

## PATIENT INFORMATION LEAFLET

### AMLOVAS 5 mg tablet

It is taken orally.

- **Active ingredient:** Each tablet contains 6,944 mg amlodipine besylate equivalent to 5 mg amlodipine base.
- **Excipients:** Microcrystalline cellulose, anhydrous dibasic calcium phosphate, sodium starch glycolate, magnesium stearate

**Before you start using this medicine, carefully read this PATIENT INFORMATION LEAFLET , because it contains important information for you.**

- *Keep this user manual. You can need to read again.*
- *If you have other questions, please talk your doctor or pharmacist.*
- *This medicine has been prescribed for you personally, do not give it to others.*
- *When you go to the doctor or hospital during the use of this medicine, tell your doctor that you are using this medicine.*
- *Follow exactly what is written in this instruction. Do not use **high or low** doses other than the dose recommended to you about the drug.*

### **In this leaflet:**

1. *What AMLOVAS is and what it is used for?*
2. *Things to be considered before you use AMLOVAS*
3. *How is AMLOVAS used?*
4. *What are the possible side effects?*
5. *Storage of AMLOVAS*

**Headings are included.**

1. **What AMLOVAS is and what it is used for?**

- AMLOVAS is taken by mouth and each tablet contains amlodipine besylate equivalent to 5 mg amlodipine. It belongs to the group of drugs known as calcium antagonists.
- AMLOVAS is available in blister packs of 20, 30 and 90 tablets.
- AMLOVAS is a medicine used to treat high blood pressure (hypertension) or a certain type of chest pain called angina.
- Hypertension: High blood pressure is caused by the pressure of the blood on the vessels. AMLOVAS reduces blood pressure by dilating the veins and making the blood circulate more easily in the veins.
- Angina is the feeling of pain or discomfort that occurs when not enough blood is getting to a part of the heart muscle. Angina is usually felt as pressure or squeezing pain in the chest area. Sometimes this pain can also be felt in the arms, shoulders, neck, jaw or back. AMLOVAS can relieve this pain.

## **2. Things to be considered before you use AMLOVAS**

### **DO NOT USE AMLOVAS in the following situations**

If,

- If you are allergic (hypersensitivity) to the active ingredient of AMLOVAS, amlodipine (amlodipine belongs to a group of drugs called dihydropyridine calcium channel blockers), dihydropyridines or any of its ingredients, or similar drugs that lower blood pressure (any calcium antagonists). This may be in the form of itching, skin redness, or shortness of breath.
- If you have severe low blood pressure (hypotension)
- If you have a narrowing of your heart valve (aortic stenosis) in the aorta (the largest artery coming out of the heart) or cardiogenic shock (a condition in which your heart cannot supply enough blood to your body)
- If heart failure has occurred after a heart attack

### **USE AMLOVAS CAREFULLY in the following situations**

Inform your doctor if you have or have had any of the following conditions:

- Recent heart attack (within the last months)
- Heart failure
- Severe elevation of your blood pressure (hypertensive crisis)

- Liver disease
- If you are elderly and need to increase the dose of medication

If these warnings apply to you, even at any time in the past, please consult your doctor.

### **Use in children and adolescents:**

AMLOVAS has not been studied in children under 6 years of age. AMLOVAS should only be used for hypertension in children and adolescents aged 6 to 17 years (see section 3).

Talk to your doctor for more detailed information.

### **Using AMLOVAS with food and drink**

You can take AMLOVAS before or after food and drink.

People taking AMLOVAS should not take grapefruit or grapefruit juice. This is because grapefruit or grapefruit juice can cause an increase in blood levels of the active ingredient, amlodipine, resulting in an unexpected increase in the blood pressure lowering effects of AMLOVAS.

### **Pregnancy**

*Consult your doctor or pharmacist before using this medication.*

The safety of AMLOVAS in humans during pregnancy has not been established. For this reason, your doctor may recommend AMLOVAS if you are pregnant but there is no safer treatment alternative and if your disease poses a greater risk to you and your baby.

