

Package leaflet: Information for the patient

Candesartan cilexetil/Amlodipine 8 mg/5 mg tablets

Candesartan cilexetil/Amlodipine 16 mg/5 mg tablets

Candesartan cilexetil/Amlodipine 16 mg/10 mg tablets

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. See section 4.

What is in this leaflet

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

1. What Candesartan/Amlodipine is and what it is used for

The products Candesartan cilexetil/Amlodipine 8 mg/5 mg, 16 mg/5 mg and 16 mg/10 mg tablets are referred to as Candesartan/Amlodipine throughout the leaflet. Candesartan/Amlodipine contains two substances called amlodipine and candesartan cilexetil. Both of these substances help to control high blood pressure.

- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.
- Candesartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Candesartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Candesartan/Amlodipine is used to treat high blood pressure in patients whose blood pressure is already controlled on the combination of amlodipine and candesartan taken separately at the same doses as in Candesartan/Amlodipine.

2. What you need to know before you take Candesartan/Amlodipine

Do not take Candesartan/Amlodipine

- if you are allergic to amlodipine or to any other calcium antagonists, candesartan cilexetil or any of the other ingredients of this medicine (listed in section 6).
- if you have severe low blood pressure (hypotension).
- if you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- if you suffer from heart failure after a heart attack.
- if you are pregnant (see pregnancy section).
- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Candesartan/Amlodipine if you have or have had any of the following conditions:

- recent heart attack
- heart failure
- severe increase in blood pressure (hypertensive crisis)
- low blood pressure (hypotension)
- you are elderly and your dose needs to be increased
- heart, liver or kidney problems, or are on dialysis
- if you have recently had a kidney transplant
- if you are vomiting, have recently had severe vomiting, or have diarrhoea
- if you have a disease of the adrenal gland called Conn’s syndrome (also called primary hyperaldosteronism)
- if you have ever had a stroke
- if you are taking an ACE-inhibitor together with a medicine which belongs to a class of medicines known as mineralocorticoid receptor antagonists (MRA). These medicines are for the treatment of heart failure (see Other Medicines)

- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also information under the heading “Do not take Candesartan/Amlodipine”.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Candesartan/Amlodipine. Your doctor will decide on further treatment. Do not stop taking Candesartan/Amlodipine on your own.

Your doctor may want to see you more often and do some tests if you have any of these conditions.

If you are going to have an operation, tell your doctor or dentist that you are taking Candesartan/Amlodipine. This is because Candesartan/Amlodipine, when combined with some anaesthetics, may cause an excessive drop in blood pressure.

You must tell your doctor if you think you are (or might become) pregnant. Candesartan/Amlodipine is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Children and adolescents

There is no experience with the use of Candesartan/Amlodipine in children (below the age of 18 years). Therefore, do not give this medicine to children and adolescents.

Other medicines and Candesartan/Amlodipine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Candesartan/Amlodipine may affect or be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions if you are taking:

- ketoconazole, itraconazole (anti-fungal medicines)
- ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV)
- rifampicin, erythromycin, clarithromycin (antibiotics - for infections caused by bacteria)
- hypericum perforatum (St. John’s Wort)
- verapamil, diltiazem (heart medicines)
- dantrolene (infusion for severe body temperature abnormalities)

- tacrolimus, sirolimus, temsirolimus, and everolimus (used to control your body’s immune response, enabling your body to accept the transplanted organ)
- simvastatin (a cholesterol lowering medicine)
- cyclosporine (an immunosuppressant)
- other medicines to help lower your blood pressure, including beta-blockers and diazoxide
- an ACE-inhibitor or aliskiren (see also information under the headings “Do not take” Candesartan/Amlodipine and “Warnings and precautions”)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation)
- acetylsalicylic acid (medicine to relieve pain and inflammation), if you are taking more than 3 g each day.
- potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood)
- heparin (a medicine for thinning the blood)
- co-trimoxazole (an antibiotic medicine) also known as trimethoprim/sulfamethoxazole
- water tablets (diuretics)
- lithium (a medicine for mental health problems)
- an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example: spironolactone, eplerenone)

Candesartan/Amlodipine with food and drink

Grapefruit juice and grapefruit should not be consumed while taking Candesartan/Amlodipine. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active ingredient amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of Candesartan/Amlodipine.

