

AMLOPRES

Consumer Medication Information Leaflet (RiMUP)

Amlodipine Besylate USP 5 mg & 10 mg Tablets

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What AMLOPRES is used for

AMLOPRES 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.

How AMLOPRES works

Amlodipine is one of a group of medicines called calcium antagonists. In patients with high blood pressure your medicine works by relaxing blood vessels, so that blood passes through them more easily. In patients with angina amlodipine works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Your medicine does not provide immediate relief of chest pain from angina.

Before you use AMLOPRES

- When you must not use it

- if you are allergic (hypersensitive) to Amlodipine, or any of the other ingredients of your medicine, or to any other calcium antagonists. This may be itching, reddening of the skin or difficulty in breathing.
- if you have narrowing of the aortic heart valve (aortic stenosis), unstable angina or cardiogenic shock;
- If you are pregnant or breast feeding.

- Before you start to use it

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

Pregnancy

The safety of AMLOPRES in human pregnancy has not been established.

If you think you might be pregnant, or are planning to get pregnant, tell your doctor before you take AMLOPRES. Women of childbearing potential should ensure that they use effective contraception.

- Taking other medicines

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

AMLOPRES 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)
- simvastatin (a cholesterol lowering medicine).

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

How to use AMLOPRES

- How much to use

Always take your medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are still not sure.

Adults: Starting dose for high blood pressure and angina: 5 mg once a day. Depend on the individual patient's response, the dosage may be increased to a maximum dose of 10 mg.

For children, safety and effectiveness of amlodipine have not been established.

- When to use it

It is best to take your medicine at the same time each day with a drink of water. Do not take amlodipine tablets with grapefruit juice.

- How long to use it

It is important to keep taking the tablets. Do not wait until your tablets are finished before seeing your doctor. 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 how to take this product, ask your doctor or pharmacist.

- If you forget to use it

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a missed dose.

- If you use too much (overdose)

Contact your doctor, the hospital, or your pharmacist immediately if you have taken more AMLOPRES than written in this leaflet, or more than your doctor has prescribed.

While you are using AMLOPRES

- Things you must do

Taking AMLOPRES with food

Your medicine can be used before or after food.

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- Things you must not do

Taking AMLOPRES with drink

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

Breast-feeding

It is not known whether amlodipine is passed into breast milk. If you are breast-feeding or about to start breast-feeding you must tell your doctor before taking AMLOPRES.

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

- Things to be careful of

Driving and using machines

AMLOPRES 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.

Side effects

The most common adverse effects of amlodipine are associated with its vasodilator action (widening of the blood vessels) and often diminish on continued therapy. They include dizziness, flushing, headache, hypotension, peripheral oedema (swelling of the ankles, feet or fingers), tachycardia (faster heart beat), and palpitations (a noticeably rapid, strong, or irregular heartbeat). Nausea (feeling sick) and other gastrointestinal disturbances, increased micturition (periodic discharge of urine from the bladder through the urethra) frequency, lethargy (mental and physical sluggishness), eye pain, visual disturbances, and mental depression have also occurred.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.gov.my [(Consumers-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of AMLOPRES

- Storage

Do not use your medicine after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

Keep out of the reach and sight of children.

Do not store above 30°C.

- Disposal

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.

Product description

- What it looks like

Amlopres-5

White to off white, round tablets with ‘5’ debossed on one side and plain on other side.

Amlopres-10

White to off white, round tablets with ‘10’ debossed on one side and plain on other side.

- Ingredients

Amlopres-5

Active ingredient:

Amlodipine (as amlodipine besylate) 5mg

Inactive ingredients:

Dibasic calcium phosphate (dehydrate), Microcrystalline cellulose (Avicel PH 102), Sodium Starch Glycolate (Primojel), Colloidal anhydrous Silica (Aerosil – 200), Magnesium stearate.

Amlopres-10

Active ingredient:

Amlodipine (as amlodipine besylate) 10mg

Inactive ingredients:

Dibasic calcium phosphate (dehydrate), Microcrystalline cellulose (Avicel PH 102), Sodium Starch Glycolate (Primojel), Colloidal anhydrous Silica (Aerosil – 200), Magnesium stearate.

- MAL number

Amlopres- 5

MAL11030011AZ

Amlopres- 10

MAL11030005AZ

Manufacturer and Product Registration Holder

Manufacturer

Cipla Ltd.
L-139 to L-146
Verna Industrial Estate
Verna Goa
India

Product Registration Holder

CIPLA MALAYSIA SDN BHD
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