

Patient Information Leaflet

Lodipam 2.5 mg Film-coated Tablets

Lodipam 5 mg Film-coated Tablets

Lodipam 10 mg Film-coated Tablets

Amlodipine



Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. Serious side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Visit your doctor immediately if you experience any of the following side effects after taking this medicine.

- Sudden wheeziness, chest pain, shortness of breath or difficulty in breathing.
- Swelling of eyelids, face or lips.
- Swelling of the tongue and throat which causes great difficulty breathing.
- Severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome) or other allergic reactions.
- Heart attack, abnormal heart beat.
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

2. What Lodipam is and what it is used for

The name of your medicine is Lodipam. It contains the active ingredient amlodipine besylate.

Lodipam is used to treat high blood pressure. Everyone has blood pressure; this pressure helps to circulate the blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure.

Lodipam helps to lower your blood pressure.

Lodipam is also used to treat angina pectoris. Angina is caused by a shortage of the supply of oxygen to the heart and is characterized by a painful and uncomfortable feeling in the chest. This feeling often spreads to the arms or neck, and sometimes also to the shoulders and back. Lodipam is not for the relief of a sudden attack of angina. If such an attack occurs, you should take other medication that your doctor will have given to you.

Your doctor may have prescribed Lodipam for another reason. Ask your doctor if you have any questions about why Lodipam was prescribed for you.

Lodipam is available only with a doctor's prescription.

3. Before you take Lodipam

Do not take Lodipam

- If you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine listed in section 7, or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- If you have severe low blood pressure (hypotension).
- If you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lodipam. You should inform your doctor if you have or have had any of the following conditions:

- Recent heart attack.
- Heart failure.
- Severe increase in blood pressure (hypertensive crisis).
- Liver disease.
- You are elderly and your dose needs to be increased.

Children and adolescents

Lodipam has not been studied in children under the age of 6 years. Lodipam should only be used for hypertension in children and adolescents from 6 years to 17 years of age. For more information, talk to your doctor.

Other medicines and Lodipam

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Lodipam may affect or be affected by other medicines, such as:

- Ketoconazole, itraconazole (anti-fungal medicines).
- Ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).
- Rifampicin, erythromycin, clarithromycin antibiotics).
- Hypericum perforatum (St. John's Wort).
- Verapamil, diltiazem (heart medicines).
- Dantrolene (infusion for severe body temperature abnormalities).
- Simvastatin (cholesterol lowering medicine).
- Cyclosporine (an immunosuppressant).

Lodipam may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure.

Lodipam with food and drink

Grapefruit and grapefruit juice should not be consumed by people who are taking Lodipam. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Lodipam.

Pregnancy and breast-feeding

The safety of amlodipine in human pregnancy has not been established. If you think you might be pregnant, or are planning to get pregnant, you must tell your doctor before you take Lodipam.

It is not known whether amlodipine is passed into breast milk. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Lodipam. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Lodipam may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

4. How to take Lodipam

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The recommended initial dose is 5 mg once daily. The dose can be increased to 10 mg once daily.

This medicine can be used before or after food and drinks. You should take this medicine at the same time each day with a drink of water.

Do not take Lodipam with grapefruit juice.

Use in children and adolescents

For children and adolescents (6 - 17 years old), the recommended usual starting dose is 2.5 mg a day. The maximum recommended dose is 5 mg a day. Lodipam 5 mg film-coated tablets can be divided into halves to provide a 2.5 mg dose. It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

If you take more Lodipam than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, light headed, faint or weak. If blood pressure drop is severe enough, shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical attention if you take too many Lodipam tablets.

If you forget to take Lodipam

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you stop taking Lodipam

Your doctor will advise you how long to take this medicine. Your condition may return if you stop using this medicine before you are advised.

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

5. Possible side effects

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

The following very common side effect has been reported. If this causes you problems or if it lasts for more than one week, you should contact your doctor.

Very common: may affect more than 1 in 10 people

- Ankle swelling (oedema).

The following common side effects have been reported. If any of these causes you problems or if they last for more than one week, you should contact your doctor.

Common: may affect up to 1 in 10 people

- Headache, dizziness, sleepiness (especially at the beginning of treatment).
- Palpitations (awareness of your heart beat), flushing.
- Abdominal pain, feeling sick (nausea).
- Altered bowel habits, diarrhoea, constipation, indigestion.
- Tiredness, weakness.
- Visual disturbances, double vision.
- Muscle cramps.

Other side effects that have been reported include the following list. If any of these get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Uncommon: may affect up to 1 in 100 people

- Mood changes, anxiety, depression, sleeplessness.
- Trembling, taste abnormalities, fainting, weakness.
- Numbness or tingling sensation in your limbs, loss of pain sensation.
- Ringing in the ears.
- Low blood pressure.
- Sneezing/running nose caused by inflammation of the lining of the nose (rhinitis).
- Cough.
- Dry mouth, vomiting (being sick).
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration.
- Disorder in passing urine, increased need to urinate at night, increased number of times of passing urine.
- Inability to obtain an erection, discomfort or enlargement of the breasts in men.
- Pain, feeling unwell.
- Joint or muscle pain, back pain.
- Weight increase or decrease.

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

- Confusion.

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

- Decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage).
- Excess sugar in blood (hyperglycaemia).
- A disorder of the nerves which can cause weakness, tingling or numbness.
- Swelling of the gums.
- Abdominal bloating (gastritis).
- Abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests.
- Increased muscle tension.
- Inflammation of blood vessels, often with skin rash.
- Sensitivity to light.
- Disorders combining rigidity, tremor, and/or movement disorders.

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.

6. How to store Lodipam

Keep out of the reach and sight of children. Don not store above 30°C.

Store in the original package in order to protect from moisture. Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

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.

7. Further Information

What Lodipam contains

- The active substance is amlodipine (as amlodipine besylate). Each film-coated tablet contains either 2.5 mg, 5 mg or 10 mg of the active substance.
- The other ingredients are: Microcrystalline cellulose, anhydrous calcium hydrogen phosphate, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide and polyethylene glycol.

What Lodipam looks like and contents of the pack

Lodipam 2.5 mg, 5 mg, and 10 mg are almost-white, octagonal shape film-coated tablets. Pack size is 30 tablets.

Marketing Authorization Holder and Manufacturer

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To report any side effect(s):

Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966 11 205 7662
- Call NPC at +966 11 203 8222, Exts: 2317 - 2356 - 2353 - 2354 - 2334 - 2340.
- Toll free phone: 8002490000
- Email: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

Other GCC States:

Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