When you are prescribed Candesartan/Amlodipine, discuss with your doctor before drinking alcohol.

Alcohol may make you feel faint or dizzy.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Candesartan/Amlodipine before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Candesartan/Amlodipine.

Candesartan/Amlodipine is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Amlodipine has been shown to pass into breast milk in small amounts. If you are breastfeeding or about to start breast-feeding you must tell your doctor before taking Candesartan/Amlodipine. Candesartan/Amlodipine is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Candesartan/Amlodipine may have moderate influence on your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Candesartan/Amlodipine contains lactose monohydrate and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Candesartan/Amlodipine

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

The recommended dose of Candesartan/Amlodipine 8 mg/5 mg is 1 tablet or 2 tablets daily.

The recommended dose of Candesartan/Amlodipine 16 mg/5 mg is 1 tablet daily.

The recommended dose of Candesartan/Amlodipine 16 mg/10 mg is 1 tablet daily. The tablet can be divided into equal doses.

You can take Candesartan/Amlodipine with or without food.

Swallow the tablet with a drink of water.

If you take more Candesartan/Amlodipine than you should

Taking too many tablets may cause your blood pressure to become low or even dangerously low. You may feel dizzy, lightheaded, faint or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness.

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake. Seek immediate medical attention if you take too many tablets.

If you forget to take Candesartan/Amlodipine

If you forget to take a tablet, leave out that dose completely. Take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Candesartan/Amlodipine

Your doctor will advise you how long to take your medicine. Your condition may return if you stop using your medicine before you are advised. Therefore do not stop taking Candesartan/Amlodipine without first talking to your doctor.

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

4. Possible side effects

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

Visit your doctor **immediately** if you experience any of the following, very rare, severe side effects after taking this medicine:

- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- swelling of eyelids, face or lips
- swelling of the tongue and throat which causes great difficulty breathing
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions
- heart attack, abnormal heart beat
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell

Candesartan may cause a reduction in number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Candesartan/Amlodipine has had any effect on your blood (agranulocytosis).

Other possible side effects:

Since Candesartan/Amlodipine is a combination of two active substances, the side effects that have been reported are linked either to the use of amlodipine or candesartan.

Side effects linked to the use of amlodipine

Very common (may affect more than 1 in 10 people):

- oedema (fluid retention)

Common (may affect up to 1 in 10 people):

- headache, dizziness, sleepiness (especially at the beginning of treatment)
- palpitations (awareness of your heart beat), flushing
- abdominal pain, feeling sick (nausea)
- altered bowel habits, diarrhoea, constipation, indigestion
- tiredness, weakness
- visual disturbances, double vision
- muscle cramps
- ankle swelling

Uncommon (may affect up to 1 in 100 people):

- mood changes, anxiety, depression, sleeplessness
- trembling, taste abnormalities, fainting
- numbness or tingling sensation in your limbs; loss of pain sensation
- ringing in the ears
- low blood pressure
- sneezing/running nose caused by inflammation of the lining of the nose (rhinitis)
- cough
- dry mouth, vomiting (being sick)
- hair loss, increased sweating, itchy skin, red patches on skin, skin discolouration
- disorder in passing urine, increased need to urinate at night, increased number of times of passing urine
- inability to obtain an erection; discomfort or enlargement of the breasts in men
- pain, feeling unwell
- joint or muscle pain, back pain
- weight increase or decrease

Rare (may affect up to 1 in 1,000 people):

- confusion

Very rare (may affect up to 1 in 10,000 people):

- decreased numbers of white blood cells, decrease in blood platelets which may result in unusual bruising or easy bleeding (red blood cell damage)
- excess sugar in blood (hyperglycaemia)
- a disorder of the nerves which can cause muscular weakness, tingling or numbness
- swelling of the gums
- abdominal bloating (gastritis)
- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice), liver enzyme increase which may have an effect on some medical tests

