coated tablets:
7, 10, 14, 20, 28, 30, 35, 42, 50, 56, 60, 98, or 100 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in [MM/YYYY].

[To be completed nationally]