**Package leaflet: Information for the patient**

**Lercanidipine Viatris 10 mg film-coated tablets**
**Lercanidipine Viatris 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 Viatris is and what it is used for

Lercanidipine Viatris contains the active ingredient lercanidipine.

Lercanidipine belongs to a group of medicines called calcium channel blockers (dihydropyridine derivatives) which are used to treat high blood pressure (hypertension). Lercanidipine works by opening up the blood vessels and increasing the flow of blood through them, helping to reduce pressure.

Lercanidipine Viatris is used to treat high blood pressure in adults over the age of 18 years (it is not recommended for children up to 18 years old).

## 2. What you need to know before you take Lercanidipine Viatris

**Do not take Lercanidipine Viatris:**
- if you are allergic to lercanidipine hydrochloride or any other ingredients of this medicine (listed in section 6).
- 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 problems.
- If you have severe kidney problems or you are undergoing dialysis
- if you are taking medicines that are inhibitors of hepatic metabolism such as:
  - antifungal medicines (such as ketoconazole or itraconazole)
  - macrolide antibiotics (such as erythromycin, troleandomycin or clarithromycin)
  - antivirals (such as ritonavir)
- if you are taking another medicine called ciclosporin or cyclosporin (used after transplants to prevent organ rejection)
- with grapefruit or grapefruit juice

**Warnings and precautions**
Talk to your doctor or pharmacist before taking Lercanidipine Viatris:
- if you have heart problem
- if you have kidney or liver problems

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 Viatris in children and adolescents aged up to 18 years have not been established.

**Other medicines and Lercanidipine Viatris**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Taking Lercanidipine Viatris with certain other medicines, may alter the effect of these medicines or of Lercanidipine Viatris. It is especially important for your doctor to know if you are already being treated with any of the following medicines:
- phenytoin, phenobarbital or carbamazepine (medicines for epilepsy)
- rifampicin (a medicine to treat tuberculosis)
- midazolam (a medicine that helps you sleep)
- cimetidine, more than 800 mg (a medicine for ulcers, indigestion, or heartburn)
- digoxin (a medicine to treat a heart problem)
- terfenadine or astemizole (medicines for allergies)
- amiodarone quinidine or sotalol (medicines to treat a fast heart-beat)
- medicines known as beta-blockers e.g. metoprolol (medicines to treat high blood pressure)
- simvastatin (a medicine to lower cholesterol in your blood)
- other medicines to treat high blood pressure

**Lercanidipine Viatris with food, drink and alcohol**
A high fat meal significantly increases blood levels of the medicine (section 3).
Do not drink alcohol during your treatment with Lercanidipine Viatris as it may increase the effectiveness of this medicine in reducing your blood pressure.
Do not take Lercanidipine Viatris tablets with grapefruit or grapefruit juice as this may increase the effect of Lercanidipine Viatris.

**Pregnancy, breast-feeding and fertility**
Lercanidipine Viatris is not recommended if you are pregnant, it should not be used during breast-feeding. There are no data from the use of Lercanidipine Viatris in pregnant women and in nursing mothers. If you are pregnant or breast-feeding, if you are not using any contraceptive method, you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**
Caution should be exercised because of the possibility of dizziness, weakness or tiredness and rarely sleepiness. Do not drive or use machines until you know how Lercanidipine Viatris affects you.

**Lercanidipine Viatris 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.

## 3. How to take Lercanidipine Viatris

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

The recommended dose is one Lercanidipine Viatris 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 20 mg daily, if needed. Taking lercanidipine with food, especially a meal containing lots of fat, increases the amount of medicine that gets into the body, which could increase the risk of side-effects occurring. The tablets should be swallowed whole with some water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

**Use in children and adolescents**
This medicine should not be used in children and adolescents up to 18 years of age.

**Elderly patients and patients with mild to moderate liver or kidney problems**
Your doctor will tell you if you need a lower dose of this medicine. If your doctor increases the dose to 20 mg, they may want to keep an eye on you.

