

CADUET(R) Tablets

Amlodipine Besylate and Atorvastatin Calcium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CADUET.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CADUET against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What CADUET is used for

CADUET is used to treat high blood pressure and high cholesterol (fat in the blood). CADUET can also be used for angina (a certain type of chest pain) and high cholesterol levels. CADUET is also used in people who have high blood pressure and coronary heart disease (CHD) or who are at risk of CHD (for example, if they have diabetes, a history of stroke, or small blood vessel disease).

CADUET is able to treat these conditions because it contains a combination of two medicines. One is amlodipine and the other is atorvastatin.

Amlodipine is used to lower high blood pressure (hypertension). There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems.

Amlodipine belongs to a group of medicines called calcium channel blockers. They work by relaxing your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart. Calcium channel blockers do not change the amount of calcium in your blood or bones.

Amlodipine is also used to treat angina. Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck, and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart. Amlodipine is not for the relief of a sudden attack of angina. Your doctor will have given you other medication to treat this.

Atorvastatin, the other medicine in CADUET, belongs to a group of medicines called HMG-CoA reductase inhibitors and is used to lower high cholesterol.

Everyone has cholesterol in his or her blood. It is a type of blood fat needed by the body for things such as building cell lining, making bile acids (which help to digest food) and some hormones. However, too much cholesterol can be a problem.

Cholesterol is present in many foods and is also made in your body by the liver. If your body makes too much cholesterol or you take too much cholesterol in your diet, then your level becomes too high.

High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

There are different types of cholesterol. LDL, or low-density lipoprotein, is the 'bad' cholesterol that can block your blood vessels. HDL, or high-density lipoprotein, cholesterol is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

When you have high levels of 'bad' cholesterol in your blood, it may begin to 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, also called plaque, on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to several types of blood vessel disease, heart attack, angina and stroke.

There is another type of blood fat called triglyceride that is a source of energy. However, high levels of triglyceride can be associated with a low level of 'good' cholesterol and may increase your risk of heart disease.

In some patients, atorvastatin is used to treat high cholesterol and high triglycerides together.

Atorvastatin does not reduce the cholesterol that comes from fat in food.

Therefore, when you are taking CADUET, you also need to follow a low fat diet. Your doctor may suggest other ways to help control your condition such as exercise, weight control and stopping smoking.

In most people, there are no symptoms of abnormal cholesterol or triglyceride levels. Your doctor can measure your levels with a simple blood test.

Your doctor may have prescribed CADUET for another reason.

Ask your doctor if you have any questions about why CADUET has been prescribed for you.

CADUET is not addictive.

This medicine is only available with a doctor's prescription.

Before you take CADUET

When you must not take it

Do not take CADUET if:

- * You are taking other calcium channel blockers. These medicines include amlodipine (as Norvasc) as this is also in CADUET; other calcium channel blockers are felodipine (Plendil ER, Agon SR, Felodur ER), or nifedipine (Adalat, Adalat Oros, Nifecard, Nifedipine-BC, Nifehexal, Nyefax, SBPA Nifedipine). (Not all brands are given). Check with your doctor or pharmacist if you are unsure.
- * You are taking other HMG-CoA reductase inhibitors. These medicines include atorvastatin (as Lipitor) as this is also in CADUET. Other HMG-CoA reductase inhibitors are fluvastatin (Lescol, Vastin), pravastatin (Pravachol),

simvastatin Lipex, Zocor) or simvastatin containing medicines (Vytorin). (Not all brands are given). Check with your doctor or pharmacist if you are unsure.

- * you have ever had an allergic reaction to CADUET or other calcium channel blockers.
- * You have ever had an allergic reaction to CADUET or other HMG-CoA reductase inhibitors used to lower cholesterol.
- * You are allergic to any of the ingredients listed at the end of this leaflet.
- * Some of the symptoms of an allergic reaction to CADUET may include a skin rash similar to hives, itchiness, shortness of breath, swelling of the face, lips or tongue.
- * you are pregnant or breastfeeding. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.
- * you have active liver disease
- * you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides
- * CADUET is not recommended for use in children, as there are no studies of its effects in children.

If you are not sure whether you should be taking CADUET, talk to your doctor.

