

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Lercanidipine Teva 10 mg Film-coated Tablets

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

#### **1. What Lercanidipine Teva is and what it is used for**

Lercanidipine Teva belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives). Lercanidipine Teva is used to treat mild to moderate **high blood pressure** also known as hypertension.

#### **2. What you need to know before you take Lercanidipine Teva**

##### **Do not take Lercanidipine Teva:**

- if you are **allergic** (hypersensitive) to lercanidipine hydrochloride or to **any of the other ingredients** of this medicine (listed in section 6)

- if you have had **allergic reactions** to medicinal products closely related to Lercanidipine Teva (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- if you are suffering from **certain heart diseases**:
  - untreated heart 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 **medicinal products** that are inhibitors of CYP3A4 isoenzyme:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin or troleandomycin)
  - antivirals (such as ritonavir)
- if you are taking another drug called ciclosporin or cyclosporin (used after transplants to prevent organ rejection)
- if you are taking grapefruit or grapefruit juice.

Do not use if you are **pregnant** or **breast-feeding** (see section Pregnancy and breast-feeding for more information).

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Lercanidipine Teva if

- You have certain other heart conditions and do not have a pacemaker, or you have pre-existing angina
- You have problems with your liver or kidneys or you are on dialysis

### **Children and adolescents**

**Lercanidipine Teva should not be used for children and adolescents under 18 years.**

### **Other medicines and Lercanidipine Teva**

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

### **Please tell your doctor or pharmacist if:**

- You are taking **beta-blockers** e.g. metoprolol, **diuretics** (water tablets) or **ACE-inhibitors** (medicines to treat high blood pressure).
- You are taking **cimetidine** (more than 800 mg per day, a medicine for ulcers, indigestion, or heartburn)

- You are taking **digoxin** (a medicine to treat a heart problem)
- You are taking **midazolam** (a medicine that helps you sleep)
- You are taking **rifampicin** (a medicine to treat tuberculosis)
- You are taking **astemizole or terfenadine** (medicines for allergies)
- You are taking **amiodarone or quinidine** (medicines to treat a fast heart beat)
- You are taking **phenytoine or carbamazepine** (medicines for epilepsy). Your doctor will want to monitor your blood pressure more frequently than usual.
- You are taking **antifungal medicines** (such as ketoconazole or itraconazole), macrolide antibiotics (such as erythromycin or troleandomycin) or antivirals (such as ritonavir). The effect of Lercanidipine Teva may be increased. Therefore the co-administration should be avoided (see “Do not take Lercanidipine Teva”).
- You are taking **ciclosporin** (a medicine which lowers the body’s resistance to disease). The effect of Lercanidipine Teva as well as of ciclosporin may be increased. Therefore the co-administration should be avoided (see “Do not take Lercanidipine Teva”).
- You are taking **simvastatin** (a medicine which lowers cholesterol level). Lercanidipine Teva should be taken in the morning and simvastatin in the evening.

### **Lercanidipine Teva with food and drink and alcohol**

- Patients should **not consume alcohol** during treatment with Lercanidipine Teva since it may increase the effect of Lercanidipine Teva.
- Patients should **not take grapefruit or grapefruit juice**.

### **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.

Do not take Lercanidipine Teva if you are pregnant or breast-feeding, or you wish to become pregnant or if you are not using any contraceptive method.

### **Driving and using machines**

Caution should be exercised because of the possibility of dizziness, weakness and tiredness. Do not drive or use machines until you know how Lercanidipine Teva affects you.

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

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 10 mg lercanidipine hydrochloride 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 active substance**. Your doctor may advise you to increase the dose to two 10 mg tablets or one 20 mg tablet (corresponding to 20 mg lercanidipine hydrochloride) daily, if needed. The tablet should be swallowed with a sufficient amount of fluid (e.g. one glass of water).

**Older people:** 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 have any further questions on the use of this product ask your doctor.

#### **If you take more Lercanidipine Teva 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 dosage may cause blood pressure to become too low, and the heart to beat irregularly or faster. It may also lead to vomiting or unconsciousness.

