

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CADUET® 5 mg/10 mg film-coated tablet

CADUET® 5 mg/20 mg film-coated tablet

CADUET® 10 mg/10 mg film-coated tablet

CADUET® 10 mg/20 mg film-coated tablet

CADUET® 10 mg/40 mg film-coated tablet

CADUET® 10 mg/80 mg film-coated tablet

Amlodipine and atorvastatin

Sugar free

Read all of this leaflet carefully before you start taking CADUET

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CADUET has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CADUET is and what it is used for
2. What you need to know before you take CADUET
3. How to take CADUET
4. Possible side effects
5. How to store CADUET
6. Contents of the pack and other information

1. What CADUET is and what it is used for

CADUET is used:

- In patients at increased risk of heart disease due to both high blood pressure (hypertension) and abnormal fat (cholesterol) levels (dyslipidaemia), or
- In patients with a certain type of chest pain known as angina and abnormal fat (cholesterol) levels (dyslipidaemia).

2. What you need to know before you take CADUET

Do not take CADUET:

- If you are hypersensitive (allergic) to amlodipine or atorvastatin or any other calcium channel blocker or any of the other ingredients of CADUET (listed in section 6).
- If you have or have had any liver disease or any unexplained abnormal blood tests for liver function.
- If you are pregnant, trying to become pregnant or breastfeeding.
- If you are able to have children and are not using adequate contraceptive measures.
- If you have severe low blood pressure (hypotension).
- If you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you have narrowing of the aortic heart valve (aortic stenosis).
- If you suffer from heart failure after a heart attack.
- If you are taking tipranavir plus ritonavir (for the treatment of HIV) or telaprevir (used to treat Hepatitis C), you should not take dose combinations of CADUET where the atorvastatin component is more than 10 mg.
- If you use the combination of glecaprevir/pibrentasvir (used to treat Hepatitis C).

Warnings and precautions

Take special care with CADUET:

Tell your doctor:

- If you have suffered heart failure.
- If you drink excessive amounts of alcohol and/or have a history of liver disease.

- If you have kidney problems.
- If you have an underactive thyroid gland (hypothyroidism).
- If you have muscle disorders or if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g. other “statins” or “fibrate” medicines).
- If you are taking any of the following medication as the risk of muscle related side effects are increased if taken together with CADUET:
 - Colchicine (used to treat gout, a kind of arthritis).
 - Vitamin B3.
 - Fibric acid derivatives (a class of medicines also used to lower blood fat levels).
 - Telaprevir, boceprevir, and the combination of elbasvir/grazoprevir (used to treat hepatitis C).
 - Saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir and fosamprenavir plus ritonavir (combination of protease inhibitors used to treat HIV).
 - Immunosuppressive medicines (medicines that inhibit or prevent activity of the immune system).
 - Azole antifungal medication (used to treat fungal infections).
 - Fusidic acid or erythromycin (antibiotics used to treat bacterial infections).
- If you have suffered a stroke.
- If you have diabetes mellitus.

Tell your doctor if serious liver injury or jaundice (yellow discolouration of skin or whites of the eyes) occurs.

If you experience unexplained muscle pain, tenderness or weakness especially if accompanied by fever or a general feeling of being unwell, tell your doctor. Your doctor may need to carry out a blood test before and possibly during your CADUET treatment to predict your risk of muscle related side effects.

Children and adolescents

Safety and effectiveness of CADUET in children and adolescents has not been proven.

Other medicines and CADUET

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines).

There are some medicines that may change the effect of CADUET, or their effect may be changed by CADUET. This type of 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 condition known as rhabdomyolysis (serious muscle pain and weakness often associated with fever). Your doctor will consider this in deciding upon your dose of CADUET.

Some medicines that may interact with CADUET include:

- Medicines used to modulate immune response e.g. ciclosporin.
- Nefazodone (an antidepressant).
- Certain antibiotics or antifungal medicines e.g. erythromycin, clarithromycin, rifampicin, itraconazole and ketoconazole.
- A herbal medicine for depression called St John's wort containing *Hypericum perforatum*.
- Other medicines to regulate lipid (fat) levels e.g. fibric acid derivatives, colestipol, niacin (nicotinic acid).
- Some calcium channel blockers used for angina or high blood pressure e.g. diltiazem.
- Medicines to regulate your heart rhythm e.g. digoxin.
- Protease inhibitors used in the treatment of HIV e.g. saquinavir plus ritonavir, lopinavir plus ritonavir, tipranavir plus ritonavir, darunavir plus ritonavir, fosamprenavir and fosamprenavir plus ritonavir (combination of protease inhibitors used to treat HIV).
- Efavirenz used in the treatment of HIV.
- Telaprevir and boceprevir (used to treat hepatitis C).
- Colchicine (used to treat gout, a kind of arthritis).
- Warfarin (which reduces blood clotting), oral contraceptives, antacids (indigestion products containing aluminium or magnesium) and fusidic acid.

