

PART III: CONSUMER INFORMATION

PrCADUET®

(amlodipine besylate and atorvastatin calcium tablets)

This leaflet is Part III of a three-part "Product Monograph" published when CADUET was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CADUET. Contact your doctor or pharmacist if you have any questions about this medication. Please read this information carefully.

ABOUT THIS MEDICATION

What is CADUET used for:

CADUET is a product that contains two active ingredients: amlodipine and atorvastatin and is to be used when your doctor deems it appropriate to use both medications.

Your doctor has prescribed CADUET to you to control your hypertension (high blood pressure) and/or to prevent angina attacks (chest pains) and to help lower your cholesterol or other fats in the blood (such as triglycerides). Even if you do not have high cholesterol, your doctor may still prescribe CADUET if you have high blood pressure and other risk factors in order to prevent your risk of cardiovascular disease such as heart attacks.

CADUET is just part of the treatment your doctor will plan with you to help keep you healthy. Depending on the condition of your health and your lifestyle, your doctor may recommend:

- a change in your diet to control your weight, reduce your cholesterol, reduce intake of saturated fats and increase fiber
- exercise that is right for you
- quitting smoking or avoiding smoky places
- giving up alcohol or drinking less

CADUET is not recommended in children.

What CADUET does:

The amlodipine portion of CADUET belongs to a class of medications called calcium channel blockers. Calcium channel blockers, like amlodipine, block the transfer of calcium into the cells of the heart and blood vessels. This helps the blood vessels to relax, thereby lowering blood pressure and resulting in less work for the heart.

The atorvastatin portion of CADUET belongs to the class of medicines known as "statins", more specifically called HMG-CoA reductase inhibitors. HMG-CoA reductase is an enzyme involved in

regulating cholesterol levels in your body. Statins are used along with changes to exercise and diet to help control the amount of cholesterol produced by the body. High levels of cholesterol and other fats can cause heart disease by clogging the blood vessels that feed blood and oxygen to the heart.

Atorvastatin can help your body:

- Decrease LDL (bad) cholesterol, triglyceride levels and other lipids/fats in the blood.
- Increase HDL (good) cholesterol
- Decrease the Total Cholesterol HDL-Cholesterol Ratio (TC: HDL-C Ratio). The ratio represents the balance between bad and good cholesterol.

Follow your doctor's instructions carefully.

When CADUET should not be used:

Do not take CADUET if you:

- are allergic to either amlodipine besylate and/or atorvastatin calcium or other medications known as dihydropyridines (for example, felodipine, and nifedipine) or any of the nonmedicinal ingredients (see What the nonmedicinal ingredients are).
- have been diagnosed with low blood pressure (less than 90 mmHg systolic).
- have active liver disease or unexplained increases in liver enzymes.
- are pregnant or breast-feeding.
- are taking Maviret™ (glecaprevir/pibrentasvir).

What the medicinal ingredients are:

amlodipine besylate and atorvastatin calcium.

What the nonmedicinal ingredients are:

calcium carbonate, colloidal silicon dioxide (anhydrous), croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, opadry II white 85F28751 or opadry II blue 85F10919, polysorbate 80, pregelatinized starch, and purified water.

What dosage forms it comes in:

CADUET tablets are available in 8 combinations of amlodipine/ atorvastatin: 5mg/10mg, 5mg/20mg, 5mg/40mg, 5mg/80mg, 10mg/10mg, 10mg/20mg, 10mg/40mg, 10mg/80mg. CADUET tablets which contain 5 mg amlodipine will be film-coated white, and those with 10 mg amlodipine will be film-coated blue.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Tell your doctor if you have any muscle pain, tenderness, soreness or weakness during treatment with CADUET.

Never change the dose of CADUET unless your doctor tells you to.

