

AMTAS TABLET

Amlodipine Besylate Tablets 5 mg and 10 mg.

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What Amtas tablets is used for

This medicine is used to treat patients suffering from:

1. Mild to moderate high blood pressure.
2. Angina pectoris:
 - (a) Chest pain due to narrowing of the coronary arteries of the heart muscle (chronic stable angina).
 - (b) The rarer form of chest pain caused by cramping of the coronary arteries of the heart muscle (vasospastic angina / Prinzmetal's or variant angina)

How Amtas works

Amlodipine is designed to work with your body by relaxing your body vessels, causing them to widen. This allows your blood to flow more easily, which in turn lets your heart work more efficiently, placing less strain on your arteries and heart. By reducing your heart workload, Amlodipine helps to keep your heart healthy.

Before you use Amtas

- When you must not use it

- If you have ever had an allergic reaction to Amlodipine or other calcium channel blockers.
- If you are allergic to any of the ingredients listed at the end of this leaflet.

- Before you start to use it

Tell your healthcare provider about all of your medical conditions, if you:

- are pregnant or intend to become pregnant while taking Amlodipine.
- are breastfeeding or wish to breastfeed.
- are allergic to any foods, dyes, preservatives or any other medicines.
- have any health problems, including:
 - heart disease such as heart failure
 - liver problems
 - any other allergies

- Taking other medicines

Taking other medicines: Some medicines may interact with Amlodipine. This means that the action of both medicines can be changed.

It is therefore important to tell your doctor if you take any of the following medicines:

- Other medicines that can lower blood pressure e.g., beta-blockers, ACE-inhibitors, alpha-1-blockers and diuretics. Amlodipine may enhance the blood pressure lowering effects of these medicines.

Medicines that may enhance the effect of Amlodipine are:

- Diltiazem
- Ketoconazole and itraconazole
- HIV-proteinase-inhibitors (e.g., ritonavir)

- Erythromycin

Medicines that may lower the effect of Amlodipine are:

- Rifampicin
- St. John's wort
- Dexamethasone (cortisone) may reduce the effect of Amlodipine
- Phenobarbital, phenytoin and carbamazepine
- Nevirapine

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

How to use Amtas

- How much to use

Take Amlodipine exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

The usual dose of Amlodipine is one 5 mg tablet each day. Your doctor may increase this to one 10 mg tablet each day.

Your doctor may prescribe another dose of Amlodipine depending on your condition and how you respond to this medicine.

- When to use it

Swallow the tablet whole with a full glass of water.

Take your tablet at about the same time each day, either morning or evening.

Taking your tablet at the same time each day will have the best

effect. It will also help you to remember when to take it. Amlodipine can be taken with or without food

- How long to use it

You must take Amlodipine every day. Continue taking your medicine for as long as your doctor tells you.

- If you forget to use it

If you miss a dose and it is less than 12 hours from when you should take it, take it straight away, and then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for hints.

- If you use too much (overdose)

If you have accidentally taken more than the prescribed dose, contact your nearest casualty department or tell your doctor/pharmacist immediately.

While you are using Amtas

- Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Amlodipine.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking Amlodipine.

If you become pregnant while taking Amlodipine, tell your doctor immediately.

- Things you must not do

Do not take Amlodipine to treat any other conditions unless your doctor says so.

Do not give this medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Amlodipine affects you. Amlodipine may cause dizziness or drowsiness in some people and affect alertness.

If this occurs, do not drive, operate machinery or do things that could be dangerous if you are not alert.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Like all medicines, Amlodipine can cause side effects, although not everybody gets them.

The following side effects have been observed during treatment with Amlodipine:

Common:

- Headache (especially at the beginning of treatment), drowsiness, dizziness
- flushing
- Nausea, stomach pain
- Ankle swelling
- generalized swelling (oedema)
- Tiredness

Uncommon:

- Sleeplessness, mood changes (including anxiety), depression
- Uncontrolled shaking (tremor), disturbed sense of taste, fainting (syncope), decreased skin sensitivity, (hypoesthesia), Tingling or numbness (paraesthesia)
- Problems with your eye-sight (visual disturbances)
- ringing or buzzing in the ears (tinnitus)
- Abnormal heartbeat (palpitations)
- Low blood pressure (hypotension) with signs of dizziness and light-headedness
- Breathing difficulties, runny or stuffy nose and sneezing (rhinitis)
- vomiting, stomach discomfort after meal (dyspepsia), altered bowel habits (including diarrhoea and constipation), dry mouth
- prickling and tingling sensation of the skin (exanthema), itching, nettle rash, hair loss, discolouration of the skin, purple skin patches (purpura), increased sweating
- Muscle cramps, back pain, muscle and joint pain
- Increased need to urinate (increased micturition frequency), passing abnormally large quantity of urine during the night, increased urinary frequency
- Impotence, breast enlargement in men
- Chest pain, weakness, pain, generally feeling unwell
- Increase or decrease in weight

Rare:

- Confusion

Very rare:

- reduced number of white blood cells, which may cause unexplained fever, sore throat, and flu-like symptoms (leukopenia)
- reduced number of blood platelets in blood, which may cause easy bruising or nasal bleeding (thrombocytopenia)
- Allergic reactions
- Increase of the blood sugar level
- increased muscle stiffness with poor control of movement (hypertonia)
- Pain or numbness in hands and feet (peripheral neuropathy) Heart attack (myocardial infarction), irregular heart beat (including slow heartbeat, fast heart rate and irregular heart beat)
- Inflammation of a blood vessel with signs of rash, purplish-red spots, fever and itching (vasculitis)
- cough
- Inflammation of the stomach lining, which causes stomach pain and nausea (gastritis); inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis), swollen gums (gingival hyperplasia)
- 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
- allergic reaction (angioedema), allergic skin rash with irregular red spots, caused by medicines (erythema exsudativum multiforme), nettle rash, severe allergic reactions with blistering eruptions of the skin and mucous membranes (exfoliative

dermatitis, Stevens-Johnson Syndrome)

- increased sensitivity of the skin to sun.

If any of the side effects get 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 visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Amtas

- Storage

Keep medicines out of the reach of children.
Store below 30°C.

- Disposal

If your doctor tells you to stop taking Amlodipine tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

- What it looks like

Amlodipine Tablets are available with two strengths:

- AMTAS-5: White to off white, round, flat, uncoated tablets with bevelled edges having breakline on one side and plain on other side.
- AMTAS-10: White to off white, round, flat, uncoated tablets with bevelled edges having breakline on one side and plain on other side.

- Ingredients

-Active Ingredient

The active substance is Amlodipine Besylate equivalent to Amlodipine.

-Inactive Ingredients

Dibasic Calcium Phosphate, Microcrystalline Cellulose, Povidone (K-30), Purified Water, Isopropyl Alcohol, Aluminium Magnesium Silicate, Sodium Starch Glycolate, Talc & Magnesium Stearate.

- MAL Number:

Amtas 5mg tablets:

MAL08031353AZ

Amtas 10mg tablets:

MAL08031352AZ

Manufacturer:

INTAS PHARMACEUTICALS LIMITED

Plot numbers 457, 458 & 191/218P, Sarkhej-Bawla Highway, Matoda, Sanand, Ahmedabad, Gujarat, IN-382210, INDIA.

Product Registration Holder:

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24/04/2023

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