

**PACKAGE LEAFLET:  
 INFORMATION FOR THE USER**

# Lercanidipine Hydrochloride 10 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 Hydrochloride 10 mg is and what it is used for
2. Before you take Lercanidipine Hydrochloride 10 mg
3. How to take Lercanidipine Hydrochloride 10 mg
4. Possible side effects
5. How to store Lercanidipine Hydrochloride 10 mg
6. Further information

**1. WHAT LERCANIDIPINE HYDROCHLORIDE 10 MG IS AND WHAT IT IS USED FOR**

Lercanidipine Hydrochloride 10 mg belongs to a group of medicines called calcium channel blockers (of the dihydropyridine group), which are used to treat high blood pressure.

Lercanidipine Hydrochloride 10 mg is used for the treatment of mild to moderate high blood pressure.

**2. BEFORE YOU TAKE LERCANIDIPINE HYDROCHLORIDE 10 MG**

**Do not take Lercanidipine Hydrochloride 10 mg if you**

- are **allergic** (hypersensitive) to lercanidipine hydrochloride or **any of the other ingredients** of Lercanidipine Hydrochloride 10 mg
- have had **allergic reactions** to drugs closely related to Lercanidipine Hydrochloride 10 mg (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- are **pregnant** or **breast-feeding**, trying to become pregnant or do not use any contraceptive method
- 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
- have **severe liver or kidney problems**
- are taking one of the following **drugs/food**:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin or troleandomycin)
  - antivirals (such as ritonavir)
  - ciclosporin (a medicine used after organ transplants to prevent rejection)
  - grapefruit juice.

**Take special care with Lercanidipine Hydrochloride 10 mg if you**

- suffer from certain arrhythmias (sick sinus syndrome) and do not have a pacemaker
- have pre-existing angina
- have mild to moderate liver or kidney problems.

**Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you take Lercanidipine Hydrochloride 10 mg with some other medicines, the effect of Lercanidipine Hydrochloride 10 mg or the other medicine may be increased or decreased. Tell your doctor or pharmacist if you are taking:

- **cimetidine** (more than 800 mg per day, a medicine for ulcers, indigestion, or heartburn)
- **digoxin** (a medicine to treat a heart problem)
- **midazolam** (a medicine that helps you sleep)
- **rifampicin** (a medicine to treat tuberculosis)
- **terfenadine or astemizole** (medicines for allergies)
- **amiodarone or quinidine** (medicines to treat a fast heart beat)
- **phenytoin or carbamazepine** (medicines for epilepsy). The blood pressure lowering effect of Lercanidipine Hydrochloride 10 mg may be reduced.
- **antifungal medicines** (such as ketoconazole or itraconazole), macrolide antibiotics (such as erythromycin or troleandomycin) or antivirals (such as ritonavir). The effect of Lercanidipine Hydrochloride 10 mg may be increased. Therefore the co-administration should be avoided (see "Do not take Lercanidipine Hydrochloride 10 mg").
- **ciclosporin** (a medicine used after organ transplants to prevent rejection). The effect of Lercanidipine Hydrochloride 10 mg as well as of ciclosporin may be increased. Therefore the co-administration should be avoided (see "Do not take Lercanidipine Hydrochloride 10 mg").
- **beta-blockers** (medicines to treat high blood pressure or certain heart diseases), although these may be safely taken with Lercanidipine Hydrochloride 10 mg. A dose adjustment of Lercanidipine Hydrochloride 10 mg could be necessary.
- **simvastatin** (a medicine which lowers cholesterol level). Lercanidipine Hydrochloride 10 mg should be taken in the morning and simvastatin in the evening.

**Taking Lercanidipine Hydrochloride 10 mg with food and drink**

Eating grapefruit or drinking grapefruit juice may increase the effect of Lercanidipine Hydrochloride 10 mg. So you should **avoid grapefruit products** during treatment with this medicine.

Drinking alcohol during your treatment with Lercanidipine Hydrochloride 10 mg may increase the effect of Lercanidipine Hydrochloride 10 mg, therefore **please do not drink alcoholic drinks**.

**Pregnancy and breast-feeding**

Do not take Lercanidipine Hydrochloride 10 mg if you are pregnant, think you are pregnant or are trying to become pregnant or are breast-feeding, or if you are not using any contraceptive method.

