

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**Lercanidipine Teva Pharma 10 mg Film-coated Tablets**

**Lercanidipine Teva Pharma 20 mg Film-coated Tablets**

Lercanidipine hydrochloride

**Read all of this leaflet carefully before you start taking this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **In this leaflet:**

1. What Lercanidipine Teva Pharma is and what it is used for
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## **1. WHAT LERCANIDIPINE TEVA PHARMA IS AND WHAT IT IS USED FOR**

Lercanidipine Teva Pharma belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives).

Lercanidipine Teva Pharma 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 under 18 years old).

## **2. BEFORE YOU TAKE LERCANIDIPINE TEVA PHARMA**

### **Do NOT take Lercanidipine Teva Pharma**

- If you are **allergic** (hypersensitive) to lercanidipine or to any **of the ingredients** in Lercanidipine Teva Pharma
- If you have had **allergic reactions** to medicines that are closely related to Lercanidipine Teva Pharma (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 a heart attack
- If you have **severe liver or kidney problems**
- If you are taking medicines that are inhibitors of the CYP3A4 isoenzyme: antifungal medicines (such as ketoconazole or itraconazole)
- If you are taking another medicine called ciclosporin or cyclosporin (a medicine used after organ transplant)
- With grapefruit or grapefruit juice
- If you are pregnant, or if you wish to become pregnant or if you are a woman of child-bearing age and do not use any contraceptive method
- If you are breast-feeding

## Take special care with Lercanidipine Teva Pharma

You should consult your doctor before taking Lercanidipine Teva Pharma tablets:

- If you have certain other heart conditions with dysfunction of the left heart ventricle, or an abnormal heart rhythm such as sick sinus syndrome and you do not have a pacemaker
- If you have angina pectoris, lercanidipine may in very rare cases cause increased frequency of attacks that may last longer and become more severe. Myocardial infarction has been reported in isolated cases.
- If you have mild or moderate problems with your liver or kidneys

## Taking other medicines

Please tell your doctor if:

- You are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- 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 **phenytoin or carbamazepine** (medicines for epilepsy). Your doctor will want to monitor your blood pressure more frequently than usual.
- You are taking **simvastatin** (a medicine which lowers cholesterol). Lercanidipine Teva Pharma should be taken in the morning and simvastatin in the evening.
- You are taking **antifungal medicines** (such as ketoconazole or itraconazole). The effect of Lercanidipine Teva Pharma may be increased, and these medicines should not be taken together (see “Do not take Lercanidipine Teva Pharma”).
- You are taking **ciclosporin** (a medicine used after organ transplant). The effect of both Lercanidipine Teva Pharma and ciclosporin may be increased, so these medicines should not be taken together (see “Do not take Lercanidipine Teva Pharma”).

## Taking Lercanidipine Teva Pharma with food and drink

You should not **consume alcohol**, **eat grapefruit** or **drink grapefruit juice** as this may increase the effect of Lercanidipine Teva Pharma.

## Pregnancy and breast-feeding

Do not take Lercanidipine Teva Pharma if you are pregnant or breast-feeding, or you wish to become pregnant or if you are not using any contraceptive method. If you are taking Lercanidipine Teva Pharma and think that you may be pregnant, consult your doctor.

Ask your doctor for advice before taking any medicine.

## Driving and using machines

Lercanidipine Teva Pharma has a negligible influence on the ability to drive or use machines. However, 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 Pharma affects you..

### **Important information about some of the ingredients of Lercanidipine Teva Pharma**

Lercanidipine Teva Pharma contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

**10 mg strength:** Lercanidipine Teva Pharma contains tartrazine aluminium lake (E102) and may cause allergic reactions.

**20 mg strength:** Lercanidipine Teva Pharma contains allura red AC aluminium lake (E129) and may cause allergic reactions.

### **3. HOW TO TAKE LERCANIDIPINE TEVA PHARMA**

Always take Lercanidipine Teva Pharma exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is one Lercanidipine Teva Pharma 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 to increase your dose to one Lercanidipine Teva Pharma 20 mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with half a glass of water.

Elderly: although no adjustment of the daily dosage is necessary, special care is needed when starting lercanidipine treatment in the elderly.

Patients with mild to moderate 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.

Lercanidipine Teva Pharma is not recommended for use in children and adolescents below 18 years of age.

#### **If you take more Lercanidipine Teva Pharma 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 Pharma**

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 Pharma**

If you stop taking Lercanidipine Teva Pharma 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 product, ask your doctor or pharmacist.

