

AMCARDIA TABLET 5 mg & 10 mg

(Amlodipine 5 mg & 10 mg)

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What AMCARDIA is used for

1. AMCARDIA is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.
2. Chronic Stable Angina. AMCARDIA is indicated for the treatment of chronic stable angina. AMCARDIA may be used alone or in combination with other antianginal agents.
3. Vasospastic Angina (Prinzmetal's or Variant Angina). AMCARDIA is indicated for the treatment of confirmed or suspected vasospastic angina. AMCARDIA may be used as monotherapy or in combination with other antianginal drugs

How AMCARDIA works

If you suffer from high blood pressure, AMCARDIA works by relaxing blood vessels, so that blood passes through them more easily.

If you suffer from angina, AMCARDIA works by

improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. AMCARDIA does not provide immediate relief of chest pain from angina.

Before you use AMCARDIA

- When you must not use it

Do not take AMCARDIA tablets, if you

- are allergic to AMCARDIA or similar calcium channel blockers (the so-called dihydropyridine derivatives like felodipine, nifedipine, nimodipine) or to any of the other ingredients.
- are suffering from cardiogenic shock. This is a condition where the heart is unable to pump sufficient blood around the body. The symptoms of cardiogenic shock are low blood pressure, low pulse and fast heartbeat.
- are suffering from narrowing of the aorta (aortic stenosis).
- suffer from chest pain at rest or with minimal effort (unstable angina pectoris).
- are pregnant or breast-feeding.
- have severe low blood pressure.

- Before you start to use it

Before taking AMCARDIA tablets, tell your doctor if you

- have heart failure or have suffered a heart attack during the past month.
- have liver problems
- are giving this medicine to a child under 18 years of age

- are elderly, your doctor may monitor you closely.

- 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.

Some medicines (including medicines obtained without prescription, herbal medications or natural products) may interact with AMCARDIA. This means that the action of both medicines can be changed.

In particular, tell your doctor if you are taking any of the following medicines:

- Medicines that can lower blood pressure (e.g. verapamil, diltiazem)
- Ketoconazole and itraconazole (antifungal medicines used to treat skin and fungal infections)
- HIV-protease-inhibitors (antiviral medicines used to treat HIV infections, e.g. ritonavir)
- Clarithromycin, erythromycin and telithromycin, rifampicin, rifabutin (antibiotics)
- Nefazodone (medicine to treat depression)
- St. John's wort (Hypericum perforatum; herbal medicine for depression)
- Dexamethasone (corticosteroid used to treat inflammatory and autoimmune conditions such as rheumatoid arthritis)
- Phenobarbital, phenytoin and carbamazepin (medicines for epilepsy)

- Nevirapine (antiviral medicine used to treat HIV and AIDS)
- Sildenafil (medicine for impotence)

Children

Safety and effectiveness have been studied in 6-17 year old boys and in girls. AMCARDIA tablets has not been studied in children under the age of 6 years. For more information, talk to your doctor.

Pregnancy and breast-feeding

You should not take this medicine if you are pregnant or breastfeeding. If you are of child bearing age, you should ensure that you use effective contraceptive protection during your treatment. If you become pregnant whilst taking these tablets, contact your doctor immediately for advice.

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

How to use AMCARDIA

- How much to use

For both hypertension and angina the usual initial dose is 5mg amlodipine once daily which may be increased to a maximum dose of 10mg.

Use in Children

This product is not recommended in children as the safety and effectiveness of amlodipine in children have not been established.

- When to use it

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

Taking AMCARDIA tablets with food and drink

AMCARDIA tablets should be taken with a glass of liquid (e.g. a glass of water) with or without food.

- How long to use it

If you stop taking AMCARDIA tablets

Your doctor has told you how long you should take AMCARDIA. If you stop the treatment suddenly, your symptoms may come back. Do not stop the treatment earlier than agreed without discussing this with your doctor. An AMCARDIA tablet is usually used for long term treatment.

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

- If you forget to use it

If you have forgotten to take a tablet, you can still take it up to 12 hours after you usually take your tablet. If it is more than 12 hours after the time that you should have taken the tablet, you should not take the missed dose and you should take the next tablet at the usual time. Never take a double dose of AMCARDIA tablets to make up for the dose that you have missed.