If while taking Lercanidipine Hydrochloride 10 mg you think that you may have become pregnant, consult your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**

Lercanidipine Hydrochloride 10 mg should not affect your ability to drive or use machines but 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 Lercanidipine Hydrochloride 10 mg affects you.

**3. HOW TO TAKE LERCANIDIPINE HYDROCHLORIDE 10 mg**

Always take Lercanidipine Hydrochloride 10 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is a tablet of Lercanidipine Hydrochloride 10 mg (corresponding to 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 drug. Your doctor may advise you to increase the

dose to two tablets Lercanidipine Hydrochloride 10 mg (corresponding to 20 mg lercanidipine hydrochloride) daily, if needed. The tablet should preferably be swallowed with some water.

**Children**

Lercanidipine Hydrochloride 10 mg should not be used in children and adolescents under 18 years of age.

**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.

**If you take more Lercanidipine Hydrochloride 10 mg than you should**

If you take more Lercanidipine Hydrochloride 10 mg than the prescribed dose or in 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 unconsciousness.

**If you forget to take Lercanidipine Hydrochloride 10 mg**

If you forget to take your tablet simply miss that dose and then go on as before. Do not take a double dose.

**If you stop taking Lercanidipine Hydrochloride 10 mg**

Do not change the prescribed dose yourself and do not stop treatment without talking with your doctor. If you stop taking Lercanidipine Hydrochloride 10 mg your blood pressure may increase again.

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 Hydrochloride 10 mg can cause side effects, although not everybody gets them. The following frequencies are used in the evaluation of side effects:

<b>Common:</b>	less than one in 10, but more than one in 100 patients treated
<b>Uncommon:</b>	less than one in 100, but more than one in 1,000 patients treated
<b>Rare:</b>	less than one in 1,000, but more than one in 10,000 patients treated

**Uncommon:**

- headache
- dizziness
- faster heart beats
- awareness of the beating of the heart
- transient episodic redness of the face and neck
- ankle swelling.

**Rare:**

- sleepiness
- nausea
- indigestion
- vomiting
- diarrhea
- abdominal pain
- rash
- muscle pain
- passage of large amounts of urine
- weakness
- tiredness
- chest pain with tightness in your chest (angina pectoris).

**Very rare:**

- allergic reaction (hypersensitivity)
- fainting
- swelling of gums
- increase in blood test values which show changes in the way the liver is working

- fall in blood pressure which can cause dizziness, light-headedness or fainting
- increase in the usual number of times one urinates
- chest pain.

If you experience any of these problems during treatment with Lercanidipine Hydrochloride 10 mg, please tell your doctor immediately.

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 HYDROCHLORIDE 10 MG**

Keep out of the reach and sight of children.

Do not use Lercanidipine Hydrochloride 10 mg after the expiry date which is stated on each blister strip and on the outer carton. The expiry date refers to the last day of that month.

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

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 Hydrochloride 10 mg contains**

The active substance is lercanidipine hydrochloride. One film-coated tablet contains 10 mg lercanidipine hydrochloride, which is 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, macrogol 6000, iron oxide yellow (E 172), titanium dioxide (E 171).

**What Lercanidipine Hydrochloride 10 mg looks like and contents of the pack**

Lercanidipine Hydrochloride 10 mg are yellow, round shaped biconvex, film-coated tablets with break-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 Hydrochloride 10 mg is available in blister packs of 28 film-coated tablets.

**Marketing Authorisation Holder And Manufacturer**

**Torrent Pharma (UK) Ltd.**

Unit 4, Charlwood Court, County Oak Way  
 Crawley, West Sussex

RH 11 7XA

United Kingdom

Telephone: (01293) 574180

Fax: (01293) 533003

Email: [drugsafety@torrentpharma.co.uk](mailto:drugsafety@torrentpharma.co.uk)

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

The Netherlands: Lercanidipine HCl Torrent 10 mg  
 Italy: Lercanidipina TecniGen 10 mg

comprese rivestite con film  
 Romania: PEGFEL, 10 mg

**This leaflet was last approved in 12/2013**



3230

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:	DATE : 11-12-2013
SIZE : 150 x 300 mm, Front /Back	CODE : 8044318-9703		
REMARK : Folding Length 35 mm			
SUBSTRATE :			
Activities	Department	Name	Date
Prepared By	Pkg.Dev		
Reviewed By	Pkg.Dev		
Reviewed By	RA		
Approved By	COA		

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.

