

PATIENT INFORMATION

AMLODIPINE AND ATORVASTATIN TABLETS, USP

(am loe' di peen and a tor'' va stat' in)

Read the patient information that comes with amlodipine and atorvastatin tablets before you start taking it, and each time you get a refill. There may be new information. This information does not replace talking with your healthcare provider about your condition or treatment. If you have any questions about amlodipine and atorvastatin tablets, ask your healthcare provider or pharmacist.

What are amlodipine and atorvastatin tablets?

Amlodipine and atorvastatin tablets are a prescription drug that combines amlodipine besylate and atorvastatin calcium in one pill.

Amlodipine and atorvastatin tablets are used in adults who need both amlodipine besylate and atorvastatin calcium.

Amlodipine besylate is used to treat:

- High blood pressure (hypertension) and
- Chest pain (angina) and
- Blocked arteries of the heart (coronary artery disease)

Atorvastatin calcium is used to lower the levels of “bad” cholesterol and triglycerides in your blood. It can also raise the levels of “good” cholesterol.

Atorvastatin calcium is also used to lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:

- age, smoking, high blood pressure, low levels of “good” cholesterol, heart disease in the family.

Atorvastatin calcium can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:

- diabetic eye or kidney problems, smoking, or high blood pressure.

Amlodipine and atorvastatin tablets have not been studied in children.

Who should not use amlodipine and atorvastatin tablets?

Do not use amlodipine and atorvastatin tablets if you:

- Have liver problems (acute liver failure or decompensated cirrhosis).
- Are allergic to anything in amlodipine and atorvastatin tablets. The active ingredients are atorvastatin calcium and amlodipine besylate. Stop using amlodipine and atorvastatin tablets and get medical help right away if you have symptoms of a serious allergic reaction including:
 - swelling of your face, lips, tongue or throat
 - problems breathing or swallowing
 - fainting or feeling dizzy
 - very rapid heartbeat
 - severe skin rash or itching
 - flu-like symptoms including fever, sore throat, cough, tiredness, and joint painSee the end of this leaflet for a complete list of ingredients.

What should I tell my healthcare provider before taking amlodipine and atorvastatin tablets?

Tell your healthcare provider about all of your health conditions, including, if you:

- have unexplained muscle aches or weakness
- drink more than 2 glasses of alcohol daily
- have heart disease
- have diabetes
- have thyroid problems
- have kidney problems
- had a stroke
- are pregnant or plan to become pregnant. Amlodipine and atorvastatin tablets may harm your unborn baby. If you become pregnant, stop taking amlodipine and atorvastatin tablets and call your healthcare provider right away.
- are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take amlodipine and atorvastatin tablets or breastfeed. You should not do both. Talk to your healthcare provider about the best way to feed your baby if you take Amlodipine and atorvastatin tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Amlodipine and atorvastatin tablets and certain other medicines can increase the risk of muscle problems or other side effects. Especially tell your healthcare provider if you take medicines for:

- your immune system (cyclosporine)
- cholesterol (gemfibrozil)
- infections (erythromycin, clarithromycin, itraconazole, ketoconazole, posaconazole, and voriconazole)
- birth control pills
- heart failure (digoxin)
- gout (colchicine)
- niacin
- fibrates
- treating HIV, AIDS, or hepatitis C (anti-virals)
 - tipranavir plus ritonavir
 - ledipasvir plus sofosbuvir
 - saquinavir plus ritonavir
 - fosamprenavir
 - elbasvir plus grazoprevir
 - nelfinavir
 - glecaprevir plus pibrentasvir
 - simeprevir
 - darunavir plus ritonavir
 - fosamprenavir plus ritonavir
 - letermovir

You can use nitroglycerin and amlodipine and atorvastatin tablets together. If you take nitroglycerin for chest pain (angina), do not stop taking it while taking amlodipine and atorvastatin tablets.

Ask your healthcare provider or pharmacist for a list of medicines if you are not sure. Know all the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I take amlodipine and atorvastatin tablets?

- Take amlodipine and atorvastatin tablets exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop amlodipine and atorvastatin tablets without talking to your healthcare provider.
- Your healthcare provider may do blood tests to check your cholesterol levels during your treatment with amlodipine and atorvastatin tablets. Your dose of amlodipine and atorvastatin tablets may be changed based on these blood test results.
- Take amlodipine and atorvastatin tablets each day at any time of day. Amlodipine and atorvastatin tablets can be taken with or without food.
- Do not break the tablets before taking them. Talk to your healthcare provider if you have a problem swallowing pills.
- Your healthcare provider may start you on a cholesterol-lowering diet before giving you amlodipine and atorvastatin tablets. Stay on this low-fat diet when you take amlodipine and atorvastatin tablets.
- If you miss a dose, take it as soon as you remember. Do not take amlodipine and atorvastatin tablets if it has been more than 12 hours since you missed your last dose. Wait and take the next dose at your regular time. Do not take 2 doses of amlodipine and atorvastatin tablets at the same time. If you take too many amlodipine and atorvastatin tablets or overdose, call your healthcare provider or Poison Control Center at 1-800-222-1222 or go to the nearest emergency room right away.

What should I avoid while taking amlodipine and atorvastatin tablets?

- Avoid drinking more than 1.2 liters of grapefruit juice each day.