CADUET with food and drink

You should not take grapefruit or grapefruit juice while using CADUET as this combination can result in an undesirable interaction.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Do not take CADUET:

- If you are pregnant, trying to become pregnant or breastfeeding your baby.
- If you are able to have children and are not using adequate contraceptive measures.

Driving and using machines

CADUET may make you feel dizzy or faint and you may experience muscle weakness and/or muscle pain that can interfere with your ability to drive or use machinery.

It is not always possible to predict to what extent CADUET may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which CADUET affects them.

3. How to take CADUET

Do not share medicines prescribed for you with any other person.

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

The smallest dose of CADUET is 5 mg/10mg once a day and can range up to 10 mg/80 mg once a day. Your doctor will decide on the appropriate dose for you. CADUET tablets can be taken at any time of the day with or without food. However, try to take your tablet at the same time every day. Remember to continue with your diet and lifestyle changes while you are taking CADUET, as per your doctor's advice.

CADUET can be taken with or without food.

Your doctor will tell you how long your treatment with CADUET will last. If you have the impression that the effect of CADUET is too strong or too weak, tell your doctor or pharmacist.

If you take more CADUET than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CADUET

If you miss a dose of CADUET, take it as soon as you remember unless it is time to take the next dose.

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

4. Possible side effects

CADUET can have side effects.

Not all side effects reported for CADUET are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CADUET, please consult your health care provider for advice.

If any of the following happens, stop taking CADUET and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Symptoms of a heart attack such as severe chest pains possibly radiating to the jaw or arm, sweating, breathlessness and nausea.
- Allergic reactions including swelling of the face, lips, tongue, and/or throat that may cause difficulty in breathing or swallowing.
- Severe skin rash, burning or numbness of the skin, peeling or blistering of the skin together with fever and feeling unwell.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CADUET. You may need urgent medical attention or hospitalisation.

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

- 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.
- Your skin and whites of your eyes get yellow which is a sign of jaundice/liver problems.
- Low blood pressure (with symptoms such as dizziness, light-headedness, blurred vision, nausea,

clammy skin, fainting).

- *Muscle problems:*

CADUET can cause a breakdown of muscle tissue that releases a damaging protein into the blood 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 may do blood tests to check your liver before you start taking CADUET and if you have symptoms of liver problems while you take CADUET. Symptoms of liver problems include:

- Feeling tired or weak.
- Loss of appetite.
- Upper belly pain.
- Dark amber coloured urine.
- Yellowing of your skin or the whites of your eyes.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Inflammation and infection of the throat and nasal passages.
- Pain in the throat and voice box.
- Nose bleeds.
- Inability to sleep.
- Reduced sensitivity to touch.
- Tingling ('pins and needles').
- Dizziness.
- Headache.
- Sleepiness.
- Nausea.
- Diarrhoea.
- Abdominal pain.

- Indigestion.
- Constipation.
- Passing wind.
- Itchy skin.
- Rash.
- Muscle pain.
- Joint pain.
- Back pain.
- Pain in the hands and feet.
- Bone pain.
- Muscle spasms.
- Joint swelling.
- Palpitations (very fast heartbeat).
- Flushing (redness and feeling hot in the face).
- Abnormal liver function tests.
- Increased blood levels of creatine phosphokinase (an enzyme found in the heart, brain and skeletal muscles).
- Lack of energy.
- Chest pain.
- Tiredness.
- Swelling due to retained fluid.

Less frequent side effects:

- Too few white blood cells (symptoms of which may be recurrent infections).
- Too few blood platelets (symptoms of which are bruising easily, prolonged bleeding from cuts, nose bleeds, bleeding gums, pinpoint-sized reddish-purple spots caused by bleeding into the skin).
- Low blood sugar.
- High blood sugar.
- Anorexia (eating disorder) relating to a fear of gaining weight).

- Weight loss.
- Weight gain.
- Nightmares.
- Mood changes.
- Tremor.
- Change in sense of taste.
- Fainting.
- Muscle stiffness/spasms.
- Nerve damage affecting extremities of the body (resulting in weakness, numbness or pain ~~on~~ in hands and feet).
- Loss of memory.
- Blurred vision.
- Visual impairment.
- Ringing in the ears.
- Irregular heartbeat.
- Inflammation of the blood vessels.
- Shortness of breath.
- Sneezing and runny nose.
- Coughing.
- Vomiting.
- Abdominal discomfort.
- Burping.
- Change in bowel habits.
- Dry mouth.
- Inflammation of the pancreas (symptoms of which are upper abdominal pain that radiates into the back which gets worse by eating, especially foods high in fat, swollen and tender abdomen, nausea and vomiting).
- Inflammation of the stomach.

