

# **CADUET<sup>®</sup> Film-coated Tablet**

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)

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PLD Title : Amlodipine besylate, Atorvastatin calcium (Caduet<sup>®</sup>)  
PLD Date : 28 January 2026  
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## What CADUET is used for

CADUET is a prescription drug that combines amlodipine besylate and atorvastatin calcium in one pill. CADUET is used in patients who need both amlodipine besylate and atorvastatin calcium.

Amlodipine besylate is used to treat:

- High blood pressure (hypertension) and
- Chest pain (angina).

Atorvastatin calcium is used to lower “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 fatal heart conditions, non-fatal tissue death of the heart muscle, stroke, certain types of heart surgery, and chest pain in patients without clinically evident heart disease, and with or without high levels of fats in the blood, but with multiple risk factors for heart disease such as:

- Smoking, high blood pressure (BP), diabetes, low HDL-C and history of heart conditions in the family.

Atorvastatin calcium can lower the risk for non-fatal tissue death of the heart muscle, fatal/non-fatal stroke, certain types of heart surgery, heart failure and chest pain in patients with clinically evident heart disease.

## How CADUET works

CADUET is a product that contains two active ingredients amlodipine (calcium antagonist) and atorvastatin (statin) and is to be used when your doctor considers

it appropriate to use both medications. Amlodipine is used to treat high blood pressure (hypertension) and atorvastatin to lower cholesterol levels.

## Before you use CADUET

### - When you must not use it

Do not take CADUET:

- if you are allergic (hypersensitive) to amlodipine or atorvastatin or any other calcium channel blocker;
- if you are allergic (hypersensitive) to any of the ingredients in this medicine (these are listed at the end of the leaflet);
- if you currently have a disease which affects the liver (if in the past you have had a disease that affected the liver, see section “Before you start to use it” below);
- if you have had any unexplained abnormal blood tests for liver function;
- if you are pregnant, trying to become pregnant or if you are breast-feeding.

## Pregnancy and lactation

Do not take CADUET if you are pregnant, breast-feeding or if you are trying to become pregnant.

This medicine may affect your unborn developing baby if you take it during pregnancy.

Do not take CADUET if you are breastfeeding or intend to breastfeed. This medicine passes into breast milk and may affect your baby.

Women of child-bearing age must take appropriate contraceptive measures while taking CADUET or any medicine. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start to use it

Check with your doctor or pharmacist before taking CADUET.

- if you have heart problems including heart failure;
- if you have kidney problems;
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of

hereditary muscle problems;

- if you have had previous muscular problems during treatment with other cholesterol (lipid) lowering medicines (e.g., other ‘-statins’ or ‘-fibrate’ medicines);
- if you have muscle weakness with minimal inflammation.
- if you have had stroke diagnosed as a hemorrhagic stroke;
- if you regularly drink increased amounts of alcoholic beverages;
- if you have/had a liver disease.
- if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your CADUET treatment to predict your risk of muscle-related side effects. The risk of muscle-related side effects, e.g., rhabdomyolysis, is known to increase when certain medicines are taken at the same time.

### - Taking other medicines

There are some medicines that may interact with CADUET. This interaction could make one or both of the medicines less effective. Alternatively, it could increase the risk or severity of side effects, including the important muscle wasting condition known as rhabdomyolysis and myopathy (described in Section “Before you start to use it”).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, including natural or herbal remedies like:

## Amlodipine

- CYP3A4 Inhibitors such as ketoconazole, itraconazole, ritonavir and diltiazem;
- Clarithromycin;

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- CYP3A4 Inducers such as rifampicin, *hypericum perforatum*;
- Tacrolimus;
- mTOR inhibitors such as sirolimus, temsirolimus, and everolimus.

## Atorvastatin

- grapefruit juice;
- medicines used to alter the way your immune system works (e.g. cyclosporine);
- certain antibiotics or antifungal medicines (e.g. erythromycin, clarithromycin, rifampin, fusidic acid, azole antifungals like itraconazole);
- if you need to take fusidic acid to treat a bacterial infection your doctor may advise you to temporarily stop using CADUET. If you need to take fusidic acid for long periods along with this medicine, your doctor will consider on a case by case basis and under close medical supervision;
- other lipid lowering medicines (e.g. fibrates, colestipol, niacin);
- antivirals called protease inhibitors used in the treatment of HIV (e.g. tipranavir/ritonavir, lopinavir/ritonavir, saquinavir/ritonavir, darunavir/ritonavir, fosamprenavir, fosamprenavir/ritonavir, nelfinavir, efavirenz) and hepatitis C (e.g. telaprevir, boceprevir, glecaprevir/pibrentasvir, elbasvir/grazoprevir);
- some medicines used for angina (chest pain) or high blood pressure (e.g. diltiazem), medicines to regulate your heart rhythm (e.g. digoxin);
- medicine used in the treatment of other viral infections (cytomegalovirus) (e.g. letermovir);
- other medicines known to interact with CADUET include oral contraceptives, colchicine (used to treat gout) and antacids (containing magnesium or aluminium for indigestion);
- consult your doctor if you get muscle weakness, tenderness or pain.

Your doctor will carefully weigh the potential benefits and risks and shall monitor you for any signs of muscle pain, tenderness, or weakness, particularly during the starting of therapy

and during any periods of higher dosage. Therefore, lower starting and maintenance doses of the atorvastatin should also be considered when taken concomitantly with the lipid controlling drugs mentioned above.

Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine, including medicines obtained without a prescription.

*Taking CADUET with food and drink*  
CADUET can be taken at any time of day, with or without food.

## Grapefruit juice

Do not drink more than one or two glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of CADUET.

## Alcohol

Avoid drinking too much alcohol while taking CADUET. See section, "*Before you start to use it*" for more information.

## How to use CADUET

### - *How much to use*

The dosage range for amlodipine/atorvastatin (CADUET) is 5 mg/10 mg to a maximum dose of 10 mg/80 mg once daily. Your doctor will adjust this based on your tolerance for each individual component.

For children between 6-17 years old, the amlodipine dose is 2.5 mg - 5 mg.

For children above 10 years old, the atorvastatin dose is 10 mg - 80 mg.

Always take CADUET exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

CADUET should be swallowed whole with a drink of water. The tablets can be taken orally at any time of day, with or without food. However, try to take your tablet at the same time every day.

Keep following your doctor's dietary advice, especially a diet restricted in fat, avoid smoking and take regular exercise.

If you have the impression that the effect of CADUET tablets is too strong or too weak, talk to your doctor or pharmacist.

### - *When to use it*

Use as directed by your doctor or pharmacist.

Continue taking CADUET for as long as your doctor recommends.

### - *How long to use it*

Continue taking CADUET for as long as your doctor recommends.

### - *If you forget to use it*

If you forget to take a dose, just take your next scheduled dose at the correct time.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### - *If you use too much (overdose)*

If you accidentally take too many CADUET tablets (more than your usual daily dose), contact your doctor or nearest hospital for advice. Take along with you any tablets that are left, the container and the whole box so that the hospital staff can easily tell what medicine you have taken.

## While you are using it

### - *Things you must do*

Keep this leaflet. You may need to read it again.

If you have any further questions, ask your doctor or pharmacist.

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## - *Things you must not do*

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

## - *Things to be careful of*

### *Driving and using machines*

CADUET will not impair your ability to drive or use machinery.

## Side effects

Like all medicines, CADUET can cause side effects, although not everybody gets them.

If any of the following happen, stop taking CADUET and tell your doctor immediately;

- Swelling of the face, tongue and windpipe which can cause great difficulty in breathing;
- If you have any unexplained muscle weakness, muscle tenderness or pain in your muscles and at the same time, you feel unwell or have a high temperature;

(Very rarely this combination of effects has become a serious life-threatening condition called rhabdomyolysis);

If you have muscle problems that do not go away even after your doctor has told you to stop taking CADUET, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems;

## Common side effects for Amlodipine

Amlodipine may cause the following side effects. Most side effects are mild or moderate:

- headache, dizziness, extreme sleepiness (somnolence);
- heart palpitations (very fast heartbeat);
- flushing (hot or warm feeling in your face);

- stomach pain, nausea;
- swelling of your legs or ankles, tiredness (fatigue)

The most frequent side effects in children are:

- headaches, dizziness
- widening of blood vessels which cause low blood pressure (vasodilation) bleeding from the nose (epistaxis)
- stomach pain
- physical weakness and lack of energy (asthenia)

## The side effects of atorvastatin include:

- inflammation of the nasal passages;
- increase in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels);
- pain in the throat, nose bleed;
- diarrhoea, indigestion, nausea, wind;
- painful, swollen joints, pain in the hands or ankles, muscle pain and cramps;
- blood test results that show your liver function may be abnormal, increase in blood creatine phosphokinase (an enzyme indicating muscle damage);

## Other possible side effects:

- nightmares;
- blurred vision;
- ringing in the ears;
- stomach pain, belching;
- hepatitis (liver inflammation), cholestasis (yellowing of the skin and whites of the eyes);
- skin rash and itching (hives);
- muscle fatigue, neck pain;
- feeling unwell, fever;
- urine tests that are positive for white blood cells;

## Side effects reported during post-marketing experience of atorvastatin:

- reduction in blood platelets which increases the risk of bleeding or bruising;
- allergic reactions (including serious allergic reaction which causes difficulty in breathing or dizziness);

- tendon injury;
- weight gain;
- reductions in sensation to pain or touch; loss of memory, dizziness, change in sense of taste;
- pancreatitis (inflammation of the pancreas leading to stomach pain);
- severe skin reactions which can cause blisters, sores, and ulceration, swelling of the area beneath the skin;
- muscle weakness, inflammation or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis), autoimmune disease presenting with weakness of the muscles close to the core of the body with cellular injury to the muscle cells but with minimal inflammation (immune-mediated necrotizing myopathy), inflammation of the muscles (myositis), back pain;
- chest pain, swelling especially in the ankles, fatigue;
- cognitive impairment (e.g. memory loss/impairment, forgetfulness, amnesia, confusion);
- increase in blood sugar levels such as HbA1c (average blood sugar for two or three months) and fasting blood sugar;
- myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing);
- ocular myasthenia (a disease causing eye muscle weakness).
- abnormal skin reactions to sunlight or UV rays

Please talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

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Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## Storage and Disposal of CADUET

### - Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not use CADUET after the expiry date which is stated on the blister, carton, and bottle. The expiry date refers to the last day of that month.

### - Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

Amlodipine/atorvastatin 5 mg/10 mg is a white, oval shape, film-coated tablet debossed, blank on one side and CDT 051 on the other side.

Amlodipine/atorvastatin 5 mg/20 mg is a white, oval shape, film-coated tablet debossed, blank on one side and CDT 052 on the other side.

Amlodipine/atorvastatin 5 mg/40 mg is a white, oval shape, film-coated tablet debossed, blank on one side and CDT 054 on the other side.

Amlodipine/atorvastatin 10 mg/10 mg is a blue, oval shape, film-coated tablet debossed, blank on one side and CDT 101 on the other side.

Amlodipine/atorvastatin 10 mg/20 mg is a blue, oval shape, film-coated tablet debossed, blank on one side and CDT 102 on the other side.

Amlodipine/atorvastatin 10 mg/40 mg

is a blue, oval shape, film-coated tablet debossed, blank on one side and CDT 104 on the other side.

Not all strengths may be marketed.

### - Ingredients

- Active ingredients  
Amlodipine besylate/atorvastatin calcium

The tablets for oral administration contain amlodipine besylate and atorvastatin calcium equivalent to 5 mg/10 mg, 5 mg/20 mg, 5 mg/40 mg, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg amlodipine/atorvastatin dosage strengths, respectively.

- Inactive ingredients  
Tablet Core – Calcium carbonate, croscarmellose sodium, microcrystalline cellulose, pregelatinised starch, polysorbate 80, hydroxypropyl cellulose, colloidal silicone dioxide and magnesium stearate.

Film-Coat – Opadry II White 85F28751, or Opadry II Blue 85F10919.

### - MAL numbers:

Product Name	Registration Number
CADUET 5 mg/10 mg	MAL20061542ACRZ
CADUET 5 mg/20 mg	MAL20061543ACRZ
CADUET 5 mg/40 mg	MAL20061544ACRZ
CADUET 10 mg/10 mg	MAL20061546ACRZ
CADUET 10 mg/20 mg	MAL20061547ACRZ
CADUET 10 mg/40 mg	MAL20061548ACRZ

## Manufacturer

Pfizer Manufacturing Deutschland GmbH,  
Betriebsstätte, Freiburg,  
Germany.

## Product Registration Holder

Viatrix Sdn Bhd  
15-03 & 15-04, Level 15, Imazium,  
No. 8, Jalan SS 21/37,  
Damansara Uptown,  
47400 Petaling Jaya,  
Selangor, Malaysia.

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28/01/2026

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