

PATIENT INFORMATION



(CAD-oo-et)

Read the patient information that comes with CADUET 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 doctor about your condition or treatment. If you have any questions about CADUET, ask your doctor or pharmacist.

What is CADUET?

CADUET is a prescription drug that combines Norvasc[®] (amlodipine besylate) and Lipitor[®] (atorvastatin calcium) in one pill.

CADUET is used in adults who need both Norvasc and Lipitor.

Norvasc is used to treat:

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

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

Lipitor is also used to lower the risk for heart attack or stroke in patients who have risk factors for heart disease such as:

- age, smoking, high blood pressure, low HDL-C, heart disease in the family, or
- diabetes with risk factor such as eye problems, kidney problems, smoking, or high blood pressure

CADUET has not been studied in children.

Who should not use CADUET?

Do not use CADUET if you:

- Are pregnant or think you may be pregnant, or are planning to become pregnant. CADUET may harm your unborn baby. If you get pregnant, stop taking CADUET and call your doctor right away.
- Are breastfeeding. CADUET can pass into your breast milk and may harm your baby. Do not breastfeed if you take CADUET.
- Have liver problems.
- Are allergic to anything in CADUET. The active ingredients are atorvastatin calcium and amlodipine besylate. See the end of this leaflet for a complete list of ingredients.

What should I tell my doctor before taking CADUET?

Tell your doctor about all of your health conditions, including, if you have:

- heart disease
- muscle aches or weakness
- diabetes
- thyroid problems
- kidney problems
- or drink more than 2 glasses of alcohol daily

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins and herbal supplements. CADUET and some other medicines can interact, causing serious side effects. Especially tell your doctor if you take medicines for:

- your immune system
- infections
- cholesterol
- birth control
- heart failure
- HIV (AIDS)

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

Know all the medicines you take. Keep a list of them with you to show your doctor and pharmacist.

How should I take CADUET?

- Take CADUET once a day, exactly as your doctor tells you. Do not change your dose or stop CADUET without talking to your doctor.
- Take CADUET each day at any time of day, at about the same time each day. CADUET can be taken with or without food.
- Do not break the tablets before taking them. Talk to your doctor if you have a problem swallowing pills.
- Your doctor should start you on a low-fat diet before giving you CADUET. Stay on this low-fat diet when you take CADUET.
- CADUET comes in many different strengths. Your doctor will test your cholesterol and blood pressure to find the right dose for you.

- If you miss a dose, take it as soon as you remember. Do not take CADUET if it has been more than 12 hours since your missed dose. Just take the next dose at your regular time. Do not take 2 doses of CADUET at the same time.
- If too much CADUET is taken by accident, call your doctor or poison control center, or go to the nearest emergency room.

What should I avoid while taking CADUET?

- Avoid getting pregnant. If you get pregnant, stop taking CADUET right away and call your doctor.
- Do not breastfeed. CADUET can pass into your breast milk and may harm your baby.

What are possible side effects of CADUET?

CADUET can cause serious side effects. These side effects happen only to a small number of people. Your doctor can monitor you for them. These side effects usually go away if your dose is lowered or CADUET is stopped. These serious side effects include:

- **Muscle problems.** CADUET can cause serious muscle problems that can lead to kidney problems, including kidney failure. You have a higher chance for muscle problems if you are taking certain other medicines with CADUET.
- **Liver problems.** CADUET can cause liver problems. Your doctor may do blood tests to check your liver before you start taking CADUET and while you take it.

Call your doctor right away if:

- you have muscle problems like weakness, tenderness, or pain that happen without a good reason, especially if you also have a fever or feel more tired than usual
 - you have nausea and vomiting, stomach pain
 - you are passing brown or dark-colored urine
 - you feel more tired than usual
 - your skin and white of your eyes get yellow
- **Chest pain that does not go away or gets worse.** Sometimes, when you start CADUET or increase your dose, chest pain can get worse or a heart attack can happen. If this happens, call your doctor or go to the emergency room right away.

Common side effects of CADUET include:

- headache
- dizziness
- tiredness
- extreme sleepiness
- stomach pain
- nausea
- gas
- rash
- constipation
- diarrhea
- swelling of your legs or ankles (edema)

- hot or warm feeling in your face (flushing)
- irregular heartbeat (arrhythmia)
- very fast heartbeat (heart palpitations)
- muscle and joint pain

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

There are other side effects of CADUET. Ask your doctor or pharmacist for a complete list.

How do I store CADUET?

- Store CADUET at room temperature, 68 to 77°F (20 to 25°C).
- Do not keep medicine that is out-of-date or that you no longer need.
- **Keep CADUET and all medicines out OF THE reach of children.** Keep medicines in places where children cannot get it.

General information about CADUET

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

This leaflet summarizes the most important information about CADUET. If you want more information, talk with your doctor. Ask your doctor or pharmacist for information about CADUET written for health professionals. You can also go to the CADUET website at www.CADUET.com, or call 866-514-0900.

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.

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Caduet (amlodipine besylate/atorvastatin calcium)

Pfizer Inc.

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WHAT ARE THE INGREDIENTS IN CADUET?

Active ingredients: amlodipine besylate, atorvastatin calcium

Inactive ingredients: calcium carbonate, croscarmellose sodium, microcrystalline cellulose, pregelatinized starch, polysorbate 80, hydroxypropyl cellulose, purified water, colloidal silicon dioxide (anhydrous), magnesium stearate

Film coating: Opadry® II White 85F28751 (polyvinyl alcohol, titanium dioxide, PEG 3000 and talc) or Opadry® II Blue 85F10919 (polyvinyl alcohol, titanium dioxide, PEG 3000, talc, and FD&C blue #2)

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