- If you use too much (overdose)

If you or someone else has taken too much AMCARDIA, contact your nearest hospital casualty department. Please carry with you the product leaflet or remaining tablets for better identification of the doctor. The person concerned should be made to lie down with their arms and legs up (resting on a couple of cushions, for example). Symptoms of an overdose are: extreme dizziness and/or feeling very light-headed,

problems with breathing, having to urinate very often.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things to be careful of

Driving and using machines

Some patients may experience side effects such as dizziness, sleepiness or blurred vision whilst taking these tablets (see section 4 of this leaflet). Such side effects are more likely to occur at the start of treatment or following an increase in dose. If you suffer from these effects, you should not drive or perform other activities that require you to be alert.

Side effects

Like all medicines, AMCARDIA tablets 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, difficulty in breathing, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).

The following side effects have been observed during treatment with AMCARDIA tablets:

Very common (Occurring in more than 1 in 10 patients treated)

- swollen ankles

Common (Occurring in less than 1 in 10, but more than 1 in 100 patients treated)

- headache (especially at the beginning of treatment),

- sleepiness, dizziness, weakness
- a quicker or irregular heartbeat, nausea, digestive problems, stomach pain
- facial redness and feeling hot (especially at the beginning of treatment)

Uncommon (Occurring in less than 1 in 100, but more than 1 in 1000 patients treated)

- enlarged breasts in men
- sleep disorders, irritability, depression
- feeling unwell, dry mouth, uncontrolled shaking, pins and needles, increased sweating
- problems with your eye-sight (visual disturbances)
- ringing or buzzing in the ears
- fainting, increased heart rate, chest pain, aggravation of angina may occur at the beginning of the treatment
- low blood pressure, inflammation of the blood vessels
- breathing difficulties, inflammation of the nasal mucosa, cough
- vomiting, diarrhea, constipation, swollen gums
- prickling and tingling sensation of the skin, itching, nettle rash, hair loss, discolouration of the skin
- muscle cramps, back pain, muscle and joint pain
- increased need to urinate
- impotence, enlargement in breast size of males.
- increase or decrease in weight

Rare (Occurring in less than 1 in 1000, but more than 1 in 10000 patients treated)

- confusion, mood changes including anxiety
- change in taste

- increase of certain liver enzymes; yellowing of the skin or whites of the eyes, this could be the result of abnormal liver function or inflammation of the liver

Very rare (Occurring in less than 1 in 10000 patients treated, including isolated cases)

- reduced number of white blood cells, which may cause unexplained fever, sore throat, and flu-like symptoms.
- reduced number of blood platelets in blood, which may cause easy bruising or nasal bleeding.
- increase of the blood sugar level.
- pain or numbness in hands and feet.
- inflammation of the stomach lining, inflammation of the pancreas.
- allergic reaction with swelling of the skin of face or extremities, swelling of lips or tongue, swelling of the mucous membranes in the mouth and throat, resulting in shortness of breath and difficulty to swallow. Contact an emergency room or a doctor immediately if this occurs.
- in isolated cases allergic skin rash with irregular red spots, caused by medicines or severe allergic reactions with blistering eruptions of the skin and mucous membranes have been observed.

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.

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 AMCARDIA

- Storage

Keep out of the reach and sight of children.

Do not use your tablets after the expiry date stated on the carton or label.

This medicine requires no special precautions for storage. Store tablets in the original package.

- 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

White to off-white round flat tablets with break line on one side.

- Ingredients

- Active ingredient (s)

AMCARDIA TABLET 5MG

- AMCARDIA contains 6.930 mg Amlodipine Besilate equivalent to Amlodipine 5.00 mg

AMCARDIA TABLET 10 mg

- AMCARDIA contains 13.87 mg Amlodipine Besilate equivalent to Amlodipine 10.00 mg

- Inactive ingredients

Colloidal anhydrous silica,
microcrystalline cellulose,
maize starch, magnesium
stearate and purified water.

- MAL number:

AMCARDIA TABLET 5 MG
MAL08111770A
AMCARDIA TABLET 10 mg
MAL08111771A

Manufacturer

**UNIQUE
PHARMACEUTICAL
LABORATORIES**
(A Div of J.B.Chemicals &
Pharmaceuticals Limited)
Plot No.216-219, G.I.D.C.
Industrial Area, Panoli 394
116, Gujarat State, India.

Product Registration Holder

Unimed Sdn Bhd
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Date of revision

- 11/06/2013