

Patient Information

Amlodipine/Valsartan/Hydrochlorothiazide

(am-LOE-di-peen, val-SAR-tan, HYE-droe-klor-oh THYE-a-zide) Tablets

Read the Patient Information that comes with amlodipine/valsartan/hydrochlorothiazide before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about Amlodipine/Valsartan/Hydrochlorothiazide?

- Amlodipine/valsartan/hydrochlorothiazide 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/valsartan/hydrochlorothiazide, tell your doctor right away.

What is Amlodipine/Valsartan/Hydrochlorothiazide?

Amlodipine/valsartan/hydrochlorothiazide contains 3 prescription medicines:

1. amlodipine a calcium channel blocker
2. valsartan, an angiotensin receptor blocker, and
3. hydrochlorothiazide a diuretic (water pill)

Amlodipine/valsartan/hydrochlorothiazide may be used to lower blood pressure in adults when 2 medicines to lower your high blood pressure are not enough.

Amlodipine/valsartan/hydrochlorothiazide has not been studied in children under 18 years of age.

Who should not take Amlodipine/Valsartan/Hydrochlorothiazide?

Do not take Amlodipine/Valsartan/Hydrochlorothiazide if you have low or no urine output (anuria).

What should I tell my doctor before taking Amlodipine/Valsartan/Hydrochlorothiazide?

Tell your doctor about all of 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/valsartan/hydrochlorothiazide?**”
- **are breastfeeding or plan to breastfeed.** Amlodipine/valsartan/hydrochlorothiazide is present in human milk. It is not known whether amlodipine/valsartan/hydrochlorothiazide affects your breastfed baby or milk production. Do not breastfeed while you are taking amlodipine/valsartan/hydrochlorothiazide.
- are allergic to any of the ingredients in amlodipine/valsartan/hydrochlorothiazide. See the end of this leaflet for a list of the ingredients in amlodipine/valsartan/hydrochlorothiazide.
- have heart problems
- have liver problems
- have kidney problems
- are vomiting or having a lot of diarrhea
- have or had gallstones
- have Lupus
- have low levels of potassium (with or without symptoms such as muscle weakness, muscle spasms, abnormal heart rhythm) or magnesium in your blood
- have high levels of calcium in your blood (with or without symptoms such as nausea, vomiting, constipation, stomach pain, frequent urination, thirst, muscle weakness, and twitching).
- have high levels of uric acid in the blood.
- have ever had a reaction called angioedema, to another blood pressure medicine. Angioedema causes swelling of the face, lips, tongue, and may cause difficulty breathing.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some of your other medicines and amlodipine/valsartan/hydrochlorothiazide could affect each other, causing serious side effects.

Especially tell your doctor if you take:

- simvastatin or other cholesterol-lowering medicine
- other medicines for high blood pressure or a heart problem
- water pills (“diuretics”)
- potassium supplements. Your doctor may check the amount of potassium in your blood periodically.
- salt substitute containing potassium. Your doctor may check the amount of potassium in your blood periodically.
- diabetes medicine, including insulin
- narcotic pain medicines
- sleeping pills and antiseizure medicines called barbiturates
- lithium, a medicine used to treat some types of depression
- aspirin or other medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), like ibuprofen or naproxen
- steroids
- alcohol
- digoxin or other digitalis glycosides (a heart medicine)
- muscle relaxants (medicines used during operations)
- certain cancer medicines, like cyclophosphamide or methotrexate
- medicines used to prevent and treat fungal infections (such as ketoconazole, itraconazole)
- medicines used to treat bacterial infections (such as clarithromycin, telithromycin)
- certain antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporine) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of valsartan.

Know the medicines you take. Keep a list of your medicines and show it to your doctor or pharmacist when you get a new medicine.

How should I take Amlodipine/Valsartan/Hydrochlorothiazide?

- Take amlodipine/valsartan/hydrochlorothiazide exactly as your doctor tells you.
- Take amlodipine/valsartan/hydrochlorothiazide one time each day.
- Amlodipine/valsartan/hydrochlorothiazide can be taken with or without food.
- If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at the regular time.
- If you take too much amlodipine/valsartan/hydrochlorothiazide, call your doctor or Poison Control Center, or go to the emergency room.
- Tell all your doctors and dentist you are taking amlodipine/valsartan/hydrochlorothiazide. This is especially important if you:
 - o are going to have surgery
 - o go for kidney dialysis

What are the possible side effects of Amlodipine/Valsartan/Hydrochlorothiazide?