PACKAGE LEAFLET:  
INFORMATION FOR THE USER

## Lercanidipine Hydrochloride 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 Hydrochloride 20 mg is and what it is used for
2. Before you take Lercanidipine Hydrochloride 20 mg
3. How to take Lercanidipine Hydrochloride 20 mg
4. Possible side effects
5. How to store Lercanidipine Hydrochloride 20 mg
6. Further information

### 1. WHAT LERCANIDIPINE HYDROCHLORIDE 20 MG IS AND WHAT IT IS USED FOR

Lercanidipine Hydrochloride 20 mg belongs to a group of medicines called calcium channel blockers (of the dihydropyridine group), which are used to treat high blood pressure.

Lercanidipine Hydrochloride 20 mg is used for the treatment of mild to moderate **high blood pressure**.

### 2. BEFORE YOU TAKE LERCANIDIPINE HYDROCHLORIDE 20 MG

**Do not take Lercanidipine Hydrochloride 20 mg if you**

- are **allergic** (hypersensitive) to lercanidipine hydrochloride or **any of the other ingredients** of Lercanidipine Hydrochloride 20 mg
- have had **allergic reactions** to drugs closely related to Lercanidipine Hydrochloride 20 mg (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- are **pregnant** or **breast-feeding**, trying to become pregnant or do not use any contraceptive method
- 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
- have **severe liver or kidney problems**
- are taking one of the following **drugs/food**:
  - antifungal medicines (such as ketoconazole or itraconazole),
  - macrolide antibiotics (such as erythromycin or troleandomycin)
  - antivirals (such as ritonavir)
  - ciclosporin (a medicine used after organ transplants to prevent rejection)
  - grapefruit juice.

### Take special care with Lercanidipine Hydrochloride 20 mg if you

- suffer from certain arrhythmias (sick sinus syndrome) and do not have a pacemaker
- have pre-existing angina
- have mild to moderate liver or kidney problems.

### Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription

If you take Lercanidipine Hydrochloride 20 mg with some other medicines, the effect of Lercanidipine Hydrochloride 20 mg or the other medicine may be increased or decreased. Tell your doctor or pharmacist if you are taking:

- **cimetidine** (more than 800 mg per day, a medicine for ulcers, indigestion, or heartburn)
- **digoxin** (a medicine to treat a heart problem)
- **midazolam** (a medicine that helps you sleep)
- **rifampicin** (a medicine to treat tuberculosis)
- **terfenadine or astemizole** (medicines for allergies)
- **amiodarone or quinidine** (medicines to treat a fast heart beat)
- **phenytoin or carbamazepine** (medicines for epilepsy). The blood pressure lowering effect of Lercanidipine Hydrochloride 20 mg may be reduced.
- **antifungal medicines** (such as ketoconazole or itraconazole), macrolide antibiotics (such as erythromycin or troleandomycin) or antivirals (such as ritonavir). The effect of Lercanidipine Hydrochloride 20 mg may be increased. Therefore the co-administration should be avoided (see "Do not take Lercanidipine Hydrochloride 20 mg").
- **ciclosporin** (a medicine used after organ transplants to prevent rejection). The effect of Lercanidipine Hydrochloride 20 mg as well as of ciclosporin may be increased. Therefore the co-administration should be avoided (see "Do not take Lercanidipine Hydrochloride 20 mg").
- **beta-blockers** (medicines to treat high blood pressure or certain heart diseases), although these may be safely taken with Lercanidipine Hydrochloride 20 mg. A dose adjustment of Lercanidipine Hydrochloride 20 mg could be necessary.
- **simvastatin** (a medicine which lowers cholesterol level). Lercanidipine Hydrochloride 20 mg should be taken in the morning and simvastatin in the evening.

### Taking Lercanidipine Hydrochloride 20 mg with food and drink

Eating grapefruit or drinking grapefruit juice may increase the effect of Lercanidipine Hydrochloride 20 mg. So you should **avoid grapefruit products** during treatment with this medicine.

Drinking alcohol during your treatment with Lercanidipine Hydrochloride 20 mg may increase the effect of Lercanidipine Hydrochloride 20 mg, therefore **please do not drink alcoholic drinks**.

### Pregnancy and breast-feeding

Do not take Lercanidipine Hydrochloride 20 mg if you are pregnant, think you are pregnant or are trying to become pregnant or are breast-feeding, or if you are not using any contraceptive method.

