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## FDA-APPROVED PATIENT LABELING

### PATIENT INFORMATION

#### **Amlodipine (am-LOE-di-peen) and Valsartan (val-SAR-tan) Tablets USP**

##### **Rx only**

Read the Patient Information that comes with amlodipine and valsartan 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. If you have any questions about amlodipine and valsartan tablets, ask your doctor or pharmacist.

#### **What is the most important information I should know about amlodipine and valsartan tablets?**

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

#### **What are amlodipine and valsartan tablets?**

Amlodipine and valsartan tablets contains 2 prescription medicines:

1. amlodipine, a calcium channel blocker
2. valsartan, an angiotensin receptor blocker (ARB).

Amlodipine and valsartan tablets may be used to lower high blood pressure (hypertension) in adults

- when 1 medicine to lower your high blood pressure is not enough
- as the first medicine to lower high blood pressure if your doctor decides you are likely to need more than 1 medicine.

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

#### **What should I tell my doctor before taking amlodipine and valsartan 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 and valsartan tablets?**”
- **are breastfeeding or plan to breastfeed.** Amlodipine and valsartan tablet is present in human milk. It is not known whether amlodipine and valsartan tablets affects your breastfed baby or milk production. Do not breastfeed while you are taking amlodipine and valsartan tablets.
- have heart problems
- have liver problems
- have kidney problems
- are vomiting or having a lot of diarrhea

- have ever had a reaction called angioedema, to another blood pressure medicine. Angioedema causes swelling of the face, lips, tongue, throat, 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 and valsartan 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.
- a salt substitute. Your doctor may check the amount of potassium in your blood periodically.
- nonsteroidal anti-inflammatory drugs (like ibuprofen or naproxen)
- medicines used to prevent and treat fungal skin 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.
- lithium, a medicine used in some types of depression

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. Talk to your doctor or pharmacist before you start taking any new medicine. Your doctor or pharmacist will know what medicines are safe to take together.

### **How should I take amlodipine and valsartan tablets?**

- Take amlodipine and valsartan tablets exactly as your doctor tells you.
- Take amlodipine and valsartan tablets once each day.
- Amlodipine and valsartan 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 your regular time.
- If you take too much amlodipine and valsartan tablets, call your doctor or Poison Control Center, or go to the emergency room.
- Tell all your doctors or dentist you are taking amlodipine and valsartan tablets if you:
  - are going to have surgery
  - go for kidney dialysis

### **What should I avoid while taking amlodipine and valsartan tablets?**

You should not take amlodipine and valsartan tablets during pregnancy. See “**What is the most important information I should know about amlodipine and valsartan tablets.**”

### **What are the possible side effects of amlodipine and valsartan tablets?**

Amlodipine and valsartan tablets may cause **serious side effects** including:

- **harm to an unborn baby causing injury and even death.** See “**What is the most important information I should know about amlodipine and valsartan tablets?**”

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

Lie down if you feel faint or dizzy. Call your doctor right away.

- **more heart attacks and chest pain (angina)** in people that already have severe heart problems. This may happen when you start amlodipine and valsartan tablets or when there is an increase in your dose of amlodipine and valsartan tablets. 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 and valsartan 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 and valsartan tablets.
- **laboratory blood test changes in people with heart failure.** Some people with heart failure who take valsartan, 1 of the medicines in amlodipine and valsartan tablets, have changes in blood tests including increased potassium and decreased kidney function.

The most common side effects of amlodipine and valsartan tablets include:

- swelling (edema) of the hands, ankles, or feet
- nasal congestion, sore throat, and discomfort when swallowing
- upper respiratory tract infection (head or chest cold)
- dizziness

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 and valsartan 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 and valsartan tablets?**

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

#### **Keep amlodipine and valsartan tablets and all medicines out of the reach of children.**

#### **General Information about amlodipine and valsartan tablets**

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

### **What are the ingredients in amlodipine and valsartan tablets?**

Active ingredients: Amlodipine besylate and valsartan

The inactive ingredients of all strengths of the tablets are colloidal silicon dioxide, croscarmellose sodium, crospovidone, magnesium stearate and microcrystalline cellulose. The film coating contains hypromellose, polyethylene glycol, iron oxide yellow and titanium dioxide. Additionally, the 5/160 mg and 5/320 mg strengths contain 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 and valsartan 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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