What are possible side effects of amlodipine and atorvastatin tablets?

Amlodipine and atorvastatin tablets can cause serious side effects including:

- **Muscle pain, tenderness and weakness (myopathy).** Muscle problems, including muscle breakdown, can be serious in some people and, rarely, cause kidney damage that can lead to death.

Tell your healthcare provider right away if you have:

- unexplained muscle pain, tenderness, or weakness, especially if you also have a fever or feel more tired than usual while you take amlodipine and atorvastatin tablets.
- muscle problems that do not go away after your healthcare provider has told you to stop taking amlodipine and atorvastatin tablets. Your healthcare provider may do further tests to diagnose the cause of your muscle problems.

Your chances of getting muscle problems are higher if you:

- are taking certain other medicines while you take amlodipine and atorvastatin tablets
- drink large amounts of grapefruit juice
- are 65 years of age or older
- have thyroid problems (hypothyroidism) that are not controlled
- have kidney problems
- are taking higher doses of amlodipine and atorvastatin tablets
- **Liver problems.** Your healthcare provider should do blood tests to check your liver before you start taking amlodipine and atorvastatin tablets and if you have symptoms of liver problems while you take amlodipine and atorvastatin tablets. Call your healthcare provider right away if you have the following symptoms of liver problems:
 - feel tired or weak
 - nausea or vomiting
 - loss of appetite
 - upper belly pain
 - dark amber colored urine
 - yellowing of your skin or the whites of your eyes
- **Low blood pressure or dizziness**
- **Muscle rigidity, tremor and/or abnormal muscle movement**
- **Increase in blood sugar level.** Your blood sugar level may increase while you are taking amlodipine and atorvastatin tablets.
- Exercise regularly and make healthy food choices to maintain healthy body weight.

Call your healthcare provider right away if:

- allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing which may require treatment right away
- you have allergic skin reactions
- Chest pain that does not go away or gets worse. Sometimes when you start amlodipine and atorvastatin tablets or increase your dose, chest pain can get worse or a heart attack can happen. If this happens, call your healthcare provider or go to the emergency room right away.

Common side effects of amlodipine and atorvastatin tablets include:

- nasal congestion, sore throat, runny nose
- diarrhea
- urinary tract infection
- nausea
- muscle spasms
- throat pain
- muscle and joint pain
- pain in extremity
- upset stomach
- musculoskeletal pain
- trouble sleeping
- swelling of your legs or ankles

Additional side effects have been reported: tiredness, tendon problems, memory loss, and confusion.

Talk to your healthcare provider or pharmacist about side effects that bother you or do not go away.

There are other side effects of amlodipine and atorvastatin tablets. Ask your healthcare provider or pharmacist for a complete list.

How do I store amlodipine and atorvastatin tablets?

- Store amlodipine and atorvastatin tablets at room temperature, 68°F to 77°F (20°C to 25°C).
- Do not keep medicine that is out-of-date or that you no longer need.
- **Keep amlodipine and atorvastatin tablets and all medicines out of the reach of children.**

General information about the safe and effective use of amlodipine and atorvastatin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use amlodipine and atorvastatin tablets for a condition for which it was not prescribed. Do not give amlodipine and atorvastatin tablets to other people, even if they have the same symptoms that you have. It may harm them.

If you want more information about amlodipine and atorvastatin tablets, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Amlodipine and atorvastatin tablets that is written for health professionals.

For more information, call Apotex Corp. at 1-800-706-5575 or go to www.apotex.com.

What is high blood pressure (hypertension)?

You have high blood pressure when the force of blood against the walls of your arteries stays high. This can damage your heart and other parts of your body. Drugs that lower blood pressure lower your risk of having a stroke or heart attack.

What is angina (chest pain)?

Angina is a pain that keeps coming back when part of your heart does not get enough blood. It feels like something is pressing or squeezing your chest under the breastbone. Sometimes you can feel it in your shoulders, arms, neck, jaw, or back.

What is cholesterol?

Cholesterol is a fat-like substance made in your body. It is also found in foods. You need some cholesterol for good health, but too much is not good for you. Cholesterol can clog your blood vessels.

What is a heart attack?

A heart attack occurs when heart muscle does not get enough blood. Symptoms include chest pain, trouble breathing, nausea, and weakness. Heart muscle cells may be damaged or die. The heart cannot pump well or may stop beating.

What is a stroke?

A stroke occurs when nerve cells in the brain do not get enough blood. The cells may be damaged or die. The damaged cells may cause weakness or problems speaking or thinking.

WHAT ARE THE INGREDIENTS IN AMLODIPINE AND ATORVASTATIN TABLETS?

Active ingredients: amlodipine besylate, atorvastatin calcium

Inactive ingredients: calcium acetate, colloidal silicon dioxide, croscarmellose sodium, ferric oxide yellow, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide. In addition, the 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg strengths also contain FD&C Blue #2.

APOTEX INC.

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5 mg/10 mg, 5 mg/20 mg, 5 mg/40 mg, 5 mg/80 mg, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg and 10 mg/80 mg

Manufactured by:	Manufactured for:
Apotex Inc.	Apotex Corp.
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Canada	USA 33326
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This Patient Information has been approved by the U.S. Food and Drug Administration.

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