

## Amlocor 5 mg; 10 mg tablets

### *Amlopidine*

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider 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, health care provider or pharmacist.

#### **What is in this leaflet**

1. What is Amlocor and what it is used for
2. Before you take Amlocor
3. How to take Amlocor
4. Possible side effects
5. How to store Amlocor
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#### **1. What Amlocor is and what it is used for**

Amlocor belongs to a group of medicines called calcium channel blockers (calcium antagonists). It reduces the peripheral resistance of the blood vessels and leads to decrease of the high blood pressure. Amlocor improves the blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented.

Amlocor is indicated for the treatment of:

- High blood pressure (hypertension): alone or in combination with other blood pressure lowering medicines.
- Angina (various forms of ischemic heart disease due to restriction of blood supply to the heart resulting in chest pain): alone or in combination with other antianalgesic agents.
- Variant angina/Prinzmetal's angina (angina caused by contraction of the heart vessels)

#### **2. Before you take Amlocor**

##### **Do not take Amlocor:**

- if you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine, or to any other calcium antagonists;
- have severe hypotension (severe low blood pressure)
- have severe narrowing of the heart valve (aortic stenosis), unstable angina or cardiogenic shock;

##### **Take special care with Amlocor**

Tell your doctor about any allergies or health conditions you have or have had in the past especially if you have kidney or liver problems .

Please inform your doctor if you have recently had a heart attack or hypertensive crisis.

##### **Patients with heart failure**

Patients with heart failure should be treated with caution.

##### **Use in patients with impaired liver function**

Patients with impaired hepatic function may have delayed clearance of amlodipine. The dosage regimen is not defined. Therefore amlodipine should be used with caution in these patients.

##### **Use in elderly patients**

In elderly patients caution is required when increasing the dose.

##### **Use in patients with renal impairment**

Amlocor may be used at the usual doses in these patients. Amlocor is not dialyzable.

##### **Use in children (under 18 years of age)**

Amlocor should not be used in children.

##### **Taking other medicines, herbal or dietary supplements**

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

##### **Effect of other medicinal products on amlodipine**

In coadministration with medicinal products like ketoconazole, itraconazole, ritonavir, the plasma concentration of amlodipine may increase, therefore caution is required when amlodipine is used with these medicines.

Coadministration of the medicinal product rifampicin and *Hypericum perforatum*-containing medicines may lead to reduced plasma concentrations of amlodipine, therefore caution should be exercised in combination of amlodipine and these medicines.

Interaction studies have shown that grapefruit juice, cimetidine, aluminium/magnesium (antacids) and sildenafil had no effect on amlodipine action.

##### **Effects of amlodipine on other medicinal products**

Amlocor may potentiate the antihypertensive effect of other medicinal products that lower blood pressure.

In clinical interaction studies, amlodipine did not influence the effects of atorvastatin, digoxin, ethanol, warfarin or cyclosporine. Amlocor does not influence laboratory parameters

##### **Taking Amlocor with food and drink**

Amlocor may be taken before or after food and drink. There is no need of a special dietary regimen.

##### **Pregnancy and breast-feeding**

###### **Pregnancy**

The safety of amlodipine in pregnant women has not been established.

If you are pregnant or are planning to have a baby, ask your doctor for advice before taking Amlocor.

###### **Breast-feeding**

It is not known whether amlodipine is excreted in breast milk. It is necessary to decide whether to continue or stop breastfeeding during treatment with amlodipine taking into account the benefit of breastfeeding for the baby and the benefit of treatment for the mother.

**Ask your doctor, health care provider or pharmacist for advice before taking any medicine.**

##### **Driving and using machines**

Amlocor is unlikely to affect your ability to drive and use machines. If, following Amlocor administration, you have complaints such as dizziness, headache, fatigue or nausea, your ability to react may be impaired.

#### **3. How to take Amlocor**

**Always take Amlocor exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.**

##### **Adults:**

The usual dose for treatment of high blood pressure and angina pectoris is 5 mg once daily which may be increased by your doctor to 10 mg daily given as a single dose.

##### **Children (under 18 years of age)**

This product is not recommended for use in children. The safety and efficacy of the medicine are not established in children.

#### **Elderly patients**

A normal dosage regimen is recommended. Nevertheless, caution is required when increasing the dose.

#### **Patients with renal impairment**

Amlodipine may be used at the usual doses in these patients. Amlodipine is not dialyzable.

#### **Patients with hepatic impairment**

In patients with hepatic impairment, no dosage regimen has been defined, therefore amlodipine should be administered with caution.