- Swelling of the gums.
- Inflammation of the liver and/or increase in liver enzymes (symptoms of which are tiredness, flu-like symptoms, dark urine, pale-coloured stool, abdominal pain, loss of appetite and unexplained weight loss).
- Torn tendon.
- Hair loss.
- Small, purple-coloured spots caused by bleeding into the skin.
- Skin discolouration.
- Increased sweating.
- Swelling under the skin (especially around eyes, lips, hands and feet).
- Hives.
- Blisters.
- Weak muscle strength.
- Neck pain.
- Swollen muscles.
- Muscle cramps.
- Muscle tissue disease/damage/breakdown.
- Urinary problems.
- Increased need to urinate especially at night.
- Presence of white blood cells in urine (as shown in urine test).
- Impotence/ inability to obtain an erection.
- Enlargement of male breasts.
- Pain.
- Feeling unwell.
- Fever.
- Swelling of hands and feet.

Additional side effects reported after the marketing of CADUET include

- Cognitive impairment (e.g. memory loss, forgetfulness, loss of memory, memory impairment and

confusion).

- Core muscle weakness making it difficult to rise from chairs, climb stairs, and/or breathe and swallow.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of CADUET.

5. How to store CADUET

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light.
- Store in the original package/carton.
- Keep the blister in the outer carton.
- Do not store in a bathroom.
- Do not take CADUET after the expiry date shown on the blister label/ carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicines in the drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CADUET contains

- The active substances are amlodipine besylate and atorvastatin calcium available as 5 mg/10 mg, 5 mg/20 mg, 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg dosage strengths respectively.
- The other ingredients are calcium carbonate, croscarmellose sodium, microcrystalline cellulose, pregelatinised starch, polysorbate 80, hydroxypropyl cellulose, purified water, colloidal silicone dioxide (anhydrous), magnesium stearate, Opadry II White or Opadry Blue.

What CADUET looks like and contents of the pack

CADUET 5 mg/10 mg: White oval shaped film-coated tablet, marked “Pfizer” on one side and “CDT 051” on the other side.

CADUET 5 mg/20 mg: White oval shaped film-coated tablet, marked “Pfizer” on one side and “CDT 052” on the other side.

CADUET 10 mg/10 mg: Blue oval shaped film-coated tablet, marked “Pfizer” on one side and “CDT 101” on the other side.

CADUET 10 mg/20 mg: Blue oval shaped film-coated tablet, marked “Pfizer” on one side and “CDT 102” on the other side.

CADUET 10 mg/40 mg: Blue oval shaped film-coated tablet, marked “Pfizer” on one side and “CDT 104” on the other side.

CADUET 10 mg/80 mg: Blue oval shaped film-coated tablet, marked “Pfizer” on one side and “CDT 108” on the other side.

CADUET tablets are available in silver aluminium foil/foil blister packs containing 30 film-coated tablets.

Holder of Certificate of Registration

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Manufacturer: Pfizer Manufacturing Deutschland GmbH, Freiburg, Germany

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CADUET 5 mg/10 mg: A39/7.0/0326

CADUET 5 mg/20 mg: A39/7.0/0327

CADUET 10 mg/10 mg: A39/7.0/0330

CADUET 10 mg/20 mg: A39/7.0/0331

CADUET 10 mg/40 mg: A39/7.0/0332

CADUET 10 mg/80 mg: A39/7.0/0333

BOTSWANA: S2

CADUET 5 mg/10 mg – Reg. No.: BOT0801488

CADUET 5 mg/20 mg – Reg. No.: BOT1202067

CADUET 10 mg/10 mg – Reg. No.: BOT0801489

CADUET 10 mg/20 mg – Reg. No.: BOT1202069

CADUET 10 mg/40 mg – Reg. No.: BOT1202070

NAMIBIA: NS2

CADUET 5 mg/10 mg – Reg. No.: 06/7.0/0256

CADUET 5 mg/20 mg – Reg. No.: 06/7.0/0257

CADUET 10 mg/10 mg – Reg. No.: 06/7.0/0258

CADUET 10 mg/20 mg – Reg. No.: 06/7.0/0259

CADUET 10 mg/40 mg – Reg. No.: 08/7.0/0093

CADUET 10 mg/80 mg – Reg. No.: 08/7.0/0094