#### 4. POSSIBLE SIDE EFFECTS

Like all medicines, Lercanidipine Teva Pharma 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 (affect 1 to 10 users in 10,000):*

- Angina pectoris (chest pain due to lack of blood to your heart)

*Very rare (affect less than 1 user in 10,000):*

- 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 Pharma 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 side effects (affect 1 to 10 users in 1,000):*

- Headache, dizziness
- Faster heartbeats, palpitations (heart pounding or racing), ankle swelling
- Sudden reddening of the face, neck or upper chest

*Rare side effects (affect 1 to 10 users in 10,000):*

- Sleepiness
- Angina pectoris (chest pain)
- Heartburn, feeling sick, diarrhoea, stomach pain, vomiting
- Skin rash
- Muscle pain
- Passage of large amounts of urine
- Tiredness

*Very rare side effects (affect less than 1 user in 10,000):*

- Swelling of gums
- Increase in the usual number of times one urinates
- Changes in liver function (detected by blood tests)

*Other side effects the frequency of which is not known (frequency cannot be estimated from the available data):*

- Disorders combining stiffness, trembling and/or movement disturbances

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### 5. HOW TO STORE LERCANIDIPINE TEVA PHARMA

Keep out of the reach and sight of children.

Do not use Lercanidipine Teva Pharma 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.

**Blisters**

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

**Bottles**

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

Bottles (after first opening container)

Store in the original package in order to protect from light. Discard 30 days after opening.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Lercanidipine Teva Pharma contains

- The active substance is lercanidipine hydrochloride.  
10 mg strength: One film-coated tablet contains 10 mg lercanidipine hydrochloride, equivalent to 9.4 mg lercanidipine.  
20 mg strength: One film-coated tablet contains 20 mg lercanidipine hydrochloride, equivalent to 18.8 mg lercanidipine.
- The other ingredients are lactose monohydrate, sodium starch glycolate (potato), microcrystalline cellulose, povidone and magnesium stearate in the tablet core, and a film-coat of  
10 mg strength: Opadry 03F32418 yellow containing hypromellose (E464), titanium dioxide (E171), tartrazine aluminium lake (E102), macrogol 6000, talc and iron oxide yellow (E172).  
20 mg strength: Opadry 03F34650 pink containing hypromellose (E464), titanium dioxide (E171), allura red AC aluminium lake (E129), macrogol 6000, talc, indigo carmine aluminium lake (E132).

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

- 10 mg strength: Yellow to dark yellow, round convex film-coated tablet debossed with the number "10" on one side and scored on the other.  
20 mg strength: Light pink to pink, round convex film-coated tablet debossed with the number "20" on one side and scored on the other.  
The tablet can be divided into equal halves.
- 10 mg strength: Lercanidipine Teva Pharma is available in blister packs of 14, 15, 28, 30, 50, 56, 60, 90, 98, 100 tablets, hospital pack of 50x1 tablet and calendar packs of 28 tablets and in bottles of 30 tablets. Not all pack sizes may be marketed.  
20 mg strength: Lercanidipine Teva Pharma is available in blister packs of 15, 28, 30, 50, 56, 60, 90, 98, 100 tablets, hospital pack of 50x1 tablet and calendar packs of 28 tablets and in bottles of 30 tablets. Not all pack sizes may be marketed.
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### Marketing Authorisation Holder and manufacturer

#### Marketing Authorisation Holder:

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

#### Manufacturers:

TEVA UK Ltd  
Brampton Road,  
Hampden Park,  
Eastbourne,  
East Sussex,  
BN22 9AG

England

Pharmachemie B.V.  
Swensweg 5, 2031GA Haarlem, The Netherlands

GALIEN LPS  
98 Rue Bellocier,  
89100 Sens  
France

TEVA Pharmaceutical Works Private Limited Company  
Pallagi út 13,  
4042 Debrecen  
Hungary

Teva Czech Industries s.r.o.  
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747 70 Opava, Komárov  
Czech Republic

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50016 Zaragoza  
Spain

Merckle GmbH,  
Ludwig-Merckle-Strasse  
389143 Blaubeuren,  
Germany

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

United Kingdom	Lercanidipine Hydrochloride 10 mg Film-Coated Tablets Lercanidipine Hydrochloride 20 mg Film-Coated Tablets
Bulgaria	TevaLer 10 mg film-coated tablets TevaLer 20 mg film-coated tablets
Ireland	Lercanidipine Teva Pharma 10 mg Film-coated Tablets Lercanidipine Teva Pharma 20 mg Film-coated Tablets
Slovenia	Lerkanidipin Teva 10 mg filmsko obložene tablete Lerkanidipin Teva 20 mg filmsko obložene tablete

**This leaflet was last revised in April 2017.**