

**Package leaflet: Information for the user**

**Lercanidipine Clonmel 10mg Film-coated Tablets  
Lercanidipine Clonmel 20mg Film-coated Tablets**

**Active substance: 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 Lercanidipine Clonmel is and what it is used for
2. What you need to know before you take Lercanidipine Clonmel
3. How to take Lercanidipine Clonmel
4. Possible side effects
5. How to store Lercanidipine Clonmel
6. Contents of the pack and other information

**1. What Lercanidipine Clonmel is and what it is used for**

Lercanidipine Clonmel is a selective calcium channel blocker belonging to a group of medicines called dihydropyridines. Selective calcium channel blockers reduce high blood pressure. They work by relaxing and thus widening the blood vessels.

**Lercanidipine Clonmel is used to:**

- treat mild to moderate high blood pressure (essential hypertension).

**2. What you need to know before you take Lercanidipine Clonmel**

**DO NOT take Lercanidipine Clonmel**

- if you are allergic to lercanidipine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have had allergic reactions to medicines closely related to Lercanidipine Clonmel (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- if you are pregnant or breast-feeding or if you might become pregnant (see section 2. Pregnancy and breast-feeding)
- if you are suffering from certain heart diseases:
  - uncontrolled cardiac failure
  - obstruction to flow of blood from the heart
  - unstable angina (angina at rest or progressively increasing)
  - within one month of heart attack
- if you have severe liver or kidney problems
- if you are taking medicines/food which may influence the effect and/or side effects of Lercanidipine Clonmel such as:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin or troleandomycin)
  - antivirals (such as ritonavir, a medicine to treat AIDS)
  - ciclosporin (a medicine used to prevent rejection after a transplant)

- grapefruit or grapefruit juice

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Lercanidipine Clonmel, especially if you have or have had any of the following medical conditions or illnesses:

- sick sinus syndrome (a heart disease which can make the heart beat too fast or too slowly) if this has not been treated by the insertion of a pacemaker
- left ventricular dysfunction (a heart disease where one of the chambers of your heart cannot fill or pump blood normally)
- ischaemic heart disease (in which the blood supply to your heart is insufficient)
- pre existing angina (chest pain)
- mild or moderate kidney or liver problems

### **Other medicines and Lercanidipine Clonmel**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Do not** take Lercanidipine Clonmel together with any medicine which inhibits the metabolism and therefore may influence the effect and/or side effects of lercanidipine. Your doctor will know which medicines these are. They include, for example:

- ciclosporin (a medicine used to prevent rejection after a transplant)
- ketoconazole or itraconazole (medicines to treat fungal infections)
- ritonavir (a medicine to treat AIDS)
- erythromycin or troleandomycin (antibiotics)

Some other medicines which are metabolised (activated or changed) by CYP3A4 or which induce this enzyme can influence the concentration of lercanidipine in your blood. Therefore, consult your doctor if you are taking any other medicine.

#### The effect of lercanidipine is enhanced by

- midazolam (a sedative)
- terfenadine, astemizole (antihistamines used to treat hay fever and other allergies)
- amiodarone, quinidine (to treat an irregular heartbeat)
- cimetidine (to treat stomach ulcers), when given at high doses (> 800 mg per day)

#### The effect of lercanidipine is reduced by

- phenytoin, carbamazepine (some anticonvulsant medicines used to treat epilepsy)
- rifampicin (an antibiotic)
- beta-blockers (medicines to treat high blood pressure and heart diseases, e.g. metoprolol)

#### Lercanidipine increases the effect of

- digoxin (to treat heart diseases)
- simvastatin (a cholesterol-lowering medicine)

### **Taking Lercanidipine Clonmel with food, drink and alcohol**

Always take your Lercanidipine Clonmel tablets at least 15 minutes before a meal (breakfast).

Alcohol intake may increase the effects and the side effects of lercanidipine. Therefore, you should not drink alcohol during treatment.

Grapefruit juice can increase the concentration of lercanidipine in your blood. You must not eat grapefruit or drink grapefruit juice while you are taking Lercanidipine Clonmel.

### **Pregnancy and breast-feeding**

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.

#### Pregnancy

You must not take Lercanidipine Clonmel if you are pregnant. If you wish to become pregnant or think you might be pregnant, you should consult your doctor. Your treatment will have to be changed.

#### Breast-feeding

Do not take Lercanidipine Clonmel while breast-feeding. Lercanidipine can reach the baby through your breast milk. If you have to continue treatment with Lercanidipine Clonmel, you should stop breast-feeding.

### **Driving and using machines**

Lercanidipine can cause dizziness, weakness, tiredness and sleepiness. If affected you should not drive or use machines.

### **Lercanidipine Clonmel 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 tablet, that is to say essentially 'sodium-free'.

## **3. How to take Lercanidipine Clonmel**

**Always take Lercanidipine Clonmel exactly as your doctor has told you. Check with your doctor if you are not sure.**

Lercanidipine Clonmel tablets or tablet halves should be swallowed whole with a glass of water preferably in the morning at least 15 minutes before breakfast.

#### Lercanidipine Clonmel 20 mg film-coated tablets

The tablets can be divided into equal doses.

Store the remaining tablet half protected from light for example by putting the tablet half back into the blister, pulling the blister foil over the tablet half and storing the blister in the outer carton. Take this remaining half with the next dose.

### **Dosage**

#### Adults

The recommended dose is 10 mg once a day. Your doctor may advise you to increase your dose to 20 mg daily, if needed.

