

Package leaflet: Information for the patient

Lacidipine 2 mg and 4 mg Film-coated Tablets

lacidipine

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

1. What Lacidipine is and what it is used for

Lacidipine tablets contain the active substance lacidipine which belongs to a group of medicines called 'calcium channel blockers'. Lacidipine helps to relax your blood vessels so that they get wider. This helps the blood to flow more easily and lowers the blood pressure.

Lacidipine taken regularly as prescribed by your doctor will help to lower your blood pressure (to treat hypertension).

2. What you need to know before you take Lacidipine

Do not take Lacidipine:

- if you are allergic to lacidipine, other calcium channel blocker medicines or any of the other ingredients of this medicine (listed in section 6)
- if you have the heart problem 'aortic stenosis'. This is a narrowing of a valve in your heart, which restricts blood flow
- if you have had a heart attack within the last month.

Do not take Lacidipine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

You should stop taking Lacidipine if you get chest pain (angina) or a fast, weak pulse, rapid shallow breathing, low blood pressure, cold clammy skin, blue lips or feel dizzy, faint, weak or sick.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lacidipine:

- if you have an uneven heart beat or any other heart problems
- if you have or have ever had any liver problems.

If you are having any blood tests, tell the person giving the test that you are taking this medicine. This is because Lacidipine can affect results relating to your liver.

Children and adolescents

Do not give this medicine to children under the age of 18 years because it is not recommended in this age group.

Other medicines and Lacidipine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Lacidipine can affect the way some other medicines work. Also some other medicines can affect the way Lacidipine works.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- other medicines used to treat high blood pressure such as beta blockers (e.g. atenolol, propranolol), diuretics (called 'water tablets' e.g. bendroflumethiazide, furosemide) and ACE-inhibitors (e.g. enalapril, ramipril)
- ciclosporin, a medicine used to stop rejection after an organ transplant
- rifampicin, a medicine used to treat tuberculosis
- itraconazole, a medicine used to treat fungal infections
- medicines used to control your heart beat (called 'anti-arrhythmics' e.g. disopyramide, flecainide, amiodarone)
- medicines used to treat depression called 'tricyclic antidepressants' (e.g. clomipramine, imipramine)
- antibiotics, medicines used to treat infections (e.g. erythromycin)
- antihistamines, medicines used to treat hayfever and other allergies (e.g. terfenadine)
- cimetidine, a medicine used to treat stomach problems
- tetracosactide, a medicine used to test the function of the adrenal glands
- corticosteroids, a group of medicines used to reduce inflammation (e.g. prednisone, hydrocortisone).

Lacidipine with food and drink

Do not eat grapefruit or drink grapefruit juice whilst taking this medicine.

Pregnancy and breast-feeding

There is no data on the use of lacidipine during pregnancy. There may be a possibility of problems such as difficulty becoming pregnant, miscarriages or a difficult labour.

Lacidipine may pass into breast milk. Lacidipine is not recommended unless your doctor advises that the benefit to you is greater than the possibility of risk to your baby.

If you are pregnant or breast-feeding, 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

You may feel dizzy while taking Lacidipine. If this happens, do not drive or use any tools or machines.

Lacidipine 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 Lacidipine

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

Use in adults

It is important to take the right number of tablets at the same time each day.

- The recommended starting dose is 2 mg every morning.
- After 3-4 weeks this may be increased to 4 mg every morning.
- If necessary, the dose may be increased again to 6 mg every morning which is the maximum daily dose.
- Swallow the tablets whole with a drink of water.
- Do not take with grapefruit juice.

The 4 mg tablet can be divided into equal doses.

Patients with liver problems

You may be given a lower dose by your doctor if you have severe liver problems.

If you take more lacidipine than you should

If you take more of this medicine than you should, talk to a doctor or go to your nearest hospital emergency department straight away. You may have low blood pressure, or changes to your heart rate. Take the medicine pack with you, even if there are no tablets left.

If you forget to take Lacidipine

If you forget a dose in the morning, take it as soon as you remember it on the same day. However, if you remember the next day, take your normal dose on that morning. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lacidipine

If you are considering or have stopped taking Lacidipine, speak to your doctor or pharmacist.

If you have any further questions on the use of the medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects or go to your nearest hospital emergency department – you may need urgent medical treatment:

- chest pain or a pressing sensation on your chest, including chest pain that is getting worse. These may be signs of angina which may be more likely to occur when you start taking this medicine or if you already have heart problems

- serious allergic reactions such as rapid swelling of the face, mouth, lips, tongue or throat which may cause difficulty breathing or swallowing.

Other possible side effects include:

Common (may affect up to 1 in 10 people)

- dizziness
- headache
- fast or uneven heart beat which you may feel as a thumping in your chest (also called palpitations)
- flushing
- swelling (water retention), particularly of the ankles
- upset stomach
- feeling sick (nausea)
- rash, redness of the skin, itching
- an increase in the amount of water (urine) that you pass
- feeling weak
- changes in results of blood tests relating to your liver

Uncommon (may affect up to 1 in 100 people)

- low blood pressure which may cause you to feel faint
- fainting
- bleeding, tender or swollen gums

Rare (may affect up to 1 in 1,000 people)

- nettle rash (urticaria)
- muscle cramps

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

- shaking (tremor)
- depression

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lacidipine

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

This medicine does not require any special temperature storage conditions.

Store in the original container in order to protect from light. Do not remove any tablets from the foil until you are ready to take them.

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 Lacidipine contains

The active substance is lacidipine. Each film-coated tablet contains 2 mg or 4 mg.

The other ingredients are lactose monohydrate (see section 2 'Lacidipine contains lactose'), povidone, crospovidone and magnesium stearate. The film coating contains hypromellose, titanium dioxide (E171) and macrogol.

What Lacidipine looks like and contents of the pack

The 2 mg tablets are film-coated, round and white in colour. They have the logo  on one side and '225' on the other side.

The 4 mg tablets are film-coated, oval and white in colour. They have the logo  on one side and '24' separated by a break line on the other side.

Lacidipine is available in blister packs of 14 and 28 film-coated tablets and calendar packs of 28 film-coated tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer

Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary.

Generics [UK] Limited t/a Mylan, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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