Before you use CADUET talk to your doctor or pharmacist if

- you have thyroid problems
- you have had a stroke or a mini stroke called a transient ischemic attack (TIA)
- you regularly drink *three or more* alcoholic drinks daily
- you are taking any other cholesterol lowering medication such as fibrates (gemfibrozil, fenofibrate), niacin or ezetimibe
- you are taking any other prescription, non-prescription or over-the-counter products especially those listed under the section “Interactions With This Medication”
- you have a family history of muscular disorders
- you had any past problems with the muscles (pain, tenderness), after using an HMG-CoA reductase inhibitor (“statin”) such as atorvastatin (LIPITOR®), fluvastatin (LESCOL®), lovastatin (MEVACOR®), pravastatin (PRAVACHOL®), rosuvastatin (CRESTOR®) or simvastatin (ZOCOR®)
- you have kidney or liver problems
- you have diabetes (as the dosage of CADUET may need to be adjusted)
- you have undergone surgery or other tissue injury
- you do excessive physical exercise
- you are 65 years old or older
- you have taken any of the following medicines before, and you had an allergic reaction:
 - amlodipine or other derivatives
 - nifedipine (e.g. ADALAT XL®)
 - felodipine (e.g. PLENDIL®, RENEDIL®)
 - atorvastatin (LIPITOR®) or other derivatives
 - simvastatin (e.g. ZOCOR®)
 - lovastatin (e.g. MEVACOR®)
 - pravastatin (e.g. PRAVACHOL®)

- fluvastatin (e.g. LESCOL®)
- rosuvastatin (e.g. CRESTOR®)
- you are taking cyclosporine (e.g. SANDIMMUNE®, NEORAL®)
- you are taking fusidic acid.

Slightly increased blood sugar can occur when you take CADUET. Discuss with the doctor your risk of developing diabetes.

CADUET may cause muscle pain, aching or weakness that does not go away even after stopping the drug.

Pregnancy:

- Before using this medication, discuss the following with your doctor:
 - If you are breast-feeding your baby, you should not take CADUET. This medicine may be present in your breast milk.
 - Cholesterol compounds are essential elements for the development of a fetus. Cholesterol-lowering drugs can harm the fetus. If you are of child-bearing age, discuss with your doctor the potential hazards to the fetus and the importance of birth control methods.
 - This medicine should not be used by pregnant women. If you become pregnant, discontinue use immediately and discuss with your doctor.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines. Also mention if you drink alcoholic beverages.

Drugs that may interact with CADUET include:

- corticosteroids (cortisone-like medicines)
- cyclosporine (e.g. SANDIMMUNE®, NEORAL®), tacrolimus
- sirolimus, temsirolimus, everolimus
- gemfibrozil
- fenofibrate (e.g. LIPIDIL MICRO®)
- bezafibrate (e.g. BEZALIP®)
- lipid-modifying doses of niacin (nicotinic acid)
- spironolactone
- cimetidine
- erythromycin, clarithromycin or azole antifungal agents (ketoconazole or itraconazole)
- nefazodone (e.g. SERZONE®)
- indinavir sulfate (e.g. CRIXIVAN®), nelfinavir mesylate (e.g. VIRACEPT®), ritonavir (e.g. NORVIR®), saquinavir mesylate (INVIRASE™), lopinavir/ritonavir (e.g. KALETRA®), telaprevir (INCIVEK™),

tipranavir (APTIVUS[®]), darunavir (PREZISTA[®]), fosamprenavir (TELZIR[®]), boceprevir (VICTRELIS[®]), elbasvir/grazoprevir (e.g. ZEPATIER[®]), simeprevir (e.g. GALEXOS[®])

- fusidic acid (e.g. FUCIDIN[®])
- digoxin
- diltiazem
- efavirenz, rifampin
- sildenafil (VIAGRA[®]) may lower your blood pressure
- beta-blockers (medicines used to lower your blood pressure)
- antacids (frequent use) and CADUET should be taken 2 hours apart
- St. John's Wort (hypericum perforatum)
- grapefruit juice
- colchicine

Certain non-prescription drugs may be harmful to you or may interfere with CADUET.

PROPER USE OF THIS MEDICATION

Take CADUET exactly as prescribed by your doctor, nurse or pharmacist. Swallow CADUET with water.

Usual Dose: The dose range for CADUET is 5/10 to 10/80 mg once daily. The maximum dose of CADUET is 10/80 mg once daily. CADUET is available in a broad dose-range. Your doctor will decide on the best dose for you. Your individual health and tolerance to medications will help your doctor decide how much of each ingredient will be best for you.

