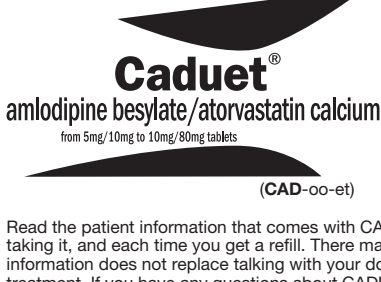


PATIENT INFORMATION



(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, 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.

Lipitor 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.

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
- if you are taking or have taken in the last 7 days a medicine called fusidic acid, (a medicine for bacterial infection) orally or by injection. The combination of fusidic acid and Caduet can lead to serious muscle problems (rhabdomyolysis). If you need to take oral fusidic acid to treat a bacterial infection you will need to temporarily stop using this medicine. Your doctor will tell you when it is safe to restart Caduet. Taking Caduet with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis).
- 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.
- 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.** Your doctor should do blood tests to check your liver before you start taking CADUET and if you have symptoms of liver problems while you take CADUET. Call your doctor right away if you have the following symptoms of liver problems:
 - feel tired or weak
 - 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**

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. This may be an early sign of a rare muscle problem.
- muscle problems that do not go away even after your doctor has advised you to stop taking CADUET. Your doctor may do further tests to diagnose the cause of your muscle problems.
- 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 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
- you have allergic skin reactions
- **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:

- Diarrhea
- Swelling of your legs or ankles
- Nausea
- Upset stomach
- Muscle and joint pain
- Alterations in some laboratory blood tests

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

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 below 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.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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.

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.

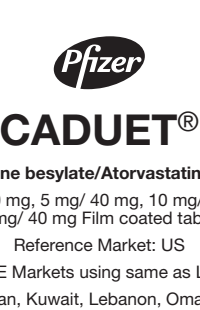
WHAT ARE THE INGREDIENTS IN CADUET?

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) Opadry® II Blue 85F10919 (polyvinyl alcohol, titanium dioxide, PEG 3000, talc, and FD&C blue #2)

Medication guide revised August 2014.



Amlodipine besylate/Atorvastatin calcium

5 mg/ 10 mg, 5 mg/ 20 mg, 5 mg/ 40 mg, 10 mg/ 10 mg, 10 mg/ 20 mg
10 mg/ 40 mg Film coated tablets

Reference Market: US

AfME Markets using same as LPD:

Bahrain, Jordan, Kuwait, Lebanon, Oman, Qatar, UAE

US Prescribing Information and Medication Guide

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use CADUET safely and effectively. See full prescribing information for CADUET.

CADUET® (amlodipine besylate and atorvastatin calcium) tablets, for oral use

INDICATIONS AND USAGE

CADUET is a combination of amlodipine besylate, a calcium channel blocker, and atorvastatin calcium, a HMG CoA-reductase inhibitor, indicated in patients for whom treatment with both amlodipine and atorvastatin is appropriate.

Amlodipine is indicated for the treatment of hypertension, to lower blood pressure (1.1). Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Amlodipine is indicated for the treatment of Coronary Artery Disease (1.2).

Atorvastatin is indicated as an adjunct therapy to diet for prevention of cardiovascular disease (1.3) and hyperlipidemia (1.4).

DOSAGE AND ADMINISTRATION

	Usual starting dose (mg daily)	Maximum dose (mg daily)
Amlodipine	5 ^a	10
Atorvastatin	10-20 ^b	80

^a Start small adults or children, fragile, or elderly patients, or patients with hepatic insufficiency on 2.5 mg once daily (2)

^b Start patients requiring large LDL-C reduction (> 45%) at 40 mg once daily (2)

DOSAGE FORMS AND STRENGTHS

Tablets contain amlodipine besylate equivalent to amlodipine 2.5, 5, or 10 mg and atorvastatin calcium equivalent to atorvastatin 10, 20, 40, or 80 mg (3).

CONTRAINDICATIONS

- Active liver disease (4)
- Pregnancy (4)
- Lactation (4)

WARNINGS AND PRECAUTIONS

- Myopathy and Rhabdomyolysis: Advise patients to promptly report to their physician unexplained and/or persistent muscle pain, tenderness, or weakness. CADUET therapy should be discontinued if myopathy is diagnosed or suspected (5.1, 8.5).
- Hepatic Transaminitis: Monitor liver enzymes before and during treatment (5.2).
- Symptomatic hypotension is possible, particularly in patients with severe aortic stenosis. However, acute hypotension is unlikely (5.4).
- Angina or myocardial infarction may occur with initiation or dose increase (5.3).

ADVERSE REACTIONS

Most common adverse reaction (3% greater than placebo) to amlodipine is edema (6.1).

Most common adverse reactions leading to atorvastatin discontinuation were myalgia and diarrhea (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer or report any suspected adverse reactions according to your local country requirements.

DRUG INTERACTIONS

Increased Risk of Myopathy/Rhabdomyolysis (2, 5.1, 7, 12.3)	
Cyclosporine, HIV protease inhibitors (tipranavir plus ritonavir), hepatitis C protease inhibitor (telaprevir)	Avoid atorvastatin
Lopinavir plus ritonavir	Use lowest dose necessary
Clarithromycin, itraconazole, HIV protease inhibitors (saquinavir plus ritonavir, darunavir plus ritonavir, fosamprenavir, fosamprenavir plus ritonavir)	Do not exceed 20 mg atorvastatin daily
HIV protease inhibitor (nelfinavir) Hepatitis C protease inhibitor (boceprevir)	Do not exceed 40 mg atorvastatin daily

- Other Lipid-Lowering Medications: Increased risk of myopathy (7).
- Rifampin: Take at same time as CADUET (7.9).
- Digoxin: Monitor digoxin levels (7.10).
- Oral Contraceptives: Norethindrone and ethinyl estradiol may be increased (7.11).

USE IN SPECIFIC POPULATIONS

- Hepatic Impairment: Plasma concentrations of atorvastatin markedly increased in patients with active liver disease (8.6, 12.3).
- Females of reproductive potential: Advise females of reproductive potential to use effective contraception during treatment with CADUET (8.3).

See 17 for PATIENT COUNSELING INFORMATION and patient labeling.
Revised: 9/2018