

PACKAGE LEAFLET

Package leaflet: Information for the patient

<[Invented name]> 8 mg + 5 mg, capsules, hard
<[Invented name]> 8 mg + 10 mg, capsules, hard
<[Invented name]> 16 mg + 5 mg, capsules, hard
<[Invented name]> 16 mg + 10 mg, capsules, hard

Candesartan cilexetil + Amlodipine

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

1. What [Invented name] is and what it is used for

[Invented name] contains two substances called amlodipine and candesartan. 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.

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

[Invented name] 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 [Invented name].

2. What you need to know before you take [Invented name]

Do not take [Invented name]:

- 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 more than 3 months pregnant (see section Pregnancy and breast-feeding)
- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- concomitant use with aliskiren-containing products is contraindicated in patients with diabetes mellitus or renal impairment (GFR < 60 ml/min/1.73 m²).

Warnings and precautions

Talk to your doctor or pharmacist before taking [Invented name] 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
- 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 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 [Invented name]".

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 [Invented name]. This is because [Invented name], 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. [Invented name] 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 section Pregnancy and breast-feeding).

Children and adolescents

There is no experience with the use of [Invented name] in children (below the age of 18 years). Therefore, do not give this medicine to children and adolescents

Other medicines and [Invented name]

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

[Invented name] may affect or be affected by other medicines, such as:

- 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)
- simvastatin (a cholesterol lowering medicine)
- other medicines to help lower your blood pressure, including beta-blockers, diazoxide and ACE inhibitors (such as enalapril, captopril, lisinopril or ramipril) or aliskiren (see also information under the headings "Do not take [Invented name]" 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)
- water capsules (diuretics)
- lithium (a medicine for mental health problems)
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ).
- cyclosporine (an immunosuppressive drug used mainly after organ transplant to avoid organ rejection)

[Invented name] with food and drink

Grapefruit juice and grapefruit should not be consumed while taking [Invented name]. 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 <[Invented name]>.

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 [Invented name] before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of [Invented name]. [Invented name] 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.

Tell your doctor if you are breast-feeding or about to start breast-feeding. [Invented name] 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

[Invented name] may have moderate influence on your ability to drive or use machines. If the capsules make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

[Invented name] contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take [Invented name]

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

Usually recommended dose is one capsule once daily.

Patients receiving candesartan and amlodipine from separate products can instead receive capsules of [Invented name] containing the same component doses.

If you take more [Invented name] than you should

Taking too many capsules 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. Seek immediate medical attention if you take too many capsules.

If you forget to take [Invented name]

If you forget to take a capsule, 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.

Formatiert: Schriftart: Nicht Kursiv

If you stop taking [Invented name]

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 [Invented name] 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.

Stop taking [Invented name] and seek medical help immediately if you have any of the following reactions:

- 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) 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 [Invented name] has had any effect on your blood (agranulocytosis).

Other possible side effects:

Since [Invented name] 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

The following side effects have been reported. If any of these cause you problems or if they last for more than one week, you should contact your doctor.

Very common: may affect more than 1 in 10 people

- ankle swelling (oedema)

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

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
- excess sugar in blood (hyperglycaemia)
- a disorder of the nerves which can cause 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
- disorders combining rigidity, tremor and/or movement disorders

Not known:

- trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk. -toxic epidermal necrolysis

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
- 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.

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 national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

Store below 30°C.

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.

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 [Invented name] contains

The active substances are amlodipine and candesartan cilexetil.

[Invented name] 8 mg + 5 mg, capsules, hard

Each capsule contains 8 mg candesartan cilexetil and 5 mg amlodipine equivalent to 6.935 mg amlodipine besilate.

[Invented name] 8 mg + 10 mg, capsules, hard

Each capsule contains 8 mg candesartan cilexetil and 10 mg amlodipine equivalent to 13.87 mg amlodipine besilate.

[Invented name] 16 mg + 5 mg, capsules, hard

Each capsule contains 16 mg candesartan cilexetil and 5 mg amlodipine equivalent to 6.935 mg amlodipine besilate.

[Invented name] 16 mg + 10 mg, capsules, hard

Each capsule contains 16 mg candesartan cilexetil and 10 mg amlodipine equivalent to 13.87 mg amlodipine besilate.

The other ingredients are: Lactose Monohydrate, Maize Starch, Carmellose Calcium, Macrogol Type 8000, Hydroxypropylcellulose/type: EXF (250-800 cps (for 10% solution)), Hydroxypropylcellulose /type: LF (65-175 cps (for 5% solution)), Magnesium stearate.

Capsule shell (8 mg + 5 mg, 8 mg + 10 mg): Quinoline yellow (E 104), Iron oxide yellow (E 172), Titanium dioxide (E 171), Gelatin

Capsule shell (16 mg + 5 mg): Quinoline yellow (E 104), Titanium dioxide (E 171), Gelatin

Capsule shell (16 mg + 10 mg): Titanium dioxide (E 171), Gelatin

Ink: Shellac (E904), Iron Oxide Black (E172), Propylene Glycol, Ammonia Solution Concentrated, Potassium Hydroxide

What [Invented name] looks like and contents of the pack

[Invented name] 8 mg + 5 mg, capsules, hard: hard gelatin capsules, size no. 3, white opaque body, dark yellow cap, filled with white to off white granulate

[Invented name] 8 mg + 10 mg, capsules, hard: hard gelatin capsules, size no. 1, white opaque body with black imprint CAN 8, yellow cap with black imprint AML 10, filled with white to off white granulate

[Invented name] 16 mg + 5 mg, capsules, hard: hard gelatin capsules, size no. 1, white opaque body with black imprint CAN 16, pale yellow cap with black imprint AML 5, filled with white to off white granulate

[Invented name] 16 mg + 10 mg, capsules, hard: hard gelatin capsules, size no. 1, white opaque body, white opaque cap, filled with white to off white granulate

Pack size: 14, 28, 30, 56, 60, 90, 98, 100 capsules, hard

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}

<{tel}>

<{fa[Invented name]}>

<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}><{Name of the medicinal product}>

<{Name of the Member State}><{Name of the medicinal product}>

This leaflet was last revised in {MM/YYYY}.

<[To be completed nationally]>