Sildenafil
A single 100 mg dose of sildenafil in subjects with essential hypertension had no effect on the ...
ultrasound.
Figure 1 - Kaplan-Meier Analysis of Composite Clinical Outcomes for Amlodipine Besylate versus 
Placebo

DOSAGE FORMS AND STRENGTHS

Important Limitation:
• Pediatric starting dose: 2.5 mg to 5 mg once daily. (2.2)

7.5  Sildenafil

HIGHLIGHTS OF PRESCRIBING INFORMATION
° Chronic Stable Angina 
and myocardial infarctions.
Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes 
and myocardial infarctions. (4.5)
Gradual onset of action, acute hypotension is unlikely. (5.1)
Amlodipine besylate tablets may be used alone or in combination with other antihypertensive agents.

11 DESCRIPTION

Amlodipine besylate tablets are indicated for the treatment of confirmed or 
angina and to reduce the risk of a coronary revascularization procedure.
Amlodipine besylate tablets are indicated for the treatment of confirmed or 
myocardial oxygen demand, at any given level of exercise.
Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC).
Control of high blood pressure should be part of comprehensive cardiovascular risk management, including, in 
management, lifestyle changes, dietary changes, and, in some cases, drug therapy. Starting therapy at 
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14 CLINICAL STUDIES

The usual initial antihypertensive oral dose of amlodipine besylate tablets is 5 mg once daily, and the 
dose may be increased after 1-2 weeks if necessary to a maximum of 10 mg once daily. (2.5)

12 CLINICAL STUDIES

For several abnormal electrocardiograms that appeared to be benign, there was no evidence of 
serious structural abnormalities in the 12 patients who received amlodipine besylate tablets.

12 CLINICAL STUDIES

Edema 5.6 14.6 1.4 5.1

Edema, peripheral edema, leg swelling, facial edema, fluid retention, weight increase, and 
swelling.

9 IN SPECIFIC POPULATIONS


dose-related within the recommended dosing range. Effects on diastolic 
with little difference in peak and trough effect. Tolerance was not demonstrated in patients studied for 
up to 4 years. (12.3)

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values were reported with or without evidence of angina in a subset of 16% of patients, median (7.5) and 
within recommended dosing range. Effects on diastolic 
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up to 4 years. (12.3)

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9 IN SPECIFIC POPULATIONS

In a nonclinical study in rats, amlodipine besylate 
caused a marked peripheral vasodilation and 
markedly increased heart rate and blood pressure in 
the absence of a significant change in cardiac output. (5.1)

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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, jaw, or back. Angina can cause your blood pressure to go up. It may be easier to take your dose if you do it at the same time every day, such as with breakfast or dinner, or at bedtime. If you take more than one dose of amlodipine besylate tablets at a time, it may be easier to take your dose if you do it at the same time every day, such as with breakfast or 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 ritonavir and amlodipine tablets together. If you take ritonavir for angina, don’t stop taking it while you are taking amlodipine 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 your 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 nonprescription 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:

- swelling of your legs or ankles
- tiredness, extreme sleepiness
- stomach pain, nausea
- dizziness
- flushing (hot or warm feeling in your face)
- headache

If it is rare, but when you first start taking 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 room temperature 20° to 25°C (between 68° to 77°F). Keep amlodipine besylate tablets out of the light. Do not store in the bathroom. Keep amlodipine besylate tablets in a dry place.

Protect from light.

General advice about amlodipine besylate tablets

Sometimes, doctors will prescribe a medicine for a condition that is not written in the patient information leaflet. 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 Epic Pharma website at www.epicpharma.com or call 1-888-374-2791.

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