

PACKAGE LEAFLET: INFORMATION FOR THE USER

CADUET

5 mg/10 mg, film-coated tablets

10mg/10 mg, film-coated tablets

AMLODIPINE, ATORVASTATIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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2. Before you take Caduet
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1. WHAT CADUET IS AND WHAT IT IS USED FOR

CADUET is applied for preventing cardiovascular problems (e.g., angina, heart attack) in patients with (high blood pressure who have additional risk factors for the development of cardiovascular diseases, such as smoking, excessive weight, increased blood cholesterol level, family history of heart disease or diabetes. The existence of the above mentioned risk factors, associated with high blood pressure, are the cause of the increased risk for cardiovascular problems in these patients.

CADUET is a medicine which contains two active substances, amlodipine (calcium channel antagonist) and atorvastatin (statin) and it is used after your doctor recommended to use both the active substances. Amlodipine is used to treat high blood pressure (hypertension), while atorvastatin reduces cholesterol.

High blood pressure (hypertension) is a condition in which there is a permanent increase in the blood pressure and it is one of the risk factors for cardiovascular problems (angina, heart attack, and stroke).

Cholesterol is a substance that is naturally present in the body, which is essential for normal growth. However, if there is too much cholesterol in the blood, it can deposit on the walls of the blood vessels, increasing the risk of blood clots and cardiovascular events. It is one of the most common causes of heart disease.

2. BEFORE YOU TAKE CADUET

Do not take Caduet

- If you are allergic (hypersensitive) to amlodipine or atorvastatin, or on any other medicine from group of calcium channel inhibitors
- If you are allergic (hypersensitive) to any of the other ingredients of the medicinal product (listed at the end of the leaflet)
- If you are suffering from liver diseases (if you have a history of liver diseases in the past, see the section, "take special care with Caduet")
- If you have abnormal liver function of an unknown cause
- If you are pregnant, trying to become pregnant, or are breast• feeding
- If you are taking any of the following medicines: ketoconazole, itraconazole (medicines for the treatment of fungal diseases), telithromycin (an antibiotic)
- If you have very low blood pressure (hypotension)
- If you have a narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition in which your heart cannot supply enough blood to the body)
- If you experienced a heart failure after a heart attack

Take special care with Caduet

- If you have problems with your kidneys
- If you have an underactive thyroid gland (hypothyroidism)
- If you have cramps or pain that is repetitive or for which there is no explanation, or if you have a hereditary disease of the muscles in your personal or family medical history;
- If you have had problems with the muscles while taking some of the medicines for lowering the level of cholesterol (lipids) (medicines from a group of statins, or fibrates)
- If you regularly consume excessive amount of alcohol
- If you had liver disease in the past
- If you are over 70 years old
- If you have already had a stroke or have a bleeding in the brain, or if you have areas filled with fluid as a result of a stroke

Check with your doctor or pharmacist before taking Caduet:

If you are suffering from severe respiratory failure

If any of these apply to you, your doctor will do blood tests before and during treatment with CADUET, to predict the risk of adverse reactions associated with the muscles. It is known that the risk of side effects associated with muscles, eg rhabdomyolysis, increases when some medications are used simultaneously (see section "taking other medicines with Caduet").

Taking other medicines with Caduet

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those that can be obtained without a prescription.

There are certain medications that can interact with Caduet. These interactions can decrease the effectiveness of one or both of the medicines. On the other hand, it may increase the risk or severity of adverse reactions, including the important muscle condition called Rhabdomyolysis and myopathy (described in section 4):

- some antibiotics, for example, rifampicin or macrolide antibiotics, for example. erythromycin, clarithromycin, telithromycin; fusidic acid or some medicines used in the treatment of fungal diseases, e.g. ketoconazole, itraconazole
- Medications that control the level of lipids (fats) in the blood: Fibrates (e.g. gemfibrozil), niacin or cholestipol
- medications that regulate heart rhythm, for example. amiodarone, diltiazem
- medicines for preventing seizures, for example. carbamazepine, Phenobarbital, phenytoin, primidone, fosphenitoin
- medicines that have an impact on the operation of your immune system, for example. Cyclosporine
- protease inhibitors used in the treatment of HIV
- medicines used to treat depression (e.g., nefazodone and imipramine)
- medicines used to treat mental disorders (for example, Neuroleptics)
- medicines used for the treatment of cardiac weakness (e.g. beta• blockers)
- medicines used to treat high blood pressure (e.g., Angiotensin II antagonists, ACE inhibitors and diuretics)
- alpha blockers used to treat high blood pressure and diseases of the prostate

