

Applicant/PHRC: **Hetero Drugs South Africa (Pty) Ltd**

Product proprietary name: **LENDIDIP 10 mg & 20 mg**

Dosage form and strength: **Each film coated tablet contains lercanidipine hydrochloride (as hemihydrate) 10 mg and 20 mg**

## APPROVED PATIENT INFORMATION LEAFLET FOR LENDIDIP

### SCHEDULING STATUS

**S3**

#### **LENDIDIP 10 mg film-coated tablets**

#### **LENDIDIP 20 mg film-coated tablets**

Each film-coated tablets contains 10 mg of lercanidipine hydrochloride (as hemihydrate)

Each film-coated tablets contains 20 mg of lercanidipine hydrochloride (as hemihydrate)

Contains sugar "lactose monohydrate"

Each 10 mg film-coated tablets contains 29,861 mg of lactose monohydrate

Each 20 mg film-coated tablets contains 59,722 mg of lactose monohydrate

### **Read all of this leaflet carefully before you start taking LENDIDIP**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other health care provider.
- LENDIDIP has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### **What is in this leaflet**

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

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## **1.What LENDIDIP is and what it is used for**

The active substance is lercanidipine hydrochloride. Lercanidipine belongs to a group of medicines called calcium channel blockers (of the dihydropyridine group) which are used to treat high blood pressure. LENDIDIP is used to treat high blood pressure, also known as hypertension.

## **2.What you need to know before you LENDIDIP**

### **Do not take LENDIDIP:**

- If you are hypersensitive (allergic) to lercanidipine hydrochloride or any of the other ingredients of LENDIDIP (listed in section 6).
- If you are suffering from certain heart diseases:
  - obstruction to flow of blood from the heart.
  - untreated heart failure.
  - unstable angina (chest discomfort occurring at rest or progressively increasing)
  - within one month of heart attack
- With grapefruit or grapefruit juice.
- If you have severe liver or kidney problems - you are undergoing dialysis.
- If you are taking medicines that are inhibitors of the hepatic metabolism, such as:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
  - antivirals (such as ritonavir).
  - antidepressants (such as fluoxetine)
- If you are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection).

## **Warnings and precautions**

Take special care with LENDIDIP

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- Certain other heart conditions, or if you have a pacemaker.
- Problems with your liver or kidney, or you are dialysis.

You must tell your doctor if you think you are (or might become) pregnant or breast-feeding (see pregnancy, breast-feeding and fertility section).

### **Children and adolescents**

The safety and efficacy of Lercanidipine HCl in children aged up to 18 years have not been established.

### **Other medicines and LENDIDIP**

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

Tell your doctor or pharmacist if:

- You are taking medicines that are inhibitors of CYP3A4 isoenzyme (medicines that will increase the absorption of lercanidipine):
  - Antifungal medicines (such as ketoconazole or itraconazole).
  - Macrolide antibiotics (such as erythromycin or troleandomycin).
  - Antivirals (such as ritonavir).
  - Antidepressants (such as fluoxetine)
- You are taking beta-blockers, diuretics or ACE- inhibitors (medicines to treat high blood pressure), although these may be safely taken with LENDIDIP
- You are taking digoxin (a medicine to treat a heart problem).
- You are taking cimetidine (a medicine for ulcers, indigestion, or heartburn).
- 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, quinidine or sotalol (medicines to treat a fast heart beat).
- You are taking phenytoin, phenobarbitone or carbamazepine (medicines for epilepsy).

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- You are taking medicines which lower the body's resistance to disease (such as cyclosporin).
- You are taking grapefruit or grapefruit juice.
- Simvastatin (a medicine to lower cholesterol in your blood)

#### **LENDIDIP with food, drink and alcohol**

Drinking alcohol during your treatment with LENDIDIP tablets may increase the effect of LENDIDIP tablets, you are therefore advised to cut out or strictly limit your consumption of alcoholic drinks.

High fat meals significantly increase the blood levels of LENDIDIP. You must therefore take the tablet at least 15 minutes before a meal.

#### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You must not use LENDIDIP if you are pregnant or breastfeeding.

#### **Driving and using machines**

LENDIDIP may cause sleepiness and tiredness. Do not drive a car or operate machinery until you know how LENDIDIP affects you.