If while taking Lercanidipine Hydrochloride 20 mg you think that you may have become pregnant, consult your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

Lercanidipine Hydrochloride 20 mg should not affect your ability to drive or use machines but 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 Lercanidipine Hydrochloride 20 mg affects you.

### 3. HOW TO TAKE LERCANIDIPINE HYDROCHLORIDE 20 mg

Always take Lercanidipine Hydrochloride 20 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The usual dose is half of a tablet of Lercanidipine Hydrochloride 20 mg (corresponding to 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 drug. Your doctor may advise you to increase the

dose to one tablet Lercanidipine Hydrochloride 20 mg (corresponding to 20 mg lercanidipine hydrochloride) daily, if needed. The tablet should preferably be swallowed with some water.

### Children

Lercanidipine Hydrochloride 20 mg should not be used in children and adolescents under 18 years of age.

### 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.

### If you take more Lercanidipine Hydrochloride 20 mg than you should

If you take more Lercanidipine Hydrochloride 20 mg than the prescribed dose or in 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 unconsciousness.

### If you forget to take Lercanidipine Hydrochloride 20 mg

If you forget to take your tablet simply miss that dose and then go on as before. Do not take a double dose.

### If you stop taking Lercanidipine Hydrochloride 20 mg

Do not change the prescribed dose yourself and do not stop treatment without talking with your doctor. If you stop taking Lercanidipine Hydrochloride 20 mg your blood pressure may increase again.

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 Hydrochloride 20 mg can cause side effects, although not everybody gets them. The following frequencies are used in the evaluation of side effects:

<b>Common:</b>	less than one in 10, but more than one in 100 patients treated
<b>Uncommon:</b>	less than one in 100, but more than one in 1,000 patients treated
<b>Rare:</b>	less than one in 1,000, but more than one in 10,000 patients treated

### Uncommon:

- headache
- dizziness
- faster heart beats
- awareness of the beating of the heart
- transient episodic redness of the face and neck
- ankle swelling.

### Rare:

- sleepiness
- nausea
- indigestion
- vomiting
- diarrhea
- abdominal pain
- rash
- muscle pain
- passage of large amounts of urine
- weakness
- tiredness
- chest pain with tightness in your chest (angina pectoris).

### Very rare:

- allergic reaction (hypersensitivity)
- fainting
- swelling of gums
- increase in blood test values which show changes in the way the liver is working

- fall in blood pressure which can cause dizziness, light-headedness or fainting
- increase in the usual number of times one urinates
- chest pain.

If you experience any of these problems during treatment with Lercanidipine Hydrochloride 20 mg, please tell your doctor immediately.

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 HYDROCHLORIDE 20 MG

Keep out of the reach and sight of children.

Do not use Lercanidipine Hydrochloride 20 mg after the expiry date which is stated on each blister strip and on the outer carton. The expiry date refers to the last day of that month.

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

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 Hydrochloride 20 mg contains

The active substance is lercanidipine hydrochloride. One film-coated tablet contains 20 mg lercanidipine hydrochloride, which is 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, macrogol 6000, iron oxide red (E 172), titanium dioxide (E 171).

#### What Lercanidipine Hydrochloride 20 mg looks like and contents of the pack

Lercanidipine Hydrochloride 20 mg are pink, round shaped biconvex, film-coated tablets with break-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 Hydrochloride 20 mg is available in blister packs of 28 film-coated tablets.

#### Marketing Authorisation Holder And Manufacturer

**Torrent Pharma (UK) Ltd.**

Unit 4, Charlwood Court, County Oak Way  
Crawley, West Sussex  
RH11 7XA

United Kingdom

Telephone: (01293) 574180

Fax: (01293) 533003

Email: [drugsafety@torrentpharma.co.uk](mailto:drugsafety@torrentpharma.co.uk)

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

The Netherlands: Lercanidipine HCl Torrent 20 mg  
Italy: Lercanidipina Tecnigen 20 mg

comprese rivestite con film  
Romania: PEGFEL, 20 mg

**This leaflet was last approved in 12/2013**



3231

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:	DATE : 11-12-2013
SIZE : 150 x 300 mm_ Front /Back	CODE : 8044319-7803		
REMARK : Folding Length 35 mm			
SUBSTRATE :			
Activities	Department	Name	Signature
Prepared By	Pkg.Dev		Date
Reviewed By	Pkg.Dev		
Reviewed By	RA		
Approved By	COA		

This colour proof is not colour binding. Follow Pantone shade reference for actual colour matching.