If you think you are pregnant or are planning to become pregnant, tell your doctor before taking AMLOVAS.

Women of childbearing potential should ensure that they use effective contraception.

*If you realize that you are pregnant during your treatment, consult your doctor or pharmacist immediately.*

### **Breast-feeding**

*Consult your doctor or pharmacist before using this medication.*

Amlodipine has been shown to pass into breast milk in small amounts. If you are breastfeeding or will start breastfeeding, tell your doctor before using AMLOVAS.

### **Vehicle and machine use**

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

### **Concomitant use with other drugs**

In particular, if you are taking or have recently taken any of the following drugs; Inform your doctor or pharmacist:

AMLOVAS may affect or be affected by the following medicines:

- Ritonavir, indinavir, nelfinavir (drugs used to treat HIV, the virus that causes AIDS), which are called protease inhibitors
- Ketoconazole or itraconazole (drugs used in fungal infections)
- Verapamil, diltiazem (heart medications)
- Rifampicin, erythromycin, clarithromycin (antibiotics)
- Aaron's beard, a herbal product used in mild depression
- Dantrolene (a drug used intravenously against a severe increase in body temperature)
- Tacrolimus, sirolimus, temsirolimus, and everolimus (a medicine used to change the way your immune system works)
- Simvastatin (cholesterol lowering)
- Cyclosporine (an immunosuppressant drug)

If you are already taking other medicines to treat your high blood pressure, AMLOVAS can lower your blood pressure even more.

*If you are currently using or have recently used any prescription or non-prescription drugs, please inform your doctor or pharmacist about them.*

### **3. How is AMLOVAS used?**

#### **Instructions for proper use and dose / frequency of administration:**

Always strictly follow your doctor's or pharmacist's instructions when using AMLOVAS.

If you are unsure, ask your doctor or pharmacist.

The recommended starting dose is one (5 mg) tablet once a day. This dose may be increased to 10 mg of AMLOVAS daily.

Keep using the tablets. Do not wait for your tablets to run out to see your doctor.

**Application route and method:**

It is taken orally.

You can use your medicine before or after food and drink. Do not take AMLOVAS with grapefruit juice. Take care to take the medicine at the same time every day.

**Different age groups:****Use in children:**

The recommended antihypertensive oral dose in children and adolescents aged 6-17 years is 2.5-5 mg once daily. A 2.5 mg form of amlodipine is not available. AMLOVAS 5 mg tablets are not manufactured to be bisected and do not yield a 2.5 mg dose.

Doses above 5 mg per day have not been studied in pediatric patients.

The effect of AMLOVAS on blood pressure in patients under 6 years of age is unknown.

**Use in the elderly:**

Your doctor will not make a special dose adjustment for you.

**Special use cases****Kidney failure:**

Your doctor will not make a special dose adjustment for you.

**Liver failure**

If you have liver failure, your doctor will adjust the dose of AMLOVAS accordingly.

*If you have the impression that the effect of AMLOVAS is too strong or too weak, talk to your doctor or pharmacist.*

**If you use more AMLOVAS than you should:**

Taking too many tablets can cause your blood pressure to drop, or even dangerously low. You may feel light-headed, dizzy, faint, or weak. If your blood pressure drop is very severe, shock may occur. Your skin may feel cold and clammy and you may lose consciousness. If you have taken too many AMLOVAS tablets; seek emergency medical assistance.

*If you have used more than you should use from AMLOVAS, talk to a doctor or pharmacist.*

**If you forget to use AMLOVAS:**

Don't worry. If you forget to take a tablet, do not take that dose that day. Take your medicine at the right time the next day.

*Do not take a double dose to make up for forgotten doses.*

**Effects that may occur when treatment with AMLOVAS is terminated:**

Your doctor will tell you how long you should use AMLOVAS.

