

CADUET®

Amlodipine Besilate and Atorvastatin Calcium Trihydrate

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 it is expected to 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). Caduet can be 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). In these people, Caduet is used to help reduce the risk of having a heart attack or stroke.

What is high blood pressure?

There are usually no symptoms of high blood pressure (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.

What is cholesterol?

Everyone has cholesterol in their 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, 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. Sometimes, the plaque can detach from the vessel wall and float in the bloodstream; it can then reach a smaller vessel and completely block it. 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, Caduet is used to treat high cholesterol and high triglycerides together.

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

What is 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. Caduet is used to treat chronic angina.

How Caduet works

Caduet contains a combination of two medicines. One is amlodipine and the other is atorvastatin.

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.

Atorvastatin belongs to a group of medicines called statins. It works by reducing the amount of cholesterol made by the liver. It reduces the 'bad' cholesterol and can raise the 'good' cholesterol. Atorvastatin also helps to protect you from a heart attack or stroke.

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

Your doctor may have prescribed it for another reason.

Caduet is not addictive.

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

Use in Children

There is not enough information to recommend the use of this medicine in children.

Before you take Caduet

When you must not take it

Do not take Caduet if you have an allergy to:

- any medicine containing amlodipine
- any medicine containing atorvastatin
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Caduet if you have active liver disease.

Do not take this medicine if you are pregnant or intend to become pregnant.

If you are a woman of child-bearing age and are taking this

medicine, use a proven method of birth control to avoid pregnancy.

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

Do not take this medicine if you are breastfeeding or intend to breastfeed.

This medicine passes into breast milk and may affect your baby.

Do not take Caduet if you are taking the antibiotic fusidic acid which is used to treat infections.

Do not take Caduet if you are taking the antivirals, glecaprevir/pibrentasvir for the treatment of Hepatitis C.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking Caduet, talk to your doctor.

Before you start to take it

Your doctor will ask you to have your liver function tested before you start to take Caduet.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems, including heart failure
- liver problems
- kidney problems
- muscle pain, tenderness or weakness from other medicines used to treat cholesterol or triglycerides
- breathing problems
- a type of stroke called a haemorrhagic stroke or a type of stroke called a lacunar stroke. If you have had one of these strokes before, this medicine may increase the risk of you having a haemorrhagic stroke.

Tell your doctor if you are consuming alcohol regularly.

If you have not told your doctor about any of the above, tell him/her before you start taking Caduet.

Taking other medicines

Tell your doctor or pharmacist if:

- you are taking other calcium channel blockers. These medicines include amlodipine which is also in Caduet; other calcium channel blockers include medicines with the active ingredient felodipine or nifedipine. Check with your doctor or pharmacist if you are unsure.
- you are taking other statins. These medicines include atorvastatin which is also in Caduet. Other statins include medicines with the active ingredient fluvastatin, pravastatin, rosuvastatin, simvastatin or simvastatin containing medicines. Check with your doctor or pharmacist if you are unsure.

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Caduet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- digoxin, a medicine used to treat some heart problems
- the antibiotics erythromycin, clarithromycin, rifampicin or fusidic acid

- phenytoin, a medicine used to treat epilepsy (seizures)
- oral contraceptives for birth control
- other medicines to treat high cholesterol or triglycerides
- other medicines to treat high blood pressure
- some medicines to treat low potassium
- cyclosporin, tacrolimus, sirolimus or everolimus, medicines used to suppress the immune system
- temsirolimus, a medicine used to treat kidney cancer
- some medicines used to treat some fungal infections, such as ketoconazole or itraconazole
- protease inhibitors for the treatment of HIV infection and/or Hepatitis C, such as efavirenz, fosamprenavir, ritonavir, boceprevir, telaprevir, tipranavir/ritonavir, elbasvir/grazoprevir and simprevir
- HCV non structural protein 5A (NS5A)/ 5B (NS5B) inhibitors such as daclatasvir and ledipasvir
- letermovir
- diltiazem, a medicine used to treat angina
- antacids, medicines used to treat reflux or ulcers
- spironolactone, a medicine used to treat high blood pressure and certain types of swelling
- vitamin B3
- colchicine, a medicine used to treat a disease with painful swollen joints caused by uric acid crystals.

It is also possible that Caduet may be affected by some medicines used to treat heart palpitations (orarrhythmias) and St John's Wort.

Your doctor and pharmacist have 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 start taking Caduet.

How to take Caduet

Take Caduet exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor may discuss with you the need to be on a diet.

Follow your agreed diet plan carefully.

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

How much to take

Caduet is taken once a day. Your doctor will decide which strength is suitable for you. This will depend on your blood pressure, cholesterol and triglyceride levels.

Your doctor may need to adjust your dose after your blood pressure and the fat levels in your blood have been checked. It is important that you keep your appointments to have these tests done.

How to take it

Swallow the tablet whole with a full glass of water.

Do not chew or crush the tablets.

When to take it

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

Taking it 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

Take Caduet every day and continue taking it for as long as your doctor tells you.

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

It is important to keep taking your medicine even if you feel well. If you stop taking Caduet, your blood pressure and cholesterol levels may rise again.

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

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

If you are not sure what to do, ask your doctor or pharmacist.

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 - for advice, or go to Accident and Emergency at the 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 taking Caduet

Things you must do

Keep all of your doctor's appointments so that your progress can be checked.

Follow the directions from your doctor about regular testing.

Your cholesterol and triglyceride levels and your liver function tests need to be checked regularly while you are taking this medicine.

A regular blood test to check an enzyme called creatine kinase (CK) may be needed. CK in your blood can rise after muscle injury which can be caused by medicines used to treat cholesterol or triglycerides, such as Caduet.

