

Package leaflet: Information for the patient

Lacidipine 2 mg film-coated tablets Lacidipine 4 mg film-coated tablets

Lacidipine

Read all of this leaflet carefully before you start using 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 tablets are and what they are used for
2. What you need to know before you use Lacidipine tablets
3. How to use Lacidipine tablets
4. Possible side effects
5. How to store Lacidipine tablets
6. Contents of the pack and other information

1. What Lacidipine tablets are and what they are used for

Lacidipine tablets contains a medicine called lacidipine. This belongs to a group of medicines called 'calcium channel blockers'. Lacidipine tablets 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 tablets 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 use Lacidipine tablets

Do not use Lacidipine tablets

- If you are pregnant, likely to get pregnant or are breast-feeding
- 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 tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lacidipine tablets.

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 using Lacidipine tablets:

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

Children and adolescents

Lacidipine tablets should not be administered to children and adolescents under 18 years.

Other medicines and Lacidipine tablets

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

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

- medicines for high blood pressure
- medicines to control your heart beat (called 'anti-arrhythmics')
- medicines for depression called 'tricyclic antidepressants'
- sleeping tablets or sedatives

- antibiotics (e.g. rifampicin)
- antihistamines – used for hay fever and other allergies
- cimetidine – used for stomach problems,
- tetracosactide and corticosteroids

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

Lacidipine tablets with food and drink

Lacidipine tablets can be taken with or without a meal. Do not take this medicine with grapefruit juice.

Pregnancy, breast-feeding and fertility

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. **There is no information** on the safe use of Lacidipine tablets in pregnancy.

Do not take Lacidipine tablets if you are pregnant, likely to get pregnant or are breast-feeding.

The active substance and excipients of Lacidipine tablets can pass into breast milk. **If you are breast-feeding, check with your doctor** before starting treatment with Lacidipine tablets.

Driving and using machines

This medicine may cause dizziness. If you experience this side effect, do not drive vehicles or operate machines which require your attention.

Lacidipine tablets 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 use Lacidipine tablets

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

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

- The usual starting dose is 2 mg a day, to be taken preferably in the morning, with or without food.
- 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.
- The tablets should not be removed from their foil pack until required for administration.
- Swallow the tablets with a drink of water.
- Do not take with grapefruit juice.

If you take more Lacidipine tablets than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack and the leaflet with you, even if there are no tablets left.

Medical treatment can be necessary. Effects of overdose will likely cause irregular heartbeat, rapid shallow breathing, low blood pressure, cold humid skin or feeling dizzy, fainting, weakness or nausea.

If you forget to take Lacidipine tablets

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 using Lacidipine tablets

Take Lacidipine tablets for the period of time prescribed by your doctor. Do not stop taking Lacidipine tablets unless instructed by your doctor. 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.

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- angina, this is a type of chest pain. This is uncommon in people taking Lacidipine and is likely to occur when you start taking this medicine.

- allergic reactions, the signs may include: rapid swelling of the face, mouth and throat which may cause difficulty breathing.

The side effects have been divided according to their frequency:

Common (may affect up to 1 in 10 people):

- Dizziness, headache, fast or uneven heart beat (also called palpitations), flushing, swelling particularly of the ankles. These side effects usually go away as treatment continues
- fast heart beat,
- upset stomach or feeling sick (nausea),
- rash, redness of the skin, itching,
- an increase in the amount of water (urine) that you pass,
- feeling weak (asthenia),
- changes in results of blood tests relating to your liver.

Uncommon (may affect up to 1 in 100 people):

- chest pain (angina) including chest pain that is getting worse,
- low blood pressure for example feeling faint, fainting,
- swelling of the gums.

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

- rapid swelling of the face, mouth and throat which may cause difficulty breathing,
- 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lacidipine tablets

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 after EXP:.

The expiry date refers to the last day of that month.

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

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 tablets contains

The active substance is lacidipine.

Lacidipine 2 mg film-coated tablets: each tablet contains lacidipine 2 mg.

Lacidipine 4 mg film-coated tablets: each tablet contains lacidipine 4 mg.

The other ingredients are:

core: lactose, povidone, magnesium stearate;

film-coat: hypromellose, talc, propylene glycol, titanium dioxide (E171).

What Lacidipine tablets looks like and contents of the pack

Lacidipine 2 mg film-coated tablets:

white, round [diameter 8.1 mm], biconvex, film-coated tablets

Lacidipine 4 mg film-coated tablets:

white, oval [13 mm x 7.4 mm], biconvex, film-coated tablets with score line on one side.

The tablet can be divided into equal doses. If, in accordance with the recommended dosage, you take a half tablet of 4 mg, then the unused half should be kept out of direct light and taken within 48 hours.

Lacidipine tablets are packed into OPA/Aluminium/PVC/Aluminium blisters, placed along with the leaflet into a carton.

Pack sizes:

Lacidipine 2 mg film-coated tablets – 7, 14, 28, 56 film-

coated tablets

Lacidipine 4 mg film-coated tablets – 7, 14, 28, 56 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Zentiva Pharma UK Limited

12 New Fetter Lane

London

EC4A 1JP

United Kingdom

Manufacturer:

Biofarm Sp. z o.o

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