#### **If you forget to take Lercanidipine Teva**

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 tablet.

### **If you stop taking Lercanidipine Teva**

If you stop taking Lercanidipine Teva 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): angina pectoris (chest pain due to lack of blood to your heart)

Very rare (may affect up to 1 in 10,000 people): chest pain, fall in blood pressure, fainting and allergic reactions (symptoms include itching, rash, hives)

If you suffer from pre-existing angina pectoris, with the group of medicines to which Lercanidipine Teva belongs, you may experience increased frequency, duration or severity of these attacks. Isolated cases of heart attack may be observed.

### **Other possible side effects:**

Uncommon (may affect up to 1 in 100 people): headache, dizziness, faster heart beats, palpitations (heart pounding or racing), sudden reddening of the face, neck or upper chest, ankle swelling.

Rare (may affect up to 1 in 1,000 people): sleepiness, feeling sick, vomiting, heartburn, stomach pain, diarrhoea; skin rash, muscle pain, passage of large amounts of urine, tiredness.

Very rare (may affect up to 1 in 10,000 people): swelling of gums, changes in liver function (detected by blood tests), increase in the usual number of times one urinates.

### **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 HPRA 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 Teva**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on each blister strip and on the outer carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect 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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Lercanidipine Teva contains**

The active substance is lercanidipine hydrochloride. One 10 mg film-coated tablet contains 10 mg lercanidipine hydrochloride, equivalent to 9.4 mg lercanidipine.

The other ingredients are

Core:

Maize starch, sodium starch glycolate (type A), silica, colloidal anhydrous, cellulose, microcrystalline, poloxamer 188, sodium stearyl fumarate, macrogol 6000.

Film-coating:

Hypromellose (E464), macrogol 6000, iron oxide yellow (E 172), titanium dioxide (E 171).

One 20 mg film-coated tablet contains 20 mg lercanidipine hydrochloride, equivalent to 18.8 mg lercanidipine.

The other ingredients are

Core:

Cellulose, microcrystalline, maize starch, sodium starch glycolate (type A), silica, colloidal anhydrous, povidone K 30, sodium stearyl fumarate.

Film-coating:

Hypromellose (E464), macrogol 6000, iron oxide red (E 172), titanium dioxide (E 171).

### **What Lercanidipine Teva looks like and contents of the pack**

**Lercanidipine Teva 10 mg** Film-coated Tablets are yellow, round shaped biconvex, film-coated tablet of 6.5 mm diameter, with score line on one side and plain on the other side. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

**Lercanidipine Teva 20 mg** Film-coated Tablets are pink, round shaped biconvex, film-coated tablets of 8.5 mm diameter, with score line on one side and plain 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: 14, 28, 30, 50 x1, 56, 98, 100 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Teva Pharma B.V.  
Swensweg 5  
2031GA Haarlem  
The Netherlands

#### **Manufacturer**

Teva UK Ltd, Brampton Road, Hampden Park, Eastbourne, East Sussex BN22 9AG, United Kingdom

Merckle GmbH, Ludwig-Merckle-Strasse 3, 89143 Blaubeuren, Germany

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

**Austria:** Lercanidipin hydrochlorid Teva 10 mg & 20 mg Filmtabletten

**Belgium:** Lercanidipine-Teva 10 mg & 20 mg filmomhulde tabletten

**Germany:** Lercanidipin-HCL Teva 10 mg & 20 mg Filmtabletten

**Ireland:** Lercanidipine Teva 10 mg & 20 mg Film-coated Tablets

**Italy:** LERCANIDIPINA TEVA 10 mg & 20 mg compresse rivestite con film

**Portugal:** Lercanidipina Teva

**Spain:** Lercanidipino Tevagen 10 mg & 20 mg comprimidos recubiertos con película EFG

**The Netherlands:** Lercanidipine HCl 10 mg & 20 mg PCH filmomhulde tabletten  
**United Kingdom:** Lercanidipine hydrochloride 10 mg & 20 mg film-coated tablets

**This leaflet was last revised in April 2019.**