
SUMMARY OF INFORMATION ABOUT AMLODIPINE BESYLATE TABLETS

Amlodipine Besylate Tablets 2.5 mg, 5 mg and 10 mg Rx only

Read this information carefully before you start amlodipine besylate tablets and each time you refill your prescription. There may be new information. This information does not replace talking with your doctor. If you have any questions about amlodipine besylate tablets, ask your doctor. Your doctor will know if amlodipine besylate tablets are right for you.

What are amlodipine besylate tablets?

Amlodipine besylate tablets are a type of medicines known as a calcium channel blocker (CCB). They are used to treat high blood pressure (hypertension) and a type of chest pain called angina. They can be used by itself or with other medicines to treat these conditions.

High Blood Pressure (hypertension)

High blood pressure comes from blood pushing too hard against your blood vessels. Amlodipine besylate tablets relaxes your blood vessels which lets your blood flow more easily and helps lower your blood pressure. Drugs that lower blood pressure lower your risk of having a stroke or heart attack.

Angina

Angina is a pain or discomfort that keeps coming back when part of your heart does not get enough blood. Angina feels like a pressing or squeezing pain, usually in your chest under the breastbone. Sometimes you can feel it in your shoulders, arms, neck, jaws, or back. Amlodipine besylate tablets can relieve this pain.

Who should not use amlodipine besylate tablets?

Do not use amlodipine besylate tablets if you are allergic to amlodipine, (the active ingredient in amlodipine besylate tablets), or to the inactive ingredients. Your doctor or pharmacist can give you a list of these ingredients.

What should I tell my doctor before taking amlodipine besylate tablets?

Tell your doctor about any prescription and non-prescription medicines you are taking, including natural or herbal remedies. Tell your doctor if you:

- ever had heart disease
- ever had liver problems
- are pregnant, or plan to become pregnant. Your doctor will decide if amlodipine besylate tablets are the best treatment for you.
- are breast-feeding. Do not breast feed while taking amlodipine besylate tablets. You can stop breastfeeding or take a different medicine.

How should I take amlodipine besylate tablets?

- Take amlodipine besylate tablets once a day, with or without food. You can take amlodipine besylate tablets with most drinks, including grapefruit juice.
- It may be easier to take your dose if you do it at the same time every day, such as with breakfast, dinner, or at bedtime. Do not take more than one dose of amlodipine besylate tablets at a time.
- If you miss a dose, take it as soon as you remember. Do not take amlodipine besylate tablets if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time.
- **Other medicines:** You can use nitroglycerin and amlodipine besylate tablets together. If you take nitroglycerin for angina, don't stop taking it while you are taking amlodipine besylate tablets.
- While you are taking amlodipine besylate tablets, do not stop taking your other prescription medicines, including any other blood pressure medicines, without talking to you doctor.
- If you took too much amlodipine besylate tablets, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.

What should I avoid while taking amlodipine besylate tablets?

- Do not breastfeed. It is not known if amlodipine besylate tablets will pass through your milk.
- Do not start any new prescription or non-prescription medicines or supplements, unless you check with your doctor first.

What are the possible side effects of amlodipine besylate tablets?

Amlodipine besylate tablets may cause the following side effects. Most side effects are mild or moderate:

- headache
- swelling of your legs or ankles
- tiredness, extreme sleepiness
- stomach pain, nausea
- dizziness
- flushing (hot or warm feeling in your face)
- arrhythmia (irregular heartbeat)
- heart palpitations (very fast heartbeat)

It is rare, but when you first start amlodipine besylate tablets or increase your dose, you may have a heart attack or your angina may get worse. If that happens, call your doctor right away or go directly to a hospital emergency room.

Tell your doctor if you are concerned about any side effects you experience. These are not all the possible side effects of amlodipine besylate tablets. For a complete list, ask your doctor or pharmacist.

How do I store amlodipine besylate tablets?

Keep amlodipine besylate tablets away from children. Store amlodipine besylate tablets at 20°–25°C (68°–77°F).

Keep amlodipine besylate tablets out of the light. Do not store in the bathroom.

Keep amlodipine besylate tablets in a dry place.

General advice about amlodipine besylate tablets

Sometimes, doctors will prescribe a medicine for a condition that is not written in the patient information leaflets. Only use amlodipine besylate tablets the way your doctor told you to. Do not give amlodipine besylate tablets to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or doctor for information about amlodipine besylate tablets, or you can visit the Lupin website at www.lupinpharmaceuticals.com or call (410) 576 – 2000.

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Mumbai 400 098

INDIA

Revised July 2007

ID#: 212225