This helps to make sure that Caduet is working and to avoid some possible side-effects.

Your blood pressure may also be checked regularly.

Tell any other doctors, dentists and pharmacists who treat 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, stop taking it and tell your doctor immediately.

Things you must not do

Do not take Caduet to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

Avoid drinking large quantities of alcohol.

Drinking large quantities of alcohol while taking Caduet may increase your chance of getting liver problems.

Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including Caduet.

Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking Caduet increases your chance of getting side effects.

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 you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Things that would be helpful for your condition

Some self-help measures suggested below may assist your condition. Your doctor or pharmacist can give you more information about these measures.

- **Weight:** While you are taking Caduet, you may need to follow a diet plan agreed to with your doctor. This may include measures to lose some weight.
- **Exercise:** Regular exercise can help lower your cholesterol levels and blood pressure and can strengthen your heart. It is important not to overdo it. Before commencing regular exercise you should consult your doctor who will suggest the most suitable exercise for you. If you experience any discomfort when exercising, see your doctor.
- **Alcohol:** Excessive alcohol intake can raise your cholesterol levels or affect your liver function, which could increase the chance of you getting unwanted side effects. Your doctor may discuss with you whether you should reduce the amount of alcohol you drink.

- **Smoking:** Smoking increases the risk of you suffering from heart problems. Your doctor may advise you to stop smoking.
- **Salt:** Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, avoid using salt at the table or in cooking.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking Caduet, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

Do not be alarmed by the list of possible side effects.

You may not experience any of them.

Tell your doctor if...

Ask your doctor or pharmacist for advice if you experience any of the following and they worry you:

- headache
- flushing
- dizziness
- tiredness or weakness
- drowsiness or sleepiness
- stomach pain or nausea (feeling sick)
- constipation, diarrhoea, wind
- heartburn, indigestion or wind
- urine infection
- headache
- stuffy or runny nose
- nose bleeds
- rash.

These are the more common side effects of Caduet. All side effects should be reported to a health professional.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- swelling of the ankles, feet, face or hands
- muscle and joint pain, muscle weakness, especially in the forearms, thighs, hips, shoulders, neck, and back
- difficulty climbing stairs or standing up from a chair
- difficulty lifting arms over the head
- falling and difficulty getting up from a fall
- symptoms of liver disease such as itching, yellowing of the skin and eyes and dark coloured urine
- feeling weak and tired, excessively thirsty and passing more urine
- dizziness or lightheadedness on standing up from a sitting or lying position
- problems with breathing, including shortness of breath, persistent cough and fever
- eye pain or change in vision
- changes in mood, feeling anxious or nervous.

These are serious side effects that may require medical attention.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- symptoms of allergy such as skin rash, itching, swelling of the face, lips, mouth, throat or neck which may cause difficulty in swallowing and breathing
- shortness of breath

- unexpected muscle pain, tenderness or weakness not caused by exercise, particularly if you also feel unwell or have a fever
- tingling in the hands or feet
- changes in heartbeat, either fast, slow or irregular
- chest pain associated with exertion (angina) that lasts longer, is more severe or occurs more often
- chest pain
- sudden severe headache, which may be accompanied by nausea, vomiting, loss of sensation, tingling in any part of the body or ringing in the ears
- severe blisters and bleeding of the lips, eyes, mouth, nose or genitals
- severe upper stomach pain, often with nausea and vomiting.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

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.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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 may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°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 medicine that is left over.

Product description

What it looks like

Caduet Tablets are available in eight strengths:

- Caduet 5 mg/10 mg - white, oval, film coated tablets debossed with "AT10" on one side and "A5" on the other
- Caduet 5 mg/20 mg - white, oval, film coated tablets debossed with "AT20" on one side and "A5" on the other
- Caduet 5 mg/40 mg - white, oval, film coated tablets debossed with "AT40" on one side and "A5" on the other
- Caduet 5 mg/80 mg - white, oval, film coated tablets debossed with "AT80" on one side and "A5" on the other

- Caduet 10 mg/10 mg - blue, oval, film coated tablets debossed with "AT10" on one side and "A10" on the other
- Caduet 10 mg/20 mg - blue, oval, film coated tablets debossed with "AT20" on one side "A10" on the other
- Caduet 10 mg/40 mg - blue, oval, film coated tablets debossed with "AT40" on one side and "A10" on the other
- Caduet 10 mg/80 mg - blue, oval, film coated tablets debossed with "AT80" on one side and "A10" on the other

A box contains 10 or 30 tablets.

Ingredients

Active ingredients

Caduet tablets contain the following strength combinations of the active ingredients amlodipine/atorvastatin:

- 5 mg/10 mg
- 5 mg/20 mg
- 5 mg/40 mg
- 5 mg/80 mg
- 10 mg/10 mg
- 10 mg/20 mg
- 10 mg/40 mg
- 10 mg/80 mg

Other ingredients

Caduet tablets also contain:

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

Caduet does not contain gluten, sugar or lactose.

Supplier

Caduet is supplied in Australia by:

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065
Australia
<http://www.aspenpharma.com.au>

Australian Registration Numbers

Caduet 5 mg/10 mg -
AUST R 100695

Caduet 5 mg/20 mg -
AUST R 100696

Caduet 5 mg/40 mg -
AUST R 100697

Caduet 5 mg/80 mg -
AUST R 100698

Caduet 10 mg/10 mg -
AUST R 100700

Caduet 10 mg/20 mg -
AUST R 100701

Caduet 10 mg/40 mg -
AUST R 100702

Caduet 10 mg/80 mg -
AUST R 100703

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