

Package leaflet: information for the user

Candesartan cilexetil Aurobindo 4 mg, tablets
Candesartan cilexetil Aurobindo 8 mg, tablets
Candesartan cilexetil Aurobindo 16 mg, tablets
Candesartan cilexetil Aurobindo 32 mg, tablets
candesartan cilexetil

Read the entire leaflet carefully before you start using this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any further questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

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1. WHAT IS CANDESARTAN CILEXETIL AUROBINDO AND WHAT IS IT USED FOR?

Your medicine is called Candesartan cilexetil Aurobindo. It contains the active substance candesartan cilexetil. This substance belongs to the group of medicines called angiotensin II receptor antagonists. This substance ensures that that your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for the heart to pump blood to all parts of your body.

This medicine is used:

- for the treatment of high blood pressure (hypertension) in adults and in children and adolescents aged 6 to 18 years
- in adult patients with impaired heart muscle function, when angiotensin converting enzyme inhibitors (ACE inhibitors) cannot be taken or as an addition to ACE inhibitors when symptoms persist despite treatment and mineralocorticoid receptor antagonists (MRAs) cannot be taken (ACE inhibitors and MRAs are medicines taken for the treatment of heart failure).

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

- you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6

- you are more than 3 months pregnant (it is also better to avoid this medicine at the beginning of pregnancy – see the section “Pregnancy and breastfeeding”)
- you have a severe liver disease or a bile obstruction (problem with the drainage of bile from your gallbladder)
- when the patient is a child under 1 year old
- you have diabetes or impaired kidney function and are being treated with a blood pressure-lowering medicine that aliskiren contains.

If you are not sure whether any of the above descriptions apply to you, consult your doctor or pharmacist before using this medicine.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine:

- if you have problems with your heart, liver, or kidneys, or if you are on dialysis
- if you have had a kidney transplant
- if you need to vomit, have recently vomited severely, or if you have diarrhea
- if you have a disease of your adrenal glands called Conn syndrome (also primary hyperaldosteronism)
- if you have low blood pressure
- if you have ever had a stroke
- you should inform your doctor if you think you are pregnant (or might become pregnant). This medicine is not recommended at the beginning of pregnancy and should not be taken, if you are more than 3 months pregnant, as it can cause serious harm to your baby when used during this period (see the section “Pregnancy and breastfeeding”)
- if you are taking one of the following medicines for the treatment of high blood pressure: an ACE inhibitor (for example enalapril, lisinopril, ramipril), especially if you have diabetes-related kidney problems aliskiren.
- if you are taking an ACE inhibitor together with a medicine that belongs to the group of medicines known as mineralocorticoid receptor antagonists (MRAs). These medicines are for the treatment of heart failure (see the section “Are you taking any other medicines?”).

Your doctor may regularly check your kidney function, blood pressure, and the number of electrolytes (e.g., potassium) in your blood.

See also the information in the section “When should you not use this medicine?”.

It is possible that your doctor wants to see you more often and perform additional tests, if one of the above-mentioned situations applies to you.

Tell your doctor or dentist that you are using this medicine if you are going to have surgery. This is important because this medicine, together with some anesthetics, can cause your blood pressure to drop extremely.

Contact your doctor if you experience abdominal pain, nausea, vomiting, or diarrhea after taking this medicine. Your doctor will decide on further treatment. Do not stop using this medicine without consulting your doctor first.

Children and adolescents

Candesartan cilexetil Aurobindo has been studied in children. Contact your doctor for more information. Candesartan cilexetil Aurobindo should not be used by children under 1 year of age due to a possible risk to kidney development.

Are you using any other medicines?

Are you using any other medicines besides this one, have you recently done so, or is there a possibility that you will use other medicines in the near future? If so, tell your doctor or pharmacist.

This medicine can affect the action of some other medicines and some medicines can affect this medicine. If you are taking certain medicines, your doctor may need to perform blood tests from time to time.

