

Package leaflet: Information for the patient

Candesartan Devatis 4 mg tablets
Candesartan Devatis 8 mg tablets
Candesartan Devatis 16 mg tablets
Candesartan Devatis 32 mg tablets

candesartan cilexetil

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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

The name of your medicine is [Product name]. The active ingredient is candesartan cilexetil. This belongs to a group of medicines called angiotensin II receptor antagonists. It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

[Product name] can be used to:

- treat high blood pressure (hypertension) in adult patients and in children and adolescents aged 6 to <18 years.
- treat adult heart failure patients with reduced heart muscle function when Angiotensin Converting Enzyme (ACE) inhibitors cannot be used or in addition to ACE-inhibitors when symptoms persist despite treatment and mineralocorticoid receptor antagonists (MRA) cannot be used (ACE-inhibitors and MRAs are medicines used to treat heart failure).

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

Do not take [Product name]:

- if you are allergic to candesartan cilexetil or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant (it is also better to avoid [Product name] in early pregnancy – 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 the patient is a child under 1 year of age.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking [Product name].

Warnings and precautions

Talk to your doctor before taking [Product name].

- if you have 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 low blood pressure.
- if you have ever had a stroke.
- you must tell your doctor if you think you are (or might become) pregnant. [Product 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 pregnancy section).
- 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
- if you are taking an ACE-inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptor antagonists (MRA). These medicines are for the treatment of heart failure (see "Other medicines and [Product name]").

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking [Product name]. Your doctor will decide on further treatment. Do not stop taking [Product name] on your own.

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 [Product 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 [Product name]. This is because [Product name], when combined with some anaesthetics, may cause an excessive drop in blood pressure.

Children and adolescents

Candesartan cilexetil has been studied in children. For more information, talk to your doctor. [Product name] must not be given to children under 1 year of age due to the potential risk to the developing kidneys.

Other medicines and [Product name]

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. [Product name] can affect the way some other medicines work and some medicines can have an effect on [Product name]. If you are using certain medicines, your doctor may need to do blood tests from time to time.

In particular, tell your doctor if you are using any of the following medicines as your doctor may need to change your dose and/or take other precautions:

- Other medicines to help lower your blood pressure, including beta-blockers, diazoxide and ACE inhibitors such as enalapril, captopril, lisinopril or ramipril.

- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).
- 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).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take [Product name]” and “Warnings and precautions”).
- If you are being treated with 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).

[Product name] with food, drink and alcohol

- You can take [Product name] with or without food.
- When you are prescribed [Product name], discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

Pregnancy and breastfeeding

Pregnancy

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

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. [Product name] is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Some people may feel tired or dizzy when taking [Product name]. If this happens to you, do not drive or use any tools or machines.

3. How to take [Product name]

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important to keep taking [Product name] every day.

You can take [Product name] with or without food.

Swallow the tablet with a drink of water.

The tablet can be divided into equal doses by breaking along the score line.

Try to take the tablet at the same time each day. This will help you to remember to take it.

High blood pressure:

- The recommended dose of [Product name] is 8 mg once a day. Your doctor may increase this dose to 16 mg once a day and further up to 32 mg once a day depending on blood pressure response.
- In some patients, such as those with liver problems, kidney problems or those who recently have lost body fluids, e.g., through vomiting or diarrhoea or by using water tablets, the doctor may prescribe a lower starting dose.

- Some black patients may have a reduced response to this type of medicine, when given as the only treatment, and these patients may need a higher dose.

Use in children and adolescents with high blood pressure:

Children 6 to <18 years of age:

The recommended starting dose is 4 mg once daily.

For patients weighing <50 kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to a maximum of 8 mg once daily.

For patients weighing ≥50 kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to 8 mg once daily and to 16 mg once daily.

Heart failure in adults:

- The recommended starting dose of [Product name] is 4 mg once a day. Your doctor may increase your dose by doubling the dose at intervals of at least 2 weeks up to 32 mg once a day. [Product name] can be taken together with other medicines for heart failure, and your doctor will decide which treatment is suitable for you.

If you take more [Product name] than you should

If you take more [Product name] than prescribed by your doctor, contact a doctor or pharmacist immediately for advice.

If you forget to take [Product name]

Do not take a double dose to make up for a forgotten tablet. Just take the next dose as normal.

If you stop taking [Product name]

If you stop taking [Product name], your blood pressure may increase again. Therefore, do not stop taking [Product 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. It is important that you are aware of what these side effects may be.

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

- difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat
- swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing
- severe itching of the skin (with raised lumps)

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

Other possible side effects include:

Common (affects 1 to 10 users in 100)

- 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 (affects less than 1 user in 10 000)

- 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.
- Nausea.
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhea.
- 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.
- Cough

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

- Diarrhoea

Additional side effects in children

In children treated for high blood pressure, side effects appear to be similar to those seen in adults, but they happen more often. Sore throat is a very common side effect in children but not reported in adults and runny nose, fever and increased heart rate are common in children but not reported in adults.

Reporting of side effects

If you get any side effects, talk to your doctor. 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 [Product name]

- 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 and blister. The expiry date refers to the last day of that month.
- Store below 25°C.

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

6. Contents of the pack and other information

What [Product name] contains

- The active ingredient is candesartan cilexetil. The tablets contain 4 mg, 8 mg, 16 mg or 32 mg of candesartan cilexetil.
- The other ingredients are mannitol, microcrystalline cellulose (only in 16 mg and 32 mg tablets), maize starch, copovidone, glycerol and magnesium stearate. The 8 mg, 16 mg and 32 mg tablets also contain red iron oxide (E172).

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

- 4 mg tablets are white, round, biconvex tablets (approximately 7.5 mm in diameter), embossed with “4” on one side and a score on the other side.
- 8 mg tablets are light pink, round, biconvex tablets (approximately 7.5 mm in diameter), embossed with “8” on one side and a score on the other side.
- 16 mg tablets are pink, round, biconvex tablets (approximately 7.5 mm in diameter), embossed with “16” on one side and a score on the other side.
- 32 mg tablets are pink, round, biconvex tablets (approximately 10 mm in diameter), embossed with “32” on one side and a score on the other side.

The tablets come in a blister packs containing 28, 56 or 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<to be completed nationally>

This medicine is authorised in the Member States of the European Economic Area under the following names:

<to be completed nationally>

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