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Patient Information

Amlodipine and Benazepril Hydrochloride Capsules, USP (am loe' di peen and ben az' e pril hye' droe klor' ide)

Read this Patient Information leaflet before you start taking amlodipine 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 and benazepril hydrochloride capsules?

- **Amlodipine and benazepril hydrochloride capsules can cause harm or death to an unborn baby.**
- **Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant.**
- **If you get pregnant while taking amlodipine and benazepril hydrochloride capsules, tell your doctor right away.**

What are amlodipine and benazepril hydrochloride capsules?

Amlodipine and benazepril hydrochloride capsules contains 2 prescription medicines that work together to lower blood pressure: amlodipine besylate, a calcium channel blocker, and benazepril hydrochloride, an ACE inhibitor. Your doctor will prescribe amlodipine 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 and benazepril hydrochloride capsules can help your blood vessels relax so your blood pressure is lower.

Amlodipine and benazepril hydrochloride capsules have not been studied in children.

Who should not take amlodipine and benazepril hydrochloride capsules?

Don't take amlodipine 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 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 and benazepril hydrochloride capsules?"
- **you are breastfeeding.** Amlodipine and benazepril hydrochloride is present in human milk. It is not known whether amlodipine and benazepril hydrochloride capsules affects your breastfed baby or milk production.
- you have a heart condition
- you have liver problems
- you have kidney problems
- you are about to have an operation (including dental surgery) or emergency treatment
- you are suffering from several episodes of vomiting or diarrhea
- you are treated for hyperkalemia (too much potassium in the blood)

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 and benazepril hydrochloride capsules could affect each other, causing serious side effects. Tell your doctor about all your medicines, especially:

- Simvastatin (a medicine used to control elevated cholesterol)
- medicines for high blood pressure or heart failure
- water pills, extra potassium or a salt substitute
- Lithium
- potassium-containing medicines, potassium supplements or salt substitutes containing potassium
- cyclosporine, an immunosuppressant medicine used in transplanted patients to reduce the risk of organ rejection
- indometacin and other nonsteroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain and inflammation
- insulin or oral antidiabetics, medicines that help a person with diabetes to control their level of glucose (sugar) in the blood
- gold for the treatment of rheumatoid arthritis
- probenecid, a medicine used to treat gout and hyperuricemia
- medicines used to prevent and treat fungal skin infections (e.g., ketoconazole, itraconazole)
- medicines used to treat AIDS or HIV infections (e.g., ritonavir, indinavir)
- medicines used to treat bacterial infections (e.g., clarithromycin)
- medicines used in organ transplant recipients or for treating some cancers (e.g. temsirolimus, sirolimus, everolimus)

Avoid alcohol until you have discussed the matter with your doctor. Alcohol may make blood pressure fall more and/or increase the possibility of dizziness or fainting.

How do I take amlodipine and benazepril hydrochloride capsules?

- Take amlodipine and benazepril hydrochloride capsules exactly as your doctor tells you.
- Take amlodipine 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 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 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 and benazepril hydrochloride capsules?

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

- **serious allergic reactions that can be life threatening.** Stop amlodipine 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 problemsThese 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
- **kidney problems.** Some people will have changes on blood tests for kidney function and need a lower dose of amlodipine 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 and benazepril hydrochloride capsules are:

- dizziness, fainting on standing up
- cough (dry, nonproductive, mainly at night, continuing)
- swelling of the feet, ankles, and hands

If any of these affects you severely, tell your doctor.

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

You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

How do I store amlodipine and benazepril hydrochloride capsules?

- Store amlodipine and benazepril hydrochloride capsules from 68°F to 77°F (20°C to 25°C).
- Keep amlodipine and benazepril hydrochloride capsules in a closed container in a dry place.
- Keep amlodipine and benazepril hydrochloride capsules and all medicines out of the reach of children.

General Information about amlodipine and benazepril hydrochloride capsules

Doctors can also use medicine for a condition that is not in the patient information leaflet. Take amlodipine 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, or call Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784).

What are the ingredients in amlodipine and benazepril hydrochloride capsules, USP?

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

Inactive ingredients: hard gelatin capsules, microcrystalline cellulose and talc.

The capsule shells for the different strengths contain the following ingredients:

10 mg/40 mg: FD&C Blue # 2, gelatin and titanium dioxide

The capsules are imprinted with edible black ink comprised of ammonium hydroxide, iron oxide black, propylene glycol and shellac.

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