**If you take more Lercanidipine Viatris Tablets than you should**
Do not take more than your doctor or pharmacist tells you.
If you take more tablets than you should contact your doctor or hospital immediately. Take any remaining tablets or this leaflet with you so the medical staff know exactly what you have taken. Taking too many tablets can cause a severe drop in blood pressure (hypotension), a very fast heart rate and unconsciousness.

**If you forget to take Lercanidipine Viatris**
If you forget to take a tablet, take it if you remember within 12 hours of your usual time. If more than 12 hours have passed, you should not take the missed tablet but should take your next tablet as the normal time when it is due. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Lercanidipine Viatris**
If you stop taking this medicine, your blood pressure may increase again. Talk to your doctor before stopping your 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.

**If you experience any of the following side effects, stop taking your medicine and seek urgent medical attention:**
**Rare: may affect up to 1 in 1,000 people**
- allergic reaction (hypersensitivity) which can cause itching, rash and hives, sweating, swelling of the face, tongue or throat, severe breathing difficulty.
- chest pain, often spreading to the arms and neck (angina pectoris)
- fainting

If you suffer from pre-existing angina, medicines like lercanidipine have been reported to rarely increase the frequency, duration or severity of these attacks, with the possibility of having a heart attack.

**Other possible side effects**

**Common: may affect up to 1 in 10 people**
- headache,
- fast heart rate,
- feeling of fast or uneven heart beat (palpitations),
- sudden reddening of your face,
- neck or upper chest (flushing),
- ankle swelling.

**Uncommon: may affect up to 1 in 100 people**
- dizziness
- fall in blood pressure,
- heartburn,
- feeling sick,
- stomach pain,
- skin rash,
- itching,
- muscle pain
- Passage of large amounts of urine,
- feeling weak or feeling tired

**Rare: may affect up to 1 in 1,000 people**
- sleepiness
- vomiting
- diarrhoea
- hives
- increase in the usual number of times you need to pass urine,
- chest pain

**Not know**
- swelling of gums
- changes in liver function (detected by blood tests),
- cloudy fluid (when performing dialysis through a tube into your abdomen),
- swelling of your face, lip, tongue or throat which may cause difficulty in breathing or swallowing

**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 HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Lercanidipine Viatris

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, label and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Viatris contains**
The active substance is lercanidipine hydrochloride.
Each 10mg tablet contains 10 mg lercanidipine hydrochloride equivalent to 9.4 mg lercanidipine.
Each 20mg tablet contains 20 mg lercanidipine hydrochloride equivalent to 18.8 mg lercanidipine.

The other ingredients are:
*Tablet core:* lactose monohydrate, microcrystalline cellulose, crospovidone, povidone, magnesium stearate
*Film coating:* hypromellose, titanium dioxide (E171), macrogol, iron oxide yellow (E172), iron oxide red (E172). 10mg only: iron oxide black (E172).

**What Lercanidipine Viatris looks like and contents of the pack**
Lercanidipine Viatris 10mg film-coated tablets are yellow-brown, round, biconvex tablets, marked "LR over 1" on one side and with a score line on the other side.
Lercanidipine Viatris 10mg film-coated tablets are available in blister packs of 7, 14, 28, 35, 50, 56, 98 and 100 and in bottles of 500 and 1000.

Lercanidipine Viatris 20mg film-coated tablets are pink, round, biconvex tablets, marked "LR over 2" on one side and with a score line on the other side.
Lercanidipine Viatris 20mg film-coated tablets is available in blister packs of 7, 14, 28, 35, 50, 56, 98 and 100 and in bottle of 500 and 1000.

Do not eat the desiccant in the bottle.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**
Viatris Limited, Damastown Industrial Park, Mulhuddart, Dublin 15, DUBLIN, Ireland.

**Manufacturer**
McDermott Laboratories Ltd. t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

| **Member State** | **Name of medicinal product** |
|---|---|
| Ireland | Lercanidipine Viatris 10 mg and 20 mg film-coated tablets |
| United Kingdom (Northern Ireland) | Lercanidipine HCl 10 mg and 20 mg film-coated tablets |

**This leaflet was last revised in February 2025**