Amlodipine/valsartan/hydrochlorothiazide may cause **serious side effects** including:

- **harm to an unborn baby causing injury or death.** See “**What is the most important information I should know about Amlodipine/Valsartan/Hydrochlorothiazide?**”
- **low blood pressure** (hypotension). Low blood pressure is most likely to happen if you:
 - o take water pills
 - o are on a low-salt diet
 - o have heart problems
 - o get dialysis treatments
 - o get sick with vomiting or diarrhea
 - o drink alcohol.

Lie down if you feel faint or dizzy. If you faint (lose consciousness), stop taking amlodipine/valsartan/hydrochlorothiazide. Call your doctor right away.

- Get emergency help if you get worse chest pain or chest pain that does not go away.
- **kidney problems.** Kidney problems may become worse in people that already have kidney disease. Some people will have changes in blood tests for kidney function and may need a lower dose of amlodipine/valsartan/hydrochlorothiazide. Call your doctor if you have swelling in your feet, ankles, or hands, or unexplained weight gain. If you have heart failure, your doctor should check your kidney function before prescribing amlodipine/valsartan/hydrochlorothiazide.
- **laboratory blood test changes in people with heart failure.** Some people with heart failure who take valsartan, one of the medicines in amlodipine/valsartan/hydrochlorothiazide, have changes in blood tests including increased potassium and decreased kidney function.
- **allergic reactions**
- **skin rash.** Call your doctor right away if you get an unusual skin rash.
- **eye problems.** One of the medicines in amlodipine/valsartan/hydrochlorothiazide can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting amlodipine/valsartan/hydrochlorothiazide. Tell your doctor right away if you have:
 - o decrease in vision
 - o eye pain

The **most common** side effects of amlodipine/valsartan/hydrochlorothiazide include:

- dizziness
- swelling (edema) of the hands, ankles, or feet
- headache
- indigestion
- tiredness
- muscle spasms
- back pain
- nausea

Protect your skin from the sun and undergo regular skin cancer screening, as one of the medicines in amlodipine/valsartan/hydrochlorothiazide may cause non-melanoma skin cancer.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of amlodipine/valsartan/hydrochlorothiazide. For more information, 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.

How should I store Amlodipine/Valsartan/Hydrochlorothiazide?

- Store amlodipine/valsartan/hydrochlorothiazide at 68° to 77°F (20° to 25°C).
- Keep amlodipine/valsartan/hydrochlorothiazide dry (protect it from moisture).

Keep Amlodipine/Valsartan/Hydrochlorothiazide and all medicines out of the reach of children.

General Information about Amlodipine/Valsartan/Hydrochlorothiazide

Medicines are sometimes prescribed for conditions that are not mentioned in the patient information leaflet. Do not use amlodipine/valsartan/hydrochlorothiazide for a condition for which it was not prescribed. Do not give amlodipine/valsartan/hydrochlorothiazide to other people, even if they have the same symptoms that you have. It may harm them.

This patient information leaflet summarizes the most important information about amlodipine/valsartan/hydrochlorothiazide. If you would like more information about amlodipine/valsartan/hydrochlorothiazide, talk with your doctor. You can ask your doctor or pharmacist for information about amlodipine/valsartan/hydrochlorothiazide that is written for health professionals. For more information go to www.strides.com or call 1-877-244-9825.

What are the ingredients in Amlodipine/Valsartan/Hydrochlorothiazide?

Active ingredients: amlodipine besylate, valsartan and hydrochlorothiazide

The inactive ingredients for all strengths of the tablets include microcrystalline

cellulose, crospovidone, colloidal silicon dioxide, and magnesium stearate. Additionally, the **5/160/12.5 mg** strength contains polyethylene glycol, polyvinyl alcohol, lactose monohydrate, triethyl citrate, hypromellose, titanium dioxide and talc; the **10/320/25 mg** strength contains the same ingredients as the **5/160/12.5 mg** strength with the exception of the talc; the **5/160/25 mg** strength contains lactose monohydrate, hypromellose, triacetin, D&C Yellow #10, titanium dioxide, and FD&C Yellow #6; the **10/160/12.5 mg** strength contains FD&C Yellow #6, triethyl citrate, yellow iron oxide, hypromellose and titanium dioxide; and the **10/160/25 mg** strength contains hypromellose, titanium dioxide, D&C Yellow #10, macrogol and polysorbate.

What is high blood pressure (hypertension)?

Blood pressure is the force of blood in your blood vessels when your heart beats and when your heart rests. You have high blood pressure when the force is too much. Amlodipine/valsartan/hydrochlorothiazide can help your blood vessels relax so your blood pressure is lower. Medicines that lower blood pressure lower your chance of having a stroke or heart attack.

High blood pressure makes the heart work harder to pump blood throughout the body and causes damage to blood vessels. If high blood pressure is not treated, it can lead to stroke, heart attack, heart failure, kidney failure and vision problems.

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