Do not stop your medication without consulting your doctor. If you stop using the drug earlier than recommended, your disease status may return to its previous state. Do not stop your medication without consulting your doctor.

If you have any questions about how to use AMLOVAS, ask your doctor or pharmacist.

**4. What are the possible side effects?**

Like all medicines, there may be side effects in people who are sensitive to the ingredients of AMLOVAS.

**If any of the following occur, stop using AMLOVAS and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:**

- Sudden wheezing, chest pain, shortness of breath or difficulty breathing
- Swelling of the eyelids, face or lips
- Swelling of the tongue and throat causing great difficulty in breathing
- Severe skin reactions including extensive skin rash, urticaria, skin redness all over your body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome), toxic epidermal necrolysis or other allergic reactions
- Heart attack, abnormal heartbeat
- Inflammation of the pancreas, which can cause severe abdominal and back pain, which the patient feels very bad about.

These are all very serious side effects. If you have one of these, you may need emergency medical attention or hospitalization.

Side effects are classified as shown in the following categories:

Very common : It can be seen in at least one of 10 patients.

Common : It can be seen less than one in 10 patients, but more than one in 100 patients.

- Uncommon : It can be seen less than one in 100 patients, but more than one in 1,000 patients.
- Rare : It can be seen less than one in 1,000 patients but more than one in 10,000 patients.
- Very rare : It can be seen in less than one in 10,000 patients.
- Unknown : It cannot be estimated from the available data.

The following **very common side effects** have been reported. If these side effects cause you problems or **last longer than a week, contact your doctor.**

### **Very common**

- Edema (fluid retention)

The following **common side effects** have been reported. If these side effects cause you problems or **last longer than a week, contact your doctor.**

### **Common**

- Headache, dizziness, somnolence (especially at the beginning of treatment)
- Palpitation (palpitation), skin flushing
- Abdominal pain, feeling of sickness (nausea)
- Changes in bowel movements, diarrhea, constipation, indigestion
- Fatigue, weakness
- Visual impairment, double vision
- Muscle cramps
- Swelling in the ankle

Other reported side effects are listed below. If any of these side effects get serious or if you notice any side effects not listed below in this leaflet, tell your doctor or pharmacist.

### **Uncommon**

- Mood swings, anxiety (anxiety, worry), depression, insomnia
- Tremors, impaired taste, fainting
- Numbness or tingling in your arms and legs, decreased pain sensation tinnitus

- Low blood pressure
- Discharge, sneezing due to inflammation (rhinitis) in the nasal wall
- Cough
- Dry mouth, vomiting
- Hair loss, increased sweating, itching on the skin, redness on the skin, skin discoloration
- Frequent urination, especially at night, urinary disorders
- Difficulty getting an erection, breast discomfort or enlargement of the breasts in men
- Pain, feeling unwell
- Joint or muscle pain, back pain
- Weight gain or decrease

**Rare**

- Confusion

**Very rare**

- A decrease in the number of white blood cells, a decrease in the number of clotting cells that can result in abnormal bruising or easy bleeding
- Increase in blood sugar (hyperglycemia)
- A nerve disorder that can cause muscle weakness, numbness or tingling
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abnormal liver functions, liver inflammation (hepatitis), yellowing of the skin (jaundice), elevated liver enzymes that may affect some medical tests
- Increase in muscle tension
- Inflammation of blood vessels, often with skin redness
- Sensitivity to light
- Disorders associated with stiffness, tremor and/or movement disorder

If any of these side effects get serious, consult a doctor.

*If you experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.*



## **5. Storage of AMLOVAS**

*Keep AMLOVAS out of the sight and reach of children and in its package.*

**Use in accordance with expiration date.**

Store at room temperature below 25°C.

Do not use AMLOVAS after the expiry date on the package.

Do not throw away expired or unused medicines! Give it to the collection system determined by the Ministry of Environment and Urbanization.

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