

PATIENT INFORMATION LEAFLET:  
INFORMATION FOR THE USER  
**LOPINE®-5 / 10**  
Amlodipine 5 / 10 mg  
Tablets

**Please read this leaflet carefully before taking this medication as it contains important information.**

- Keep this leaflet; you may need to read it again.
- Ask your doctor or pharmacist if you have any questions.
- If you have taken any other medication ask your doctor or pharmacist for advice.
- This medication was prescribed for you only. Do not give it to others, even if their symptoms are similar to yours, as it may harm them.
- Contact your doctor or pharmacist if you experience any side effects, including any not mentioned in this leaflet. See section 4.

**What's in this leaflet?**

- What is LOPINE® and when to use it?
- What should I know before taking LOPINE®?
- How to take LOPINE®?
- What are the possible side effects?
- How to store LOPINE®?
- Pack content and other information.

**1. WHAT IS LOPINE® AND WHEN TO USE IT?**

Pharmaco-therapeutic class – ATC code: C08CA01.

The active ingredient in LOPINE® is amlodipine, a calcium channel blocker.

LOPINE® is used to treat high blood pressure (hypertension), or chest pain caused by certain types of angina, a rare form of which is Prinzmetal's angina.

In patients with high blood pressure, the medication acts by relaxing the blood vessels, thus allowing the blood to pass through them more easily.

In patients with angina, LOPINE® works by improving the blood supply to the heart muscle, which then receives more oxygen thus preventing the development of chest pain. However, the medication does not provide immediate relief for angina chest pain

**2. WHAT SHOULD I KNOW BEFORE TAKING LOPINE®?**

**Never take LOPINE®:**

- If you are allergic to amlodipine, or any calcium channel blockers, or to any other ingredient contained in this medication (see section 6). Allergy symptoms include: itchiness, skin redness or breathing difficulties.
- If you have a severe decrease in blood pressure (hypotension).
- If you have narrowing of the aortic valve (aortic stenosis) or a condition in which your heart is unable to bring enough blood to the body (cardiogenic shock).
- If you have heart failure following a heart attack.

**Warnings and precautions**

Ask your doctor or pharmacist before taking LOPINE®.

**Inform your doctor if any of the following applies to you:**

- You have recently had a heart attack
- You have heart failure
- Your blood pressure has increased severely (hypertensive crisis)
- You have a liver disorder
- You are an elderly person and the dosage needs to be increased.

**Children and adolescents**

There have been no studies carried out in children under 6 years old. Therefore LOPINE® must only be used to treat high blood pressure in children and adolescents aged 6 to 17 (see section 3). Please ask your doctor for any further information.

**LOPINE® and other medications**

Please inform your doctor or pharmacist if you take, have recently taken or are likely to take any other medication. The effect of LOPINE® may be altered by certain medications,

or their effect may be altered:

- Ketoconazole, itraconazole (antifungal medications),
  - Ritonavir, indinavir, nelfinavir (protease inhibitors used to treat HIV infection),
  - Rifampicin, erythromycin, clarithromycin (antibiotics)
  - Hypericum perforatum (St. John's Wort)
  - Verapamil, diltiazem (heart medication)
  - Dantrolene (drip for severe increases in body temperature)
  - Tacrolimus (used to control your body's immune response, allowing your body to accept a transplant)
  - Simvastatin (medication to lower cholesterol)
  - Ciclosporin (immunosuppressive drug).
- LOPINE® may lower your blood pressure even more if you simultaneously take other medications to treat increased blood pressure.

**LOPINE® with food, drinks and alcohol**

People who take LOPINE® must avoid drinking grapefruit juice or eating grapefruit. Grapefruit and grapefruit juice may cause an increase in the blood levels of the active ingredient amlodipine, which may result in an unpredictable increase in the hypotensive effect of LOPINE®.

**Pregnancy, breastfeeding and fertility**

The safety of amlodipine in pregnancy has not been established.

Before taking LOPINE® inform your doctor if you are pregnant or breastfeeding, if you suspect or plan a pregnancy.

Small amounts of amlodipine are excreted in breast milk. If you are breastfeeding or plan to breastfeed inform your doctor before taking LOPINE®.

In any event, ask your doctor or pharmacist before taking any medication.

**Driving and using machinery**

LOPINE® may affect your ability to drive or use machinery. Do not drive or use machinery if you experience any nausea, dizziness, fatigue or headaches. Contact your doctor immediately.

**3. HOW TO TAKE LOPINE®?**

Always comply with the doctor's prescription or pharmacist's recommendations. If in doubt, ask your doctor or pharmacist.

The usual starting dosage of LOPINE® is 5 mg once a day. However, this dosage may be increased to 10 mg once a day. LOPINE® can be taken with or without food. It is best to take the medication at the same time with a glass of water. Do not take LOPINE® with grapefruit juice.

This treatment is important, do not wait to finish all the tablets before seeing your doctor.

**Use in children and adolescents:** For children and adolescents (6 to 17), the usual recommended starting dosage is 2.5 mg per day. The maximum recommended dosage is 5 mg per day. LOPINE® is not currently available in 2.5 mg tablets.