Be sure to inform your doctor if you are using any of the following medicines, as your doctor may need to adjust the dosage and/or take other precautions:

- other medicines that help lower your blood pressure, such as beta-blockers, diazoxide and ACE inhibitors (for example enalapril, captopril, lisinopril or ramipril)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (pain-relieving drugs with anti-inflammatory effects)
- acetylsalicylic acid (if you use more than 3 grams per day; pain-relieving drug with anti-inflammatory effects)
- potassium supplements or salt substitutes containing potassium (products that increase the amount of potassium in your blood)
- heparin (a medicine to thin your blood)
- co-trimoxazole (an antibiotic), also known as trimethoprim/sulfamethoxazole
- water pills (diuretics)
- lithium (a medicine for mental health problems)
- if you are taking an ACE inhibitor or aliskiren (see also the information in the sections "When should you not use this medicine?" and "When should you be extra careful with this medicine?")
- if you are being treated for your heart failure with an ACE inhibitor together with certain other medicines; these medicines are called mineralocorticoid receptor antagonists (MRAs) (for example spironolactone, eplerenone).

What should you pay attention to with food, drink, and alcohol?

- you can take this medicine with or without food
- when this medicine is prescribed to you, talk to your doctor before drinking alcohol. Some people who drink alcohol while using this medicine feel faint or dizzy.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

Your doctor will usually advise you to stop taking this medicine before you become pregnant or as soon as you know you are pregnant, and will recommend using another medicine instead. This medicine is not recommended at the beginning of pregnancy and should not be taken when you are more than 3 months pregnant, as it can cause serious harm to your baby if taken after the third month of pregnancy.

Breastfeeding

This medicine is not recommended for mothers who are breastfeeding, 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 feel tired or dizzy when they use this medicine. If this happens to you, you should not drive. Also, do not use tools or machines in that case.

Candesartan cilexetil Aurobindo contains lactose

This medicine contains lactose, which is a type of sugar. If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE THIS MEDICINE?

Always take this medicine exactly as your doctor or pharmacist has told you. Doubt you about the correct use? Then contact your doctor or pharmacist.

It is important that you continue to take this medicine every day. You can take this medicine with or without food. Swallow the tablet with some water. Try to take the tablet at the same time every day. This helps you remember to take the tablet.

Increased blood pressure::

- recommended dose of this medicine is 8 mg once a day. Your doctor may increase this dose to 16 or 32 mg once a day, depending on the effect on your blood pressure
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- some patients, such as those with liver or kidney problems or who have recently lost a lot of fluid, for example due to vomiting, diarrhea, or the use of diuretics, the doctor may prescribe a lower starting dose
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- some Negroid patients may have a reduced response to this type of medication when given as the sole treatment. patients may need a higher dose. may require a higher dosage.

Use by children and adolescents with high blood pressure

Children aged 6 to 18 years

The recommended starting dose is 4 mg once daily.

For patients weighing less than 50 kg

In some patients whose blood pressure is not sufficiently lowered, the doctor may decide to increase the dose to a maximum of 8 mg once daily.

For patients weighing 50 kg or more

In some patients whose blood pressure is not sufficiently lowered, the doctor may decide to increase the dose to 8 mg once daily or up to 16 mg once daily.

Heart failure in adults

The recommended starting dose of this medicine is 4 mg once daily. Your doctor may increase this dose to 32 mg once daily by doubling the dose every 2 weeks. This medicine can be combined with other heart failure medications. Your doctor will decide which treatment is suitable for you.

Have you taken too much of this medicine?

If you have taken more of this medicine than prescribed by your doctor, you should immediately ask your doctor or pharmacist for advice.

Have you forgotten to take this medicine?

Do not take a double dose to make up for a forgotten dose. Take the next tablet at the usual time.

If you stop taking this medicine

If you stop taking this medicine, your blood pressure may go up. Therefore, do not stop using this medicine without first talking to your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can have side effects, although not everyone experiences them. It is important that you know what these side effects can be.

Stop using this medicine immediately and seek medical help if you experience any of the following allergic reactions:

- breathing problems, with or without swollen face, lips, tongue and/or throat
- swollen face, lips, tongue and/or throat, causing difficulty swallowing
- severe itching of your skin (with bumps).

This medicine can cause you to have fewer white blood cells. Your resistance to infections may therefore decrease. You may notice that you are tired, have a fever, or an infection. If this happens, tell your doctor. Your doctor may occasionally check your blood to see if this medicine affects your blood (agranulocytosis).

Other possible side effects include:

Common (occurs in 1 to 10 patients)

- feeling dizzy/dizzy feeling
- headache

- respiratory infection
- low blood pressure. This can make you feel weak or dizzy
- changes in your blood values:
more potassium in your blood, especially if you already have kidney problems or suffer from heart failure. If this is severe, you may notice that you feel tired or weak, have an irregular heartbeat, or experience tingling.
- an effect on the functioning