Follow your doctor's dosing instructions carefully. Take your CADUET as a single dose once a day. Never change the dose unless your doctor tells you to. It does not matter if you take CADUET with food or without food. Ideally, so you won't forget, you should get in the habit of taking your medicine at the same time every day. Follow the plan that you and your doctor make for diet, exercise, weight control and smoking cessation.

We often cannot see or feel the problems that high cholesterol and high blood pressure cause until a lot of time has passed or until a major event like a heart attack occurs. You and your doctor will be following your cholesterol and blood pressure levels to bring them down and keep them in a safe range. Here are some important tips to consider:

- Report to all follow-up visits scheduled by your doctor. This is important to follow through with all lab tests requested by your doctor. These tests will help to follow/track your health in general, for example, your kidneys, liver and blood sugar levels.

- It is important to take all of your medication and to refill your prescription on time so as not to miss any doses.
- Don't drink too much alcohol while you are taking CADUET. Talk to your doctor about how much is too much for you.
- If you get sick, have an operation, or need medical treatment, inform your doctor or pharmacist that you are taking CADUET.
- If you have to take any other medicine – prescription, non-prescription or over-the-counter - while you are taking CADUET, talk to your doctor or pharmacist first.
- If you have to see a different doctor for any reason, be sure to inform him/her that you are taking CADUET.

Missed Dose:

If you miss taking your medicine, take it as soon as you can. But if it is almost time for your next dose, skip the missed dose and just take the next dose. Don't take a double dose.

Overdose:

If you think you have taken too much of CADUET contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication may cause unwanted effects. CADUET is generally well tolerated. However, check with your doctor or pharmacist promptly if any of the following persist or become troublesome:

- stomach pain or upset, vomiting or throwing up, loss of appetite and inability to eat, or malaise (general feeling of being unwell), burping
- gas, constipation, diarrhea
- headache, neck pain
- fever
- hair loss
- skin rash, hives, itchiness
- insomnia (difficulty sleeping), drowsiness, fatigue, nightmares
- impotence (inability of develop or maintain an erection of the penis)
- blurred vision, ringing in the ears

Possible side effects reported with some statins:

- breathing problems including persistent cough and/or shortness of breath or fever
- mood related disorders including depression
- poor memory, confusion and memory loss

CADUET can cause abnormal blood test results.

Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect	Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical attention
	Only if severe	In all cases	
Common	Swelling of the ankles	✓	
Rare	Pancreatitis (severe upper abdominal pain that radiates to the back)		✓
	Muscle pain that you cannot explain		✓
	Muscle cramps, tenderness or weakness		✓
	Generalized weakness, especially if you don't feel well		✓
	Brownish or discoloured urine		✓
	Increased frequency, severity, duration of angina (chest pains)		✓
	Low blood pressure: (dizziness, or dizziness when rising from sitting or laying down)	✓	
	Change in rhythm or pace of heart beats		✓
	Numbness or tingling in hands/fingers	✓	
	Shortness of breath		✓
	Abnormal vision		✓
	Jaundice (yellowing of the skin and eyes) from a liver disorder called hepatitis (inflammation of the liver)		✓
	Unknown	Increased blood sugar: frequent urination, thirst and hunger	✓
Extrapyramidal			✓

symptoms: muscle stiffness, body spasms, upward eye rolling, exaggeration of reflexes, drooling, difficulty moving how and when you want			
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This is not a complete list of side effects. If you notice anything unusual or any unexpected effects while taking CADUET, contact your doctor or pharmacist.

HOW TO STORE IT

Keep your medicine at 25°C; excursions are permitted to 15-30°C (room temperature), away from warm and damp places, like the bathroom or kitchen. **Always keep medicine well out of the reach of children.**

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Please note that the information contained in the enclosed pamphlet is general. Your doctor and pharmacist are your primary sources of information about your health and the medicine you take. Consult with your doctor or pharmacist if you have questions about your health, any medication you take or the information we are providing you.

This document plus the full Product Monograph, prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc., at: 1-800-463-6001

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