



Amlorine 5 Tablets 5 mg

Amlorine 10 Tablets 10 mg

Read 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 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 or pharmacist.

In this leaflet:

1. What Amlorine is and what it is used for
2. Before you take Amlorine
3. How to take Amlorine
4. Possible side effects
5. How to store Amlorine
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1. WHAT AMLORINE IS AND WHAT IT IS USED FOR

Amlorine 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. Amlorine is also indicated in prophylaxis of chronic stable angina pectoris.

Amlorine belongs to a group of drugs called calcium antagonists. In patients with high blood pressure Amlorine works by relaxing the blood vessels, so that blood passes through them more easily. In angina the heart receives too little oxygen. Amlorine widens the blood vessels of the heart, so that the heart receives more oxygen and as a result chest pain is prevented.

2. BEFORE YOU TAKE AMLORINE

Do not take Amlorine:

- if you are hypersensitive (allergic) to amlopidine, other calcium antagonists or to any of the ingredients of the product.
- if you experience cardiogenic shock.
- if you suffer from aortic stenosis (narrowing of the aortic heart valve).
- if you suffer from unstable angina.
- if you are pregnant, planning to become pregnant or if you are breast-feeding.

Take special care with Amlorine:

- if you had a heart attack.
- if you suffer from impaired liver function.
- if you are in hypertensive crisis.

As experience is insufficient Amlorine should not be used in children.

Taking other medicines:

Always tell your doctor or pharmacist if you are taking, or have recently taken any, other medicines. This includes medicines obtained without prescription, natural remedies and strong vitamins and minerals.

Taking Amlorine with food and drink:

You can take Amlorine with food and drink.

Pregnancy and Breastfeeding:

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

Pregnancy:

Amlorine should not be administered during pregnancy or to women of child bearing potential, unless effective contraception is used.

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

Breastfeeding:

Amlorine should not be administered to women who are breastfeeding.

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

Driving and using machines:

Use of Amlorine is unlikely to impair a patient's ability to drive or use machinery.

3. HOW TO TAKE AMLORINE

Take Amlorine tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure. The usual dose is:

Adults:

The normal dose is 5 mg daily. If necessary the dose can be increased to 10 mg once daily, depending on the individual patient's response.

Elderly

Normal dosage regimens are recommended as for adults.

Patients with impaired liver function

The dose must be adjusted. Follow your doctor's instructions.

Patients with renal impairment

Normal dosage is recommended.

The tablet should be taken with a glass of water.

If you take more Amlorine than you should:

Contact your doctor or emergency department if you have taken more Amlorine than stated in this leaflet or more than the doctor has prescribed. Take this leaflet and any tablets you still have with you.

If you forget to take Amlorine:

If you forgot to take a dose, take it as soon as you remember it unless it is nearly time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amlorine:

The treatment must only be changed or stopped in consultation with your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Amlorine can cause side effects.

Common side effects (occurring in between 1 and 10 in 100 patients):

Headache, dizziness, somnolence, palpitations, flushing, abdominal pain, nausea, oedema, fatigue.

Uncommon side effects (occurring in between 1 and 10 in 1,000 patients):

Insomnia, mood changes, tremor, taste perversion, syncope, hypoaesthesia, paraesthesia, visual disturbances, tinnitus, hypotension, dyspnoea, rhinitis, vomiting, dyspepsia, altered bowel habits, dry mouth, alopecia, purpura, skin discolouration, increased sweating, pruritus, rash, arthralgia, myalgia, muscle cramps, back pain, micturition disorder, nocturia, increased urinary frequency, impotence, gynaecomastia, chest pain, asthenia, pain, malaise, weight increase, weight decrease.

Amlorine

Rare side effects (occurring in between 1 and 10 in 10,000 patients):

Thrombocytopenia, allergic reactions, hyperglycaemia, peripheral neuropathy, myocardial infarction, arrhythmia, ventricular tachycardia and atrial fibrillation, vasculitis, coughing, pancreatitis, gastritis, gingival hyperplasia, hepatitis, jaundice and hepatic enzyme elevations, angioedema, erythema multiforme, urticaria.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE AMLORINE

Keep out of the reach and sight of children.

Expiry date:

Do not use Amlorine after the expiry date stated on the inner and outer packaging.

Storage Conditions:

Store below 25°C, away from light and moisture.

6. FURTHER INFORMATION

What Amlorine contains:

- The active substance is Amlodipine Besilate equivalent to Amlodipine 5 mg or 10 mg respectively.
- The other ingredients are Microcrystalline Cellulose, Calcium Phosphate, Sodium Starch Glycolate and Magnesium Stearate.

Pack sizes:

Amlorine 10 mg Tablets and Amlorine 5 mg Tablets: They come in pack sizes of 10, 14, 20, 28, 30, 50, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Remedica Ltd, Limassol Industrial Estate, Limassol, Cyprus, EU.

This leaflet was last approved on:

Amlorine
5 (100) mg TABLETS