Other medicines that are known to have interaction with Caduet include ezetimibe (which lowers cholesterol), warfarin (which reduces blood clotting), oral contraceptives (for preventing conception), stiripentol (an anticonvulsant to treat epilepsy), cimetidine (to treat heartburn and ulcers), fenazon (Painkiller) and antacids (remedies for indigestion that contain aluminum or magnesium), amifostin (which is used in the treatment of cancer) , sildenafil (for erectile dysfunction), dantrolene and baclofen (muscle relaxant), steroids.

- St. John's wort, the product being purchased without a prescription.

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

Taking food and drinks with Caduet

CADUET tablets can be taken at any time of the day, with or without food.

Grapefruit juice

Do not drink more than 1- 2 glasses of grapefruit juice on the day while you are taking CADUET, because large amounts of this juice can modify the effects of Caduet.

Alcohol

During the use of Caduet avoid excessive alcohol consumption. See the section, "take special care with Caduet" for more information.

Pregnancy and breastfeeding

Caduet may not be administered during pregnancy, while you are breastfeeding, or if you plan to become pregnant. Women of childbearing potential must use contraception during the use of Caduet. Contact the doctor or pharmacist for advice before using any medicine.

Driving and using machines

Do not drive a vehicle or operate machinery if you feel dizzy after the use of Caduet.

3. HOW TO TAKE CADUET

You need to take CADUET exactly according to the instructions provided by your doctor. Consult with a doctor or pharmacist if you are not sure.

Adults

The usual starting dose of Caduet is one tablet of 5 mg/10 mg a day. If needed, your doctor may increase your dose to one CADUET 10 mg/10 mg tablet a day.

Swallow the tablets whole, with water. Tablets can be taken by mouth at any time of the day, with or without food. However, try to take this medicine always at the same time.

Continue to follow doctors ' instructions regarding the diet, which is especially important for a diet with reduced fat intake, avoid smoking and regularly exercise.

If it seems that the effect of the medicine is too strong or too weak, tell your doctor or pharmacist.

Children and adolescents:

The medicine is not recommended for use in children and adolescents.

If you take more medicine CADUET than you should

If you have accidentally taken too many tablets of CADUET (more than your usual daily doses), immediately inform your doctors or go to the nearest hospital. Take remaining tablets with you, in the original package, to help hospital staff see what medicine you took.

If you forget to take Caduet

If you forget to take a tablet of CADUET, take your next dose at the usual time.
Do not take a double dose to make up for the missed dose.

If you stop taking Caduet

Do not stop using Caduet until your doctor tells you to.

If you have any further questions about the application of Caduet, contact your doctor, or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

If any of the following occurs, stop taking CADUET and immediately contact your doctor:

- If you have swelling of the face, tongue and trachea, which can cause difficulty breathing
- If you experience unexplained muscle weakness, muscle pain, tenderness, and if at the same time you don't feel well, or you have a fever. (Very rare, the combination of these effects can cause a life-threatening condition called rhabdomyolysis).

Common side effects that may occur in less than 1 person in 10 patients:

- allergic reaction
- headache (especially at the beginning of treatment), dizziness, a sense of fatigue, drowsiness
- irregular heartbeat, flushing
- inflammation of the nasal canal, pain in the throat, bleeding in the nose
- feeling of weakness, abdominal pain, indigestion, the changes in the ordinary work of the intestines (including diarrhoea, constipation and flatulence)
- muscle pain and joint pain, muscle spasms, back pain, pains in the limbs, swelling of the arms, hands, legs, ankles, or feet
- increase in the level of sugar in the blood (if you have diabetes, you should continue to closely monitor the level of sugar in the blood), the increase of creatine phosphokinase in the blood, the blood tests that indicate your liver function may become abnormal

Uncommon side effects that may occur in less than 1 person in 100 patients:

- hepatitis (inflammation of the liver)
- runny nose, loss of appetite, decrease in the levels of sugar in the blood (if you have diabetes you need to continue to carefully monitor blood sugar), getting the weight or losing weight
- difficulty sleeping, the emergence of nightmares, mood changes (including anxiety), depression, tremor, damage to sensory nerves (decrease sensitivity) of arms and legs, loss of memory
- problems with your eyesight (including double vision), blurred vision, ringing or buzzing in the ears
- palpitations (abnormal awareness of all hearts), shortness of breath, fainting, increased sweating, decreased blood pressure
- dry mouth, changes in taste, vomiting, burping
- hair loss, bruising or tiny dots on the skin, discoloration of the skin, reduced skin sensation to touch or pain, numbness or tingling in the fingers, hands, and feet, skin rash, hives or itching.
- urinary disorders (including excessive urination at night and increased frequency of urination), impotence, breast enlargement in males
- feeling of physical discomfort, muscle fatigue, pancreatitis (inflammation of the pancreas that leads to pain in the abdomen), pain, neck pain, pain in the chest

Rare side effects that may occur in less than 1 in 1000 patients:

- vision problems
- unexpected bleeding or bruising
- severe inflammation of the muscles, very strong muscle pain or cramps that in very rare cases, lead to rhabdomyolysis (destruction of muscle cells)
- reduction in the number of platelets in the blood (platelets)
- liver problems (yellowing of the skin or whites of the eyes)
- severe skin reaction of allergic nature, skin redness, rash in the form of blisters, peeling of skin that easily detaches through the entire body and can begin with symptoms similar to the flu, accompanied with high fever
- swelling in the deep layers of the skin• including swelling of the lips, eyelids and tongue
- Inflammation or skeletal muscle swelling, rash with blisters
- inflammation of the tendons, tendon injuries
- confusion

Very rare side effects that may occur in less than 1 in 10000 patients

- allergic reactions – symptoms can include sudden wheezing and chest pain or tightness in the chest, swelling of eyelids, face, lips, mouth, tongue or throat, difficulty in breathing, the collapse of the
- Gynecomastia (enlarged breasts in men and women)
- decreased number of white blood cells in the blood
- stiffness and muscle tension
- abnormal heart rhythm, heart attack, inflammation of the small blood vessels, pain in the stomach (gastritis)
- overgrowth of the gums, cough
- hearing loss, liver failure
- photosensitivity (skin sensitivity to light)

Other possible side effects:

- sexual difficulties
- depression
- problems with breathing, including persistent cough and/or shortness of breath or fever
- disorders which include tremor, stiffness and/or disorders of movement

If you notice any side effects, talk to your doctor or pharmacist.

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

5. HOW TO STORE CADUET

Keep out of reach and sight of children.

Keep at temperature below 30 ° c.

CADUET must not be used after the expiry date stated on the carton. The expiry date refers to the last day of that month.

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

The shelf life of the medicinal product:

3 years.

6. FURTHER INFORMATION

What Caduet contains

Active substance

The active substance of CADUET tablets are amlodipine and atorvastatin. CADUET 5 mg/10 mg tablets contain 5 mg of amlodipine (amlodipine in the form of besilate) and 10 mg of atorvastatin (in the form of atorvastatin calcium trihydrate).

CADUET 10 mg/10 mg tablets contain 10 mg amlodipine (amlodipine in the form of besilate) and atorvastatin 10 mg (in the form of atorvastatin calcium trihydrate).

The other ingredients

Tablet core: calcium carbonate, carmellose sodium, networked, cellulose, cellulose, pregelatinized corn starch, polysorbate 80, cellulose, silicon dioxide, colloidal anhydrous, magnesium stearate

Coating: CADUET 5 mg/10 mg tablets: Opadry II White 85F28751 (polyvinyl alcohol, titanium dioxide (E171), MACROGOL 3000, TALC).

Coating: CADUET 10 mg/10 mg tablets: Opadry II Blue 85F10919 (polyvinyl alcohol, titanium dioxide (E171), MACROGOL 3000, talc, indigo Carmine (E132) lacquer aluminum).

What Caduet looks like and contents of the pack

Caduet 5 mg/10 mg tablets: white, oval, film• coated tablets, debossed with "Pfizer" on one side and "CDT 051" from the other side.

Caduet 10 mg/10 mg tablets: Blue, oval, film coated tablets with "Pfizer" on one side and "CDT 101" on the other side.

CADUET tablets are available in blister packs of 30 tablets.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

Pfizer Luxembourg S.A.R.L,
51 Avenue J.F Kennedy, L• 1855, Luxembourg, Luxembourg

Manufacturer of the medicinal product

Pfizer Manufacturing Deutschland GmbH
Betriebsstatte Freiburg, Mooswaldallee 1, Freiburg, Germany