

AMCARDIA TABLETS

Amlodipine Besilate (5mg, 10mg)

What is in this leaflet

1. What Amcardia Tablet is used for
2. How Amcardia Tablet works
3. Before you use Amcardia Tablet
4. How to use Amcardia Tablet
5. While you are using it
6. Side effects
7. Storage and Disposal of Amcardia Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Amcardia Tablet is used for

Amcardia Tablet is used for the treatment of hypertension and chest pain. It may be used alone or in combination with other antihypertensive and antianginal (treat chest pain) medicines.

How Amcardia Tablet works

Amcardia contains an active ingredient, Amlodipine Besilate which belongs to a class of drugs called calcium channel blockers. Amlodipine blocks calcium from entering certain tissues and arteries. This makes it easier for them to relax so that blood can flow more easily to the heart which then helps in lowering the blood pressure and reduces risk of heart attack or stroke.

Before you use Amcardia Tablet

- When you must not use it

Do not use Amcardia Tablet if:

- You are sensitive to amlodipine or any other ingredients of this product.

Pregnancy and lactation

Do not take Amcardia Tablet if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Amcardia Tablet if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine. It is recommended that breast-feeding be discontinued while Amcardia is administered.

- Before you start to use it

Do not take Amcardia Tablet if you have:

- Heart failure

- Liver failure
- Taken/taking medications that reduce your blood pressure

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Amcardia Tablet

- How much to use

The initial dose is 5mg once daily which may be increased to a maximum dose of 10mg depending on the individual's response.

Use in the Elderly:

A normal dosage regimen is recommended. Amcardia Tablet, used at similar doses in elderly or younger individual, is equally well tolerated.

Use in Patients with Impaired Liver Function:

As with all calcium antagonists, amlodipine half-life is prolonged in individuals with impaired liver function and dosage recommendations have not been established. The drug should therefore be administered with caution in these individuals.

Use in Renal Failure:

Amlodipine may be used in such individuals at normal doses.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Amcardia Tablet for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the

medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of overdosage includes;

- Hypotension (low blood pressure)
- Effect of calcium entry blockade

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Amcardia Tablet.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Amcardia Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine 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, Amcardia Tablet can cause side effects, although not everybody gets them. Tell your doctor or pharmacist immediately if you experience any of the following side effects after taking this medicine as the symptoms can be severe.

Most common:

- headache
- swelling

Cardiovascular:

- irregular heartbeat
- slower than normal heart rate
- chest pain
- low blood pressure
- deficient blood distribution to the limbs
- temporary loss of consciousness
- tachycardia (fast or irregular heart rate)
- balance trouble
- blood pressure falls when suddenly standing up from a lying or sitting position

Central and Peripheral Nervous System:

- reduced sense of touch or sensation
- burning or prickling sensation
- tremor
- sensation of spinning dizziness

Gastrointestinal:

- anorexia (eating disorder)
- constipation
- indigestion
- difficulty swallowing
- diarrhea
- farting
- vomiting
- increase in the size of the gums

General:

- weakness
- back pain
- hot flushes (sudden feeling of feverish heat)
- uneasiness
- pain
- severe chills with violent shivering

- weight gain

Musculoskeletal System:

- joint pain
- wear and tear on the joints
- muscle cramps
- muscle pain

Psychiatric:

- sexual dysfunction (male and female)
- difficulty falling and/or staying asleep
- nervousness
- depression
- abnormal dreams
- anxiety
- depersonalization (feeling of being detached from one's thoughts, feelings, and body)

Respiratory System:

- Shortness of breath
- nosebleeds

Skin and Appendages

- severe itchy skin
- rash
- redness of the skin or mucous membranes
- flat or raised red bump on the skin

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.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Amcardia Tablet**- Storage**

Keep out of the reach and sight of children.

Store in a dry place, below 30°C. Protect from light.

- 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)
Amlodipine Besilate

- Inactive ingredients
Colloidal Anhydrous Silica, Magnesium Stearate, Maize Starch, Microcrystalline Cellulose and Purified Water.

- MAL number(s):

Amcardia Tablet 5mg
MAL08111770AZ

Amcardia Tablet 10mg
MAL08111771AZ

Manufacturer

Unique Pharmaceutical Laboratories
Plot No. 215-219, GIDC Industrial Area Panoli, Dist. Bharuch 394116, India

Product Registration Holder

Unimed Sdn. Bhd.
53, Jalan Tembaga SD 5/2B,
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Date of revision

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