It is not always possible to predict to what extent LENDIDIP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LENDIDIP affects them.

#### **LENDIDIP contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking LENDIDIP.

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### **3. How to take LENDIDIP**

Do not share medicines prescribed for you with any other person.

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

The usual dose is one LENDIDIP 10 mg film-coated tablet daily at the same time each day, preferably in the morning at least 15 minutes before breakfast. Your doctor may advise you to increase the dose to one LENDIDIP 20 mg film-coated tablet daily, if needed.

The tablets should preferably be swallowed whole with some water.

If you have the impression that the effect of LENDIDIP is too strong or too weak, talk to your doctor or pharmacist.

#### **If you take more LENDIDIP than you should**

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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 LENDIDIP**

Do not take a double dose to make up for forgotten individual doses.

### **4. Possible side effects**

LENDIDIP can have side effects.

Not all side effects reported for LENDIDIP are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LENDIDIP, please consult your health care provider for advice.

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If any of the of the following happens, stop taking LENDIDIP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 'swelling of the ankles or legs, face, lip, tongue, or throat, difficulty in swallowing or breathing'
- 'rash or itching',
- 'fainting'

These are all very serious side effects. If you have them, you may have had a serious reaction to LENDIDIP. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina
- changes in the way your heart beats, for example, if you notice it beating faster.
- 

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- fast heart rate
- feeling of fast or uneven heartbeat (palpitations)

Less frequent side effects:

- dizziness
- low blood pressure
- heartburn
- feeling sick
- stomach pain
- muscle pain

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- passing large amounts of urine
- feeling weak or feeling tired
- sleepiness
- vomiting
- diarrhoea
- hives
- increase in the usual number of times one urinates
- changes in liver function
- cloudy fluid

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

#### *Reporting of side effects*

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to the Holder of certificate of registration through the mail: [pvg.cdma@hererodrugs.com](mailto:pvg.cdma@hererodrugs.com) By reporting side effects, you can help provide more information on the safety of LENDIDIP.

#### **5. How to store LENDIDIP**

Store all medicines out of reach of children.

Store at or below 25 °C

Store in the original package.

Protect from light/ moisture.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

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

### **What LENDIDIP contains**

The active substance is lercanidipine hydrochloride.

The other ingredients are:

- Lactose monohydrate
- Cellulose microcrystalline
- Sodium starch glycolate
- Povidone (k-30)

### **Composition of Opadry II yellow 85F520410**

- Polyvinyl alcohol-part hydrolyzed E1203
- Titanium dioxide E171
- Macrogol/PEG E1521
- Talc E553b
- Iron oxide yellow E172
- Iron oxide red E172

### **Composition of Opadry II pink 85F540460**

- Polyvinyl alcohol-part hydrolyzed E1203
- Titanium dioxide E171
- Macrogol/PEG E1521
- Talc E553b
- Iron oxide red E172

### **What LENDIDIP looks like and contents of the pack**

Yellow, film coated, round shaped, biconvex tablets debossed with “3” and “4” on either side of score line on one side of the tablet and “HL” on the other side.



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10 x 10's Aclar-Alu Blister

White opaque 250 µ PVC/102 µ Aclar film with 0,025 mm Plain aluminium foil (Hard Tampered) with 7GSM HSL coating on bright side

9 x 10's Alu-Alu Blister

Form pack film with Desiccant with 20 µ Plain aluminum foils with 15GSM PE coating on bright side width 148 mm (sealable to form pack film with desiccant).

500's simulated Bulk Pack

Clear 100 µ poly bag 9 x 12 inches with triple laminated bag (9"x12") with silica gel sachet 5 gram

#### **Holder of Certificate of Registration**

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus

Building No.2, First Floor

74 Waterfall Drive

Midrand, 2066

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#### **This leaflet was last revised in**

08 July 2025

#### **Registration numbers**

**LENDIDIP 10 mg:** 57/7.1/0043

**LENDIDIP 20 mg:** 57/7.1/0044

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**Access to the corresponding Professional Information**

Hetero Drugs South Africa (Pty) Ltd

Waterfall Corporate Campus

Building No.2, First Floor

74 Waterfall Drive

Midrand, 2066

Telephone number: 012 644 1220

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