**If you have taken more LOPINE® than you should have:** Overdose can sometimes cause a dangerous drop in blood pressure. You may feel lightheaded, dizzy, faint or weak. A drastic drop in blood pressure may cause a shock. Your body may become cold and clammy and you may lose consciousness. Consult a doctor if you have taken too much LOPINE®

**If you have forgotten to take LOPINE®:** Do not worry. If you have forgotten to take a tablet skip it completely. Take the next tablet at the usual time. Do not take a double dosage to compensate for the forgotten one.

**If you stop taking LOPINE®:** Treatment duration will be established by your doctor. Your illness may return if you discontinue treatment before indicated.

If you have any further questions pertaining to the use of this medication ask your doctor or pharmacist.

**4. WHAT ARE THE POSSIBLE SIDE EFFECTS?**

As with all medications, some patients may experience side effects, but these are not systematic.

Consult your doctor immediately if you experience any of the following side effects after taking this medication:

- Sudden wheezing, chest pain, shortness of breath or breathing difficulties;
  - Swelling of the eyelids, face or lips;
  - Swelling of the tongue and throat resulting in severe breathing difficulties;
  - Severe skin reactions including intense rash, hives, redness of the skin throughout the body, severe itching, blistering, peeling and swelling of the skin, mucous membrane inflammation (Stevens-Johnson syndrome, toxic epidermal necrolysis);
  - Heart attack, abnormal heartbeat;
  - Inflammation of the pancreas that may cause severe abdominal and dorsal pain with severe discomfort.
- The following very common side effects** have been observed. You should contact your doctor if any of these effects become troublesome or last more than a week.

**Very common side effects:** may affect more than 1 in 10 patient:  
Oedema (water retention)

**The following common side effects** have been observed. You should contact your doctor if any of these effects become troublesome or last more than a week.

**Common side effects:** may affect 1 in 10 and 1 in 100 patient:

- Headache, dizziness, drowsiness (especially at the beginning of treatment);
- Palpitations (awareness of your heartbeat), flushes (abrupt redness of the face);
- Abdominal pain, nausea;
- Dry mouth;
- Abdominal transit disorder, diarrhoea, constipation, indigestion;
- Fatigue, weakness;
- Visual disorders, double vision;
- Muscle cramps; Swelling (oedema) of the ankles

Other side effects that have not been listed above have been observed. If you experience any of these side effects or any other not mentioned in this leaflet, please inform your doctor or pharmacist.

**Uncommon side effects:** may affect 1 in 100 and 1 in 1000 patient:

- Mood swings, anxiety, depression, insomnia;
- Tremor, taste altered, loss of consciousness;
- Sensations of numbness or tingling in the limbs; loss of the sensation of pain;
- Ringing in the ears;
- Decreased blood pressure;
- Sneezing and runny nose caused by inflammation of the mucous membrane of the nose (rhinitis);
- Cough;
- Vomiting (nausea);
- Hair loss, increased sweating, itchy skin, red patches on the skin, change of skin colour;
- Difficulty urinating, increased urge to urinate at night, increased urination;
- Inability to get an erection breast development in men;
- Pain, discomfort;
- Joint or muscle pain; back pain;
- Weight loss or increase.

**Rare side effects:** may affect 1 in 1000 and 1 in 10000 patients:

- Confusion.

**Very rare side effects:** may affect less than 1 in 10000 patient:

- Decreased white blood cell count, decreased blood platelets that can lead to abnormal formation of hematomas or frequent bleeding;
- Increased blood sugar (hyperglycaemia);
- Nerve disorder resulting in muscle weakness, tingling or numbness;
- Swelling of the gums;
- Abdominal bloating (gastritis);
- Liver function abnormalities, liver inflammation (hepatitis), yellowing of the skin (jaundice), elevated liver enzymes that may affect some medical tests;

- Increased muscle tension;
- Inflammation of the blood vessels, often accompanied by a rash;
- Sensitivity to light.

**Declaring side effects**

Inform your doctor or pharmacist if you experience any side effect, including any not mentioned in this leaflet.

By declaring the side effects your help provide more information on the safety of this medication.

**5. How to store LOPINE®**

Store below 30°C, protect from light and moisture.

Keep out of reach and sight of children.

Do not use after the expiry date.

Only under prescription.

Do not dispose of in the sewer or with household wastes. Ask your pharmacist how to dispose of unused drugs. These measures allow protecting the environment

**6. Pack content and other information**

**LOPINE®-5 tablet**

Each tablet contains:

Amlodipine Besylate

equivalent to Amlodipine 5 mg

Excipients q.s.

Excipients: Microcrystalline Cellulose, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate.

**LOPINE®-10 tablet**

Each tablet contains:

Amlodipine Besylate

equivalent to Amlodipine 10 mg

Excipients q.s.

Excipients: Microcrystalline Cellulose, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Magnesium Stearate.

**What is LOPINE® tablet and outer package content**

LOPINE® comes in tablet form in a box of 30.

This leaflet was last updated in 07/2020.

If you have any questions about this product or would like to report an adverse reaction contact us by phone : +225 21 25 52 38.

MA Holder & operator:

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Manufactured by:

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