

AMLOPRES TABLETS

Consumer Medication Information Leaflet (RiMUP)

Amlodipine Besilate 5 mg & 10 mg

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What AMLOPRES is used for

Your medicine 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 take 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 take it

You should inform your Doctor if you have or have had any of the following conditions:

- Recent heart attack or heart failure
- Severe increase in blood pressure (Hypertensive Crisis)
- Liver disease

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:

- Atorvastatin (cholesterol lowering agent)
- Digoxin (works on the heart)
- Warfarin (reduces thickness of blood)
- Cyclosporin (a medicine that completely suppresses body defence mechanism)
- Sildenafil (medicine for erectile dysfunction)
- Cimetidine (blocks acidity of stomach)

How to use AMLOPRES

How much to take

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.

The usual initial dose is 5 mg amlodipine once daily. If necessary, your doctor may increase the dose to 10 mg amlodipine once daily

When to use it

It is best to take your medicine at the same time each day with a drink of water.

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 take it

Do not worry. If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a missed dose.

If you use too much (overdose)

Taking too many tablets 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 calmly and you could lose consciousness. Seek immediate medical attention if you take too many AMLOPRES tablets.

While you are using AMLOPRES

Things you must do

Swallow the tablets with a glass of water. **DO NOT CHEW.**

Things you must not do

Breastfeeding

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

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

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Things to be careful of

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

Like all medicines AMLOPRES can cause side effects, although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine.

Although they are very rare, the symptoms can be severe.

- 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 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 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 side-effects: affects 1 to 10 users in 100

- Headache, dizziness, sleepiness (especially at the beginning of treatment)
- Palpitations (awareness of your heartbeat), flushing
- Abdominal pain, feeling sick (nausea)
- Ankle swelling (oedema), tiredness

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 side-effects: affects 1 to 10 users in 1,000

- Mood changes, anxiety, depression, sleeplessness
- Trembling, taste abnormalities, fainting, weakness. Numbness or tingling sensation in your limbs; loss of pain sensation
- Visual disturbances, double vision, ringing in the ears
- Low blood pressure
- Shortness of breath/running nose caused by inflammation of lining of nose (rhinitis)
- Altered bowel habit, diarrhea, constipation, indigestion, dry mouth, vomiting (being sick)
- Hair loss, increased sweating, itchy skin, red patches on skin, skin discoloration
- 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
- Weakness, pain, feeling unwell
- Joint or muscle pain, muscle cramps, back pain
- Weight increase or decrease

Very rare: affects less than 1 user in 10,000

- Decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- Excess sugar in blood (hyperglycaemia)
- A disorder of the nerves which can cause weakness, tingling or numbness
- Cough
- Swelling of the gums
- Abdominal bloating (gastritis)
- Abdominal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests

- Inflammation of blood vessels, often with skin rash

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction monitoring by calling Tel: 03-78835550 or visiting the website portal.bpfk.gov.my (consumers → reporting)

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 25°C

Disposal

Medicines should not be disposal of via wastewater of 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

What Amlodipine Tablets 5 mg looks like

Description: White round tablets with “5” debossed on one side and plain on other side

What Amlodipine Tablets 10 mg looks like

Description: White to off white round tablets with “10” debossed on one side and plain on other side

Ingredients

Active ingredients

The active pharmaceutical ingredient is Amlodipine (as amlodipine besilate)

Inactive ingredients

Dibasic calcium phosphate (dehydrate), Microcrystalline

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Cellulose (Avicel PH 102), Sodium Starch Glycolate (Primojel), Colloidal Anhydrous Silica (Aerosil-200), Magnesium Stearate

MAL number:

AMLOPRES-5: MAL11030011A

AMLOPRES-10: MAL11030005A

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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Date of Revision

21/05/2014