#### Older people

In general, no dose adjustment is required for older people.

#### Patients with impaired kidney or liver function

In mild to moderate kidney or liver impairment the usual starting dose is 10 mg once a day. The doctor will increase the dose carefully. If you have severe kidney or liver impairment, you must not take Lercanidipine Clonmel.

#### Use in children and adolescents

Lercanidipine Clonmel is not recommended for use in children below the age of 18 years due to insufficient data on safety and efficacy.

**If you take more Lercanidipine Clonmel than you should**

If you take too many tablets, contact your doctor or nearest hospital emergency department immediately for advice. An overdose can cause a large fall in blood pressure (hypotension), a rapid or slow heartbeat, unconsciousness and other serious effects. Other symptoms listed under section 4. Possible side effects may be intensified in the event of an overdose.

**If you forget to take Lercanidipine Clonmel**

Do not take a double dose to make up for a forgotten tablet, just take your next dose as usual.

**If you stop using Lercanidipine Clonmel**

Do not stop treatment with Lercanidipine Clonmel without consulting your doctor first.

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.

The following side effects have been associated with Lercanidipine Clonmel:

**Uncommon (may affect up to 1 in 100 people):**

- fast heartbeat (tachycardia)
- palpitations (feeling the heart beat)
- peripheral oedema (a build up of fluid in the extremities, especially the legs)
- headache
- dizziness
- flushing (redness of the skin, particularly of the face)

**Rare (may affect up to 1 in 1,000 people):**

- angina pectoris (chest pain)
- some medicines similar to Lercanidipine Clonmel may lead to precordial pain (pain in the front of the chest)
- sleepiness (somnolence)
- feeling sick (nausea)
- indigestion
- diarrhoea
- abdominal pain
- vomiting
- polyuria (passing large amounts of urine)
- skin rash
- muscle pain
- weakness
- tiredness (fatigue)

**Very rare (may affect up to 1 in 10,000 people):**

- if you already have angina pectoris, the symptoms may occur more often, last longer or be more severe
- isolated cases of heart attack (myocardial infarction) may occur
- fainting (syncope)
- increased liver enzyme levels (this is usually reversible when treatment is stopped)
- enlarged gums (gingival hypertrophy)
- urinary frequency (passing urine at shorter intervals than usual)

- hypotension (low blood pressure)
- chest pain

#### 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 HPRÁ Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Lercanidipine Clonmel**

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 carton and blister pack. The expiry date refers to the last day of that month.

Store the tablets in the original package in order to protect from light.

The tablet halves should be protected from light.

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 Lercanidipine Clonmel contains**

The active substance is lercanidipine.

#### Lercanidipine Clonmel 10 mg film-coated tablets

One tablet contains 10 mg lercanidipine hydrochloride as lercanidipine hydrochloride hemihydrate.

#### Lercanidipine Clonmel 20 mg film-coated tablets

One tablet contains 20 mg lercanidipine hydrochloride as lercanidipine hydrochloride hemihydrate.

#### **The other ingredients are**

Tablet-core:

- lactose monohydrate
- pregelatinised maize starch
- croscarmellose sodium
- hypromellose
- silica, colloidal anhydrous
- magnesium stearate

Film-coating:

- hypromellose
- macrogol 8000
- titanium dioxide (E171)
- talc

Lercanidipine Clonmel 10 mg film-coated tablets also contain iron oxide yellow (E172).

Lercanidipine Clonmel 20 mg film-coated tablets also contain iron oxide red (E172).

#### **What Lercanidipine Clonmel tablets look like and contents of the pack**

Lercanidipine Clonmel 10 mg film-coated tablets are yellow, round, biconvex film-coated tablets of 6.5 mm with score line.

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

Lercanidipine Clonmel 20 mg film-coated tablets are pink, round, biconvex film-coated tablets of 8.1 mm with score line. The tablets can be divided into equal doses.

Lercanidipine Clonmel is available in packs containing 10, 14, 28, 30, 50, 56, 84, 98, 100, 126 or 154 tablets in white-opaque aluminium/PVC/PVdC blisters.

Not all pack sizes may be marketed.

**Marketing authorisation holder and manufacturer**

Marketing authorisation holder:

Clonmel Healthcare Ltd, Waterford Road, Clonmel. Co. Tipperary, Ireland.

Manufacturer:

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany.

Centrafarm Services BV, Nieuwe Donk 9, 4879 AC Etten Leur, The Netherlands.

Clonmel Healthcare Ltd, Waterford Road, Clonmel. Co. Tipperary, Ireland.

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

- AT: Lercanidipin STADA 10 mg and 20 mg Filmtabletten
- BE: Lercanidipine EG 10 mg and 20 mg filmomhulde tabletten
- BG: ARETA 10 mg and 20 mg
- DK: Lercastad
- ES: Lercanidipino STADA 10 mg and 20 mg comprimidos recubiertos con película EFG
- IE: Lercanidipine Clonmel 10 mg and 20 mg Film-coated Tablets
- IT: LERCANIDIPINA EG – 10 mg and 20 mg compresse rivestite con film
- LU: Lercanidipine EG 10 mg and 20 mg filmomhulde tabletten
- NL: Lercanidipine HCl STADA 10 mg and 20 mg, filmomhulde tabletten
- PT: Lercanidipina Ciclum
- RO: Lercanidipină STADA-HEMOFARM 10 mg and 20 mg comprimate filmate
- SE: Lercastad 10 mg and 20 mg filmdragerade tabletter

**This leaflet was last revised in February 2020.**