

Package leaflet: Information for The Patient

Amline 5 mg Tablets Amline 10 mg Tablets

Amlodipine

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 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 of the 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 Amline is and what it is used for
2. What you need to know before you take Amline
3. How to take Amline
4. Possible side effects
5. How to store Amline
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1. What Amline is and what it is used for

Amline contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists. Amline is used to treat high blood pressure (hypertension) or a certain type of chest pain called angina, a rare form of which is Prinzmetal's or variant angina. In patients with high blood pressure this medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina Amline works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. This medicine does not provide immediate relief of chest pain from angina.

2. What you need to know before you take Amline

Do not take Amline

- If you are allergic (hypersensitive) to amlodipine or any of the other ingredients of your medicine listed in section 6, 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

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

Amline has not been studied in children under the age of 6 years. Amline should only be used for hypertension in children and adolescents from 6 years to 17 years of age (see section 3). For more information, talk to your doctor.

Other medicines and Amline

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

Amline 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)
- Tacrolimus (medicine used to alter the way your immune system works)
- Simvastatin (cholesterol lowering medicine)
- Cyclosporine (an immunosuppressant)

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

Amline with food and drink

Grapefruit juice and grapefruit should not be consumed by people who are taking Amline. 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 Amline.

Pregnancy and breast-feeding

Pregnancy

The safety of amlodipine in human pregnancy has not been established. If you are pregnant, think you might be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking Amline.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Amline 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.

3. How to take Amline

Always take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The usual initial dose is Amline 5 mg once daily. The dose can be increased to Amline 10 mg once daily. Your medicine can be used before or after food and drinks. You should take your medicine at the same time each day with a drink of water. Do not take Amline 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.

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor.

If you take more Amline than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, 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 Amline tablets.

If you forget to take Amline

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 forgotten dose.

If you stop taking Amline

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

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.

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; and inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

The following common side effects have been reported: 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, ankle swelling.

If any of these cause you problems or if they last for more than one week, you should contact your doctor.

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.

The following **uncommon** side effects were reported: mood changes, anxiety, depression, sleeplessness; trembling, taste abnormalities, fainting, 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; and weight increase or decrease.

The following side effects have been **rarely** reported: confusion.

The following side effects have been **very rarely** reported: 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 (hyperglycemia); a disorder of the nerves which can cause, muscular 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; and disorders combining rigidity, tremor, and/or movement disorders.

Not known: frequency cannot be estimated from the available data

- Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

If any of the side effects gets serious, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Amline

- Keep this medicine out of the sight and reach of children.
- Do not use your medicine after the expiry date which is stated on the blister and the outer packaging. The expiry date refers to the last day of that month.
- Do not store above 30°C. Keep away from light and humidity.
- Do not throw away any medicines via wastewater. 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 Amline contains

The active substance in Amline 5 mg tablets is amlodipine (as amlodipine besylate). The active substance in Amline 10 mg tablets is amlodipine (as amlodipine besylate). The other ingredients are microcrystalline cellulose, magnesium stearate, pregelatinized starch, silica colloidal anhydrous, sodium starch glycolate.

What Amline looks like and contents of the pack

Amline 5 mg tablets: White round shaped scored tablets.
Amline 10 mg tablets: White round shaped tablets.
Amline is available in boxes containing 30 tablets.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l. – Leidan-El
P.O. Box 90201 Jdeidet-El-Metn, Lebanon
Contact us: pharmaline@maliagroup.com

Amline 5 mg Reg. N° Lebanon 154820/1
Amline 10 mg Reg. N° Lebanon 154920/1

This is a medicament

- A 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 experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment for yourself.
- Do not repeat the same prescription without consulting your doctor.