

# Amlophar®

**Calcium-Channel Blocker**  
**Antihypertensive, Anti-anginal Agent**  
**Capsules**

**5mg**  
**Amlodipine (as Amlodipine Besylate)**

**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 any 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 side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Amlophar is and what it is used for
2. Before you take Amlophar
3. How to take Amlophar
4. Possible side effects
5. How to store Amlophar
6. Further information

#### 1. What Amlophar is and what it is used for

**Amlophar** contains the active substance amlodipine which belongs to a group of medicines called calcium antagonists.

**Amlophar** 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, **Amlophar** 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. Before you take Amlophar

##### Do not take Amlophar

- If you are allergic (hypersensitive) to amlodipine, or any of the other ingredients of this medicine listed in section 6. Further information, 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 **Amlophar**.

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

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

##### Other medicines and Amlophar

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

**Amlophar** 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, sirolimus, temsirolimus, and everolimus (medicines used to alter the way your immune system works)
- Simvastatin (cholesterol lowering medicine)
- Cyclosporine (an immunosuppressant)

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

##### Amlophar with food and drink

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

##### Pregnancy and breast-feeding

###### Pregnancy

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 **Amlophar**.

###### 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 **Amlophar**.

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

##### Driving and using machines

**Amlophar** may affect your ability to drive or use machines. If the capsules 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 Amlophar

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended initial dose is **Amlophar** 5mg once daily. The dose can be increased to 10mg 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 **Amlophar** with grapefruit juice.

##### Use in children and adolescents

For children and adolescents (6-17 years old), the recommended usual starting dose is 2.5mg a day. The maximum recommended dose is 5mg a day. It is important to keep taking the capsules. Do not wait until your capsules are finished before seeing your doctor.

##### If you take more Amlophar than you should

Taking too many capsules 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 **Amlophar** capsules.

##### If you forget to take Amlophar

Do not worry. If you forget to take a capsule, 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 Amlophar

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.**

#### 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, toxic epidermal necrolysis) or other allergic reactions
- Heart attack, abnormal heart beat
- Inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

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**

- Oedema (Fluid retention)

The following **common side effects** have been reported. If any of these cause 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
- Ankle swelling

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
- 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 discolouration
- 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
- Excess sugar in blood (hyperglycaemia)
- 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
- 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

#### 5. How to store Amlophar

- Keep out of the reach and sight of children.
- Do not take **Amlophar** after the expiry date which is stated on the carton and on the blister.
- Store below 30°C, in a dry place.
- Do not take **Amlophar** if you notice any visible sign of deterioration.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Further Information

##### What Amlophar contains

The active ingredient is Amlodipine. Each capsule contains 5mg of Amlodipine as Amlodipine Besylate.

The other ingredients: Microcrystalline cellulose, dibasic calcium phosphate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, gelatin, quinoline yellow E104 and titanium dioxide E171.

##### What are the available packs of Amlophar

**Amlophar** Capsules are available in packs of 30 capsules (2 blisters of 15 capsules each).

#### 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 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 the children

**Council of Arab Health Ministers,  
Union of Arab Pharmacists**



Produced by: **jufphar**  
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