

Package leaflet: Information for the patient

Lercanidipine Mylan 20mg 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 Mylan is and what it is used for
2. What you need to know before you take Lercanidipine Mylan
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1. What Lercanidipine Mylan is and what it is used for

Lercanidipine Hydrochloride 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 Hydrochloride 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 Mylan

Do not take Lercanidipine Mylan

- if you are allergic to lercanidipine or any of the other ingredients of this medicine (listed in section 6)
- if you have had allergic reactions to medicines closely related to lercanidipine (such as amlodipine, nicardipine, felodipine, isradipine, nifedipine or lacidipine)
- if you are pregnant or breast-feeding, if you are planning to have a baby or are a woman of child-bearing age and are not using an effective form of contraception.
- 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 one of the following medicines/food:
 - antifungal medicines (such as ketoconazole or itraconazole)
 - macrolide antibiotics (such as erythromycin or troleandomycin)
 - antivirals (such as ritonavir, a medicine to treat AIDS)
 - ciclosporin (a medicine used to prevent rejection after a transplant)

- grapefruit or grapefruit juice

Warnings and precautions

Talk to your doctor or pharmacist before taking Lercanidipine Hydrochloride:

- if you have certain other heart conditions like abnormal heart rhythms if you have not been fitted with a pacemaker, or if you have angina
- if you have mild or moderate kidney or liver problems

Some medicines similar to lercanidipine (dihydropyridines like amlodipine or felodipine for example) have been known to lead to chest pain or angina. Very rarely patients with pre-existing angina may experience increased frequency, duration or severity of these attacks. Very rare cases of heart attack may be observed.

Children and adolescents

The safety and efficacy of lercanidipine in children and adolescents aged up to 18 years have not been established. No data are available.

Other medicines and Lercanidipine Mylan

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

Do not take Lercanidipine Mylan if you are taking any of the following medicines:

- antifungal medicines (such as ketoconazole or itraconazole)
- macrolide antibiotics (such as erythromycin or troleandomycin)
- antivirals (such as ritonavir, a medicine to treat AIDS)
- ciclosporin (a medicine used to prevent rejection after a transplant)

Talk to your doctor or pharmacist if you are taking any of the following medicines:

- beta-blockers (e.g. metoprolol)
- cimetidine, a medicine for ulcers, indigestion, or heartburn
- digoxin (a medicine to treat heart problems)
- midazolam (a medicine that helps you sleep but may be used for other reasons)
- rifampicin (a medicine to treat tuberculosis)
- terfenadine or astemizole (medicine to treat allergies)
- medicines to treat a fast heart beat (e.g. amiodarone or quinidine)
- medicines to treat epilepsy (e.g. phenytoin or carbamazepine)

Lercanidipine Mylan with food, drink and alcohol

Do not drink alcohol during your treatment with Lercanidipine Mylan as it may increase the effectiveness of this medicine in reducing your blood pressure.

Do not take Lercanidipine Mylan tablets with grapefruit or grapefruit juice.

Pregnancy, breast-feeding and fertility

Pregnancy

Do not take lercanidipine if you are pregnant, think you may be pregnant, are planning to have a baby or are a woman of child-bearing age and are not using an effective form of contraception, as medicines like lercanidipine may affect the development of your unborn baby

Breast-feeding

Do not take lercanidipine if you are breast-feeding as lercanidipine may pass into breast milk

Fertility

Medicines like lercanidipine have been reported to affect the sperm. If you are trying to have a baby, let your doctor or fertility nurse know that you are 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 Hydrochloride affects you.

Lercanidipine Mylan contains lactose

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

3. How to take Lercanidipine Mylan

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 Hydrochloride 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 Mylan 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 Mylan

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 Mylan

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:

- 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)
- low blood pressure (hypotension) which can cause dizziness

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.

Uncommon: may affect up to 1 in 100 people

- headache
- dizziness
- faster heart beats
- palpitations (heart pounding or racing)
- sudden reddening of the skin (flushing)
- swelling of the hands and feet.

Rare: may affect up to 1 in 1,000 people

- sleepiness
- feeling sick (nausea) and being sick (vomiting)
- diarrhoea
- rash
- muscle pain
- passage of large amounts of urine
- tiredness and weakness
- indigestion and stomach pain

Very rare: may affect up to 1 in 10,000 people

- fainting (syncope)
- swelling of gums
- increase level of liver enzymes which can be seen in blood tests which show changes in the way the liver is working
- increase in the usual number of times you need to pass urine

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 HPRAs Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lercanidipine Mylan

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 Mylan contains

The active substance is lercanidipine hydrochloride. Each 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).

What Lercanidipine Mylan looks like and contents of the pack

Lercanidipine Hydrochloride 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 Hydrochloride 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 dessicant in the bottle.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer

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

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

Member State	Name of medicinal product
Austria	Lercanidipin Arcana 20mg Filmtabletten
Belgium	Lercanidipine Jenson Pharmaceutical Services 20 mg filmomhulde tabletten
Germany	Lercanipin-Dura 20 mg filmtabletten
Ireland	Lercanidipine Mylan 20mg Film-coated Tablets
Luxembourg	Lercanijenson 20 mg comprimés pelliculés
Norway	Lerkanidipin Mylan 20 mg filmdrasjerte tabletter
Portugal	Zanali 10mg and 20mg comprimido revestido por pelicula
Romania	Lercanidipina Jenson 20 mg, comprimate filmate
Spain	Lercanidipino MYLAN 20 mg comprimidos recubiertos con pelicula EFG
The Netherlands	Lercanidipine HCl Mylan 20mg, filmomhulde tabletten
United Kingdom	Lercanidipine Hydrochloride 20mg film-coated tablets

This leaflet was last revised in July 2014