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Information for Patients

Patient Information

Amlodipine, Valsartan and Hydrochlorothiazide (am-LOE-dih-peen, val-SAR-tan and hye-droe-klor-oh-THYE-ah-zide) Tablets USP

Rx Only

Read the Patient Information that comes with amlodipine, valsartan and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets?

- Amlodipine, valsartan and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets, tell your doctor right away.

What are amlodipine, valsartan and hydrochlorothiazide tablets?

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

Amlodipine, valsartan and hydrochlorothiazide tablets have not been studied in children under 18 years of age.

Who should not take amlodipine, valsartan and hydrochlorothiazide tablets?

Do not take amlodipine, valsartan and hydrochlorothiazide tablets if you have low or no urine output (anuria).

What should I tell my doctor before taking amlodipine, valsartan and hydrochlorothiazide tablets?

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 and hydrochlorothiazide tablets?**”

- **are breastfeeding or plan to breastfeed.** Amlodipine, valsartan and hydrochlorothiazide is present in human milk. It is not known whether amlodipine, valsartan and hydrochlorothiazide tablets affects your breastfed baby or milk production. Do not breastfeed while you are taking amlodipine, valsartan and hydrochlorothiazide tablets.
- are allergic to any of the ingredients in amlodipine, valsartan and hydrochlorothiazide tablets. See the end of this leaflet for a list of the ingredients in amlodipine, valsartan and hydrochlorothiazide tablets.
- 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 and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets?

- Take amlodipine, valsartan and hydrochlorothiazide tablets exactly as your doctor tells you.
- Take amlodipine, valsartan and hydrochlorothiazide tablets one time each day.
- Amlodipine, valsartan and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets, call your doctor or Poison Control Center, or go to the emergency room.
- Tell all your doctors and dentist you are taking amlodipine, valsartan and hydrochlorothiazide tablets. This is especially important if you:
 - are going to have surgery
 - go for kidney dialysis

What are the possible side effects of amlodipine, valsartan and hydrochlorothiazide tablets?

Amlodipine, valsartan and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets?**”
- **low blood pressure** (hypotension). Low blood pressure is most likely to happen if you:
 - take water pills
 - are on a low -salt diet
 - have heart problems
 - get dialysis treatments
 - get sick with vomiting or diarrhea
 - drink alcohol

Lie down if you feel faint or dizzy. If you faint (lose consciousness), stop taking amlodipine, valsartan and hydrochlorothiazide tablets. 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 and hydrochlorothiazide tablets. 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 and hydrochlorothiazide tablets.
- **laboratory blood test changes in people with heart failure.** Some people with heart failure who take valsartan, one of the medicines in amlodipine, valsartan and hydrochlorothiazide

tablets, 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 and hydrochlorothiazide tablets can cause eye problems that may lead to vision loss. Symptoms of eye problems can happen within hours to weeks of starting amlodipine, valsartan and hydrochlorothiazide tablets. Tell your doctor right away if you have:
 - decrease in vision
 - eye pain

The **most common** side effects of amlodipine, valsartan and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets. 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 and hydrochlorothiazide tablets?

- Store amlodipine, valsartan and hydrochlorothiazide tablets at room temperature between 59°F and 86°F (15°C and 30°C).
- Keep amlodipine, valsartan and hydrochlorothiazide tablets dry (protect it from moisture).

Keep amlodipine, valsartan and hydrochlorothiazide tablets and all medicines out of the reach of children.

General Information about amlodipine, valsartan and hydrochlorothiazide tablets

Medicines are sometimes prescribed for conditions that are not mentioned in the patient information leaflet. Do not use amlodipine, valsartan and hydrochlorothiazide tablets for a condition for which it was not prescribed. Do not give amlodipine, valsartan and hydrochlorothiazide tablets 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 and hydrochlorothiazide tablets. If you would like more information about amlodipine, valsartan and hydrochlorothiazide tablets, talk with your doctor. You can ask your doctor or pharmacist for information about amlodipine, valsartan and hydrochlorothiazide tablets that is written for health professionals. For more information, go to www.lupinpharmaceuticals.com or call 1-800-399-2561.

What are the ingredients in amlodipine, valsartan and hydrochlorothiazide tablets?

Active ingredients: amlodipine besylate, valsartan, and hydrochlorothiazide

The inactive ingredients of all strengths of the tablets include colloidal silicon dioxide, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide.

Additionally, the 10/160/12.5 mg strength contains yellow iron oxide; the 5/160/25 mg strength contains red iron oxide and yellow iron oxide, the 10/160/25 mg strength contains black iron oxide, red iron oxide and yellow iron oxide and the 10/320/25 mg strength contains iron oxide red.

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 and hydrochlorothiazide tablets 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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