- increased muscle tension
- inflammation of blood vessels, often with skin rash
- sensitivity to light

Not known (frequency cannot be estimated from the available data):

- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk

Side effects linked to the use of candesartan

Common (may affect up to 1 in 10 people):

- feeling dizzy/spinning sensation
- headache
- respiratory infection
- low blood pressure. This may make you feel faint or dizzy.
- changes in blood test results: an increased amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe you may notice tiredness, weakness, irregular heart beat or pins and needles.
- effects on how your kidneys work, especially if you already have kidney problems or heart failure. In very rare cases, kidney failure may occur.

Very rare (may affect up to 1 in 10,000 people):

- swelling of the face, lips, tongue and/or throat
- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea
- a reduction in your red or white blood cells. You may notice tiredness, an infection or a fever
- skin rash, lumpy rash (hives)
- itching
- back pain, pain in joints and muscles
- changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms.
- cough
- nausea
- changes in blood test results: a reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps.

Not known (frequency cannot be estimated from the available data):

- diarrhoea.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search

for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Candesartan/Amlodipine

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Candesartan cilexetil/Amlodipine contains

The active substances are candesartan cilexetil and amlodipine.

Candesartan cilexetil/Amlodipine 8 mg/5 mg: Each tablet contains 8 mg candesartan cilexetil and 6.9 mg amlodipine besilate equivalent to 5 mg amlodipine.

Candesartan cilexetil/Amlodipine 16 mg/5 mg: Each tablet contains 16 mg candesartan cilexetil and 6.9 mg amlodipine besilate equivalent to 5 mg amlodipine.

Candesartan cilexetil/Amlodipine 16 mg/10 mg: Each tablet contains 16 mg candesartan cilexetil and 13.9 mg amlodipine besilate equivalent to 10 mg amlodipine.

Candesartan cilexetil/Amlodipine 8 mg/5 mg and 16 mg/10 mg: The other ingredients are hypromellose, lactose monohydrate, croscarmellose sodium, maize starch, triethyl citrate, magnesium stearate

Candesartan cilexetil/Amlodipine 16 mg/5 mg tablets: The other ingredients are lactose monohydrate; mannitol; maize starch; carmellose calcium; hypromellose; macrogol 8000; stearic acid; magnesium stearate; silica, colloidal anhydrous.

What Candesartan cilexetil/Amlodipine looks like and contents of the pack

Candesartan cilexetil/Amlodipine 8 mg/5 mg: White to off-white, round biconvex tablets, embossed with “8” on one side and “5” on the other side. Tablet diameter is 6.0 ± 0.2 mm.

Candesartan cilexetil/Amlodipine 16 mg/5 mg: White to light beige, round bilayer tablets, embossed “16” on one side and “5” on the other side. Tablet diameter is 8 ± 0.3 mm.

Candesartan cilexetil/Amlodipine 16 mg/10 mg: White to off-white, round biconvex tablets, with halving score on both sides, embossed with “16 16” on

one side and “10 10” on the other side. Tablet diameter is 8.0 ± 0.2 mm. The tablet can be divided into equal doses.

Pack size: 28, 30, 84 and 90 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For information on large print, Braille or audio CD call eMC accessibility on 0800 198 5000

ZENTIVA**MOCK-UP ONLY****GENERAL INFO:**

PRODUCT NAME: Candesartan cilexetil/Amlodipine

TERRITORY: UK

PACK SIZE: N/A

AW VERSION: V10

CREATION DATE: 24.04.2026

AW BY: GD

SUPPLIER: N/A

TECHNICAL INFO:

LAETUS (pharma code): N/A

FONT + MIN. SIZE: Helvetica Neue LT W1G 9 pt

DIMENSIONS: 700 × 160 mm

COLOURS: [1] Black**TECH. COLOURS: [1]** DieCut