#### **If you take more Amlonor than you should**

*If you take more Amlonor than prescribed, seek immediate medical attention.*

Overdose of amlodipine may lead to blood vessels dilation with prolonged lowering of the blood pressure and possible complications of the cardiovascular system.

#### **Treatment**

Clinically significant low blood pressure as a result of overdose of amlodipine, requires placing the patient in supine position, with raising of the arms and legs and careful infusion of saline solution. Vital signs should be strictly monitored and symptomatic treatment initiated if necessary. Hemodialysis is ineffective.

#### **If you forget to take Amlonor**

If you forget to take a tablet, take the next dose at the right time.

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

#### **If you stop taking Amlonor**

Do not stop treatment with Amlonor without consulting your doctor. Your doctor will determine the duration of treatment and how to discontinue it.

*If you have any further questions on the use of this product, ask your doctor, health care provider or pharmacist.*

## **4. Possible side effects**

*Like all medicines, Amlonor can cause side effects, although not everybody gets them.*

The adverse reactions below are classified according to MedRA frequency and system organ class. The frequency grouping is defined using the following convention: Very common ( $\geq 1/10$ ); Common ( $\geq 1/100$  to  $< 1/10$ ); Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ); Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); Very Rare ( $< 1/10,000$ ); and Not known (cannot be estimated from the available data).

#### **Blood and lymphatic system disorders**

**Very rare:** changes in blood cell composition, with decreased number of white blood cells or decrease in blood platelets.

#### **Immune system disorders**

**Very rare:** allergic reactions

#### **Metabolism and nutrition disorders**

**Very rare:** increased sugar in blood

#### **Psychiatric disorders**

**Uncommon:** sleeplessness, mood changes, anxiety, depression

#### **Nervous system disorders**

**Common:** sleepiness, dizziness, headache (especially at the beginning of treatment)

**Uncommon:** trembling, taste abnormalities, syncope, reduced sense of touch, tingling sensation

**Very rare:** hypertension, peripheral nerve disorders

#### **Eye disorders**

**Uncommon:** visual disturbances, double vision

#### **Ear and labyrinth disorders**

**Uncommon:** ringing in the ears

#### **Cardiac disorders**

**Uncommon:** palpitations

**Very rare:** myocardial infarction, arrhythmia (abnormal heart rhythm)

#### **Vascular disorders**

**Common:** reddening of the skin

**Uncommon:** low blood pressure

**Very rare:** cough

#### **Gastrointestinal disorders**

**Common:** abdominal pain, nausea

**Uncommon:** vomiting, impaired digestion, diarrhea, constipation, dry mouth

**Very rare:** pancreatitis, gastritis, swelling of the gums

#### **Hepato-biliary disorders**

**Very rare:** hepatitis (liver inflammation), jaundice, elevation of liver enzymes

#### **Skin and subcutaneous tissue disorders**

**Uncommon:** hair loss, red patches on skin, skin discoloration, increased sweating, itchy skin, rash

**Very rare:** photosensitivity (sensitivity to light), urticaria, severe hypersensitivity reactions such as angioedema, exfoliative dermatitis, Stevens-Johnson syndrome, Quincke oedema

#### **Musculoskeletal system and connective tissue disorders**

**Common:** ankle swelling

**Uncommon:** joint or muscle pain, muscle cramps, back pain

#### **Kidney and urinary tract disorders**

**Uncommon:** disorder in passing urine, increased need to urinate at night, increased number of times of passing urine

#### **Reproductive system and breast disorders**

**Uncommon:** impotence, gynecomastia (enlargement of the breasts in men)

#### **General disorders and administration site conditions**

**Common:** swelling, tiredness

**Uncommon:** chest pain, weakness, pain, feeling unwell

#### **Investigations**

**Uncommon:** weight increase or decrease

*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.*

## **5. How to store Amlonor**

Keep out of the reach and sight of children.

Store under 30°C.

Do not use this medicine after the expiry date which is stated on the pack. 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.

## **6. Further information**

### **What Amlonor contains**

- The active substance is amlodipine. Each tablet contains 5 mg or 10 mg amlodipine as amlodipine besilate.

- The other ingredients are: cellulose, microcrystalline; calcium hydrogenphosphate, anhydrous; sodium starch glycolate; magnesium stearate.

### **What Amlonor looks like and contents of the pack**

Amlonor is supplied as tablets.

The tablets are white or almost white, round and flat.

3 blisters of 10 tablets or 2 blisters of 15 tablets with a patient information leaflet in a box.

### **Marketing Authorisation Holder and Manufacturer**

ADIPHARM EAD

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Sofia 1700, Bulgaria

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