

FDA-Approved Patient Labeling

AMLODIPINE BESYLATE AND BENAZEPRIL HYDROCHLORIDE CAPSULES

Read this Patient Information leaflet before you start taking amlodipine besylate and benazepril hydrochloride capsules and each time you get a refill. There may be new information. This leaflet does not replace talking with your doctor. If you have any questions, ask your doctor or pharmacist.

What is the most important information I should know about amlodipine besylate and benazepril hydrochloride capsules?

Amlodipine besylate and benazepril hydrochloride capsules can harm an unborn baby and even cause death. If you get pregnant, stop taking amlodipine besylate and benazepril hydrochloride capsules. Call your doctor right away. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.

What is amlodipine besylate and benazepril hydrochloride capsule?

Amlodipine besylate and benazepril hydrochloride capsule contains two prescription medicines that work together to lower blood pressure: amlodipine besylate (the active ingredient found in Norvasc[®]), a calcium channel blocker, and benazepril hydrochloride (Lotensin[®]), an ACE inhibitor. Your doctor will prescribe amlodipine besylate and benazepril hydrochloride capsules only after other medicines haven't worked.

High Blood Pressure (hypertension). Blood pressure is the force of blood in your blood vessels. You have high blood pressure when the force is too much. Amlodipine besylate and benazepril hydrochloride capsules can help your blood vessels relax so your blood pressure is lower. Amlodipine besylate and benazepril hydrochloride capsules have not been studied in children.

Who should not take amlodipine besylate and benazepril hydrochloride capsules?

Don't take amlodipine besylate and benazepril hydrochloride capsules if you are allergic to any of the ingredients. There is a complete list at the end of this leaflet.

What should I tell my Doctor before taking amlodipine besylate and benazepril hydrochloride capsules?

Tell your doctor about all your medical conditions, including if:

- **you are pregnant or plan to become pregnant.** See "What is the most important information I should know about amlodipine besylate and benazepril hydrochloride capsules?"
- **you are breastfeeding.** Amlodipine besylate and benazepril hydrochloride may pass into your milk. Don't breastfeed while you are taking amlodipine besylate and benazepril hydrochloride capsules.
- you have a heart condition
- you have liver problems
- you have kidney problems
- you have diabetes (high blood sugar)
- you have systemic lupus erythematosus (SLE), scleroderma or a collagen vascular disease. Ask your doctor if you are not sure.

Keep a list of your medicines with you, including vitamins and natural or herbal remedies, to show your doctor or pharmacist. Some of your other medicines and amlodipine besylate and benazepril hydrochloride capsules could affect each other, causing serious side effects. Tell your doctor about all your medicines, especially:

- medicines for high blood pressure or heart failure
- water pills, extra potassium or a salt substitute
- Lithium (Eskalith[®], Lithobid[®])

How do I take amlodipine besylate and benazepril hydrochloride capsules?

- Take amlodipine besylate and benazepril hydrochloride capsules exactly as your doctor tells you.
- Take amlodipine besylate and benazepril hydrochloride capsules at the same time each day, with or without food.
- If you miss a dose, take it as soon as you remember. If it is more than 12 hours, just take your next dose at the regular time.
- Your doctor may test for kidney problems or check your blood potassium level.
- If you take too much amlodipine besylate and benazepril hydrochloride capsules, call your doctor or Poison Control Center, or go to the emergency room.
- Tell all your doctors or dentist you are taking amlodipine besylate and benazepril hydrochloride capsules if you:
 - are going to have surgery
 - are getting allergy shots for bee stings
 - go for kidney dialysis

What are the possible side effects of amlodipine besylate and benazepril hydrochloride capsules?

Amlodipine besylate and benazepril hydrochloride capsules can cause serious side effects including:

- **serious allergic reactions that can be life threatening.**

Stop amlodipine besylate and benazepril hydrochloride capsules and get emergency help right away if you get:

- swelling of your face, eyelids, lips, tongue or throat
- have trouble swallowing
- asthma (wheezing) or other breathing problems

These allergic reactions are rare but happen more times in people who are African-American.

- **low blood pressure** (hypotension). Low blood pressure is most likely to happen if you also take water pills, are on a low salt diet, get dialysis treatments, have heart problems, or get sick with vomiting or diarrhea. Lie down if you feel faint or dizzy.
- **liver problems.** Call your doctor if:
 - you have nausea
 - you feel more tired or weaker than usual
 - you have itching
 - your skin or eyes look yellow

- you have pain in your upper right stomach
- you have flu-like symptoms
- **low white blood cells.** Low white blood cells happen more in people who have kidney problems and collagen vascular diseases. Low white blood cells can give you a higher chance for getting infections. Call your doctor if you get a fever, sore throat, or other signs of infection that do not go away.
- **kidney problems.** Kidney problems may get worse in people that already have kidney disease. Some people will have changes on blood tests for kidney function and need a lower dose of amlodipine besylate and benazepril hydrochloride capsules. Call your doctor if you get swelling in your feet, ankles, or hands or unexplained weight gain.
- **more chest pain and heart attacks** in people that already have severe heart problems. Get emergency help if you get worse chest pain or chest pain that does not go away.

The more common side effects of amlodipine besylate and benazepril hydrochloride capsules are:

- Cough
- Dizziness
- Headache
- Swelling of the feet, ankles, and hands

These are not all side effects of amlodipine besylate and benazepril hydrochloride capsules. For a complete list, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

How do I store amlodipine besylate and benazepril hydrochloride capsules?

- Store amlodipine besylate and benazepril hydrochloride capsules at room temperature (59 to 86°F).
- Keep amlodipine besylate and benazepril hydrochloride capsules in a closed container in a dry place.
- Keep amlodipine besylate and benazepril hydrochloride capsules and all medicines out of the reach of children.

General Information about amlodipine besylate and benazepril hydrochloride capsules

Doctors can also use medicine for a condition that is not in the patient information leaflet. Take amlodipine besylate and benazepril hydrochloride capsules the way your doctor tells you. Do not share it with other people. It may harm them.

For more information, ask your doctor or pharmacist, address medical inquiries to www.lupinpharmaceuticals.com or 1- 800-399-2561.

What are the ingredients in amlodipine besylate and benazepril hydrochloride capsules?

Active ingredients: amlodipine besylate (the active ingredient found in Norvasc[®]), benazepril hydrochloride (Lotensin[®])

Inactive ingredients: crospovidone, hydrophobic fumed silica, lactose anhydrous, magnesium stearate, microcrystalline cellulose, povidone, gelatin, titanium dioxide (not present in 10 mg/20 mg strength), black iron oxide, red iron oxide (present in 5 mg/10 mg, 5 mg/20 mg and

10 mg/ 20 mg strength), yellow iron oxide, (present in 5 mg/10 mg strength), D&C Yellow #10 (present in 5 mg/40 mg strength), FD&C Blue #1 (present in 10 mg/40 mg strength), FD&C Blue #2 (present in 10 mg/20 mg strength), FD&C Green #3 (present in 5 mg/40 mg strength), FD&C Red #40 (present in 10 mg/40 mg strength), FD&C Yellow #6 (present in 5 mg/ 40 mg strength), shellac, propylene glycol, potassium hydroxide.

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