Do not take CADUET if:

- * the packaging shows signs of tampering or does not look quite right.
- * the expiry date marked on the packaging has passed, even though the tablets may look all right.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if:

- * If you intend to become pregnant or plan to breast feed. CADUET should not be used during pregnancy or while breastfeeding.
- * you have any health/medical problems, including:
 - heart disease such as heart failure
 - liver problems
 - kidney problems
 - muscle pain, tenderness or weakness from other medicines used to treat cholesterol or triglycerides

If you have not told your doctor about any of these medical conditions, tell him/her before you take CADUET.

Tell your doctor:

- * If you are consuming alcohol regularly
- * you are allergic to any foods, dyes, preservatives or any other medicines

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and CADUET may interfere with each other.

These include the following:

- * digoxin, a medicine used to treat some heart problems
- * the antibiotics erythromycin, clarithromycin and rifampicin
- * phenytoin, a medicine used to treat epilepsy
- * oral contraceptives for birth control
- * other medicines to treat high cholesterol or triglycerides
- * medicines that suppress the immune system
- * medicines used to treat some fungal infections

* protease inhibitors for the treatment of HIV infection

These medicines may be affected by CADUET or may affect how well it works. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking CADUET.

If you have not told your doctor about any of the above, tell him/her before you take CADUET.

It is also possible that CADUET may be affected by grapefruit juice, some medicines used to treat heart palpitations (or arrhythmias) and St John's Wort.

How to take CADUET

Take CADUET exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take

Your doctor will decide the dose you should take. This will depend on your blood pressure, cholesterol and triglyceride levels.

CADUET is available in eight strengths; CADUET 5mg/10mg, CADUET 5mg/20mg, CADUET 5mg/40mg, CADUET 5mg/80mg, CADUET 10mg/10mg, CADUET 10mg/20mg, CADUET 10mg/40mg and CADUET 10mg/80mg. Your doctor will start you on one of these tablet strengths. Your doctor may need to adjust this dose after your blood pressure and cholesterol and fat levels in your blood have been checked. It is important that you keep your appointment to have these tests done.

How to take it

Swallow the tablet whole with a full glass of water.

Take your tablet once a day at about the same time each day, either morning or evening.

Taking your tablet at the same time each day will have the best effect. It will also help you to remember when to take it.

CADUET can be taken with or without food.

How long to take it

You must take CADUET every day. Continue taking your medicine for as long as your doctor tells you.

CADUET helps to lower cholesterol levels and blood pressure and control the symptoms of angina but does not cure your condition.

You may have to take this kind of medicine for the rest of your life.

If you stop taking CADUET, your blood pressure and cholesterol levels may rise again.

If you forget to take it

If you miss a dose and it is less than 12 hours from when you should take it, take it straight away, and then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre - the telephone number is 131 126 in Australia. In New Zealand the contact numbers are 0800 POISON

or 0800 764 766). Otherwise go to Accident and Emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much CADUET. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these facilities handy.

If you take too many tablets, you may feel dizzy, lightheaded or faint and have an irregular heartbeat.

While you are using it

Things you must do

Have your cholesterol and triglyceride levels checked when your doctor says.

This helps to make sure that CADUET is working.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking CADUET.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking CADUET.

If you become pregnant while taking CADUET tell your doctor immediately.

Things you must not do

Do not take CADUET to treat any other conditions unless your doctor says to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how CADUET affects you.

CADUET may cause dizziness or drowsiness in some people and affect alertness.

If this occurs, do not drive, operate machinery or do things that could be dangerous if you are not alert.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CADUET.

CADUET helps most people but it may have some unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

Tell your doctor if you experience any of the following and they worry you:

- * swelling of the ankles, feet, face or hands
- * headache
- * flushing
- * palpitations
- * dizziness
- * tiredness
- * drowsiness or sleepiness
- * stomach pain or nausea
- * constipation, diarrhoea, wind
- * heartburn or indigestion
- * trouble sleeping

These are the more common side effects of CADUET.

Tell your doctor immediately or go to the casualty department of your nearest hospital if you notice any of the following.

- * swelling of the face, lips, mouth throat or neck which may cause difficulty in swallowing and breathing
- * unexpected muscle pain, tenderness or weakness not caused by exercise
- * tingling in the hands or feet

- * changes in heart beat either fast or slow
- * chest pain
- * dizziness
- * shortness of breath
- * symptoms of allergy such as skin rash, itching
- * symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine

These are rare, possibly serious side effects. You may need urgent medical attention.

Tell your doctor if you experience any of the following:

- * sexual problems
- * swollen gums
- * weight gain
- * feeling nervous, depressed or moody
- * changes in vision or sight
- * loss or thinning of hair
- * ringing in the ears

These may or may not be due to CADUET but you should tell your doctor if they worry you.

Tell your doctor if you notice any other effects.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you notice any other symptoms that worry you, check with your doctor.

Ask your doctor or pharmacist if you don't understand anything in this list.

If you are 65 years or older, you should be especially careful while taking CADUET. Report any side effects promptly to your doctor.

Some people in this age group may be more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

After taking CADUET

Storage

Keep your tablets in the pack until it is time to take them.

If you take your tablets out of the pack they will not keep as well.

Keep your tablets in a cool dry place where temperatures stay below 30 degrees C.

Do not store CADUET or any other medicine in the bathroom or near a sink.

Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep CADUET where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking CADUET, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What it looks like

CADUET Tablets are available in eight strengths:

- * CADUET 5 mg/10mg - white, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "051" on the other.
- * CADUET 5 mg/20 mg - white, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "052" on the other.
- * CADUET 5 mg/40mg - white, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "054" on the other.

- * CADUET 5 mg/80 mg - white, oval, film coated tablets debossed with "Pfizer" on one side and CDT and "058" on the other.
- * CADUET 10mg/10 mg - blue, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "101" on the other
- * CADUET 10 mg/20 mg blue, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "102" on the other
- * CADUET 10 mg/40 mg blue, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "104" on the other
- * CADUET 10 mg/80 mg. blue, oval, film coated tablets debossed with "Pfizer" on one side and "CDT" and "108" on the other.

A box contains 30 tablets.

Ingredients

Active ingredients

- * CADUET 5 mg/10 mg Tablets contain amlodipine besylate equivalent to amlodipine 5 mg and atorvastatin calcium equivalent to atorvastatin 10mg.
- * CADUET 5 mg/20 mg Tablets contain amlodipine besylate equivalent to amlodipine 5 mg and atorvastatin calcium equivalent to atorvastatin 20 mg.
- * CADUET 5 mg/40 mg Tablets contain amlodipine besylate equivalent to amlodipine 5 mg and atorvastatin calcium equivalent to atorvastatin 40 mg.
- * CADUET 5 mg/80 mg Tablets contain amlodipine besylate equivalent to amlodipine 5 mg and atorvastatin calcium equivalent to atorvastatin 80 mg.
- * CADUET 10 mg/10 mg Tablets contain amlodipine besylate equivalent to amlodipine 10 mg and atorvastatin calcium equivalent to atorvastatin 10mg.
- * CADUET 10 mg/20 mg Tablets contain amlodipine besylate equivalent to amlodipine 10 mg and atorvastatin calcium equivalent to atorvastatin 20 mg.

- * CADUET 10 mg/40 mg Tablets contain amlodipine besylate equivalent to amlodipine 10 mg and atorvastatin calcium equivalent to atorvastatin 40 mg.
- * CADUET 10 mg/80 mg Tablets contain amlodipine besylate equivalent to amlodipine 10 mg and atorvastatin calcium equivalent to atorvastatin 80 mg.

Inactive Ingredient

The inactive ingredients are:

- * calcium carbonate
- * croscarmellose sodium
- * microcrystalline cellulose
- * pregelatinised starch
- * polysorbate 80
- * hydroxypropylcellulose
- * colloidal silicon dioxide (anhydrous)
- * magnesium stearate
- * purified water
- * Opadry II complete film coating system 85F28751 White
- * Opadry II complete film coating system 85F10919 Blue

CADUET does not contain gluten, sugar or lactose.

Manufacturer

CADUET is supplied in Australia by:
Pfizer Australia Pty Ltd
ABN 5000 8422 348
38-42 Wharf Road
West Ryde NSW 2114
Australia

Toll Free Number: 1800 675 229

Caduet is supplied in New Zealand by:
Pfizer New Zealand Ltd
PO Box 3998
Auckland
New Zealand

Toll Free Number: 0800 736 363

Australian Registration Numbers

CADUET 5mg/10mg -
AUST R 100695
CADUET 5mg/20mg -
AUST R 100696
CADUET 5mg/40mg -
AUST R 100697
CADUET 5mg/80mg -
AUST R 100698
CADUET 10mg/10mg -
AUST R 100700
CADUET 10mg/20mg -
AUST R 100701
CADUET 10mg/40mg -
AUST R 100702
CADUET 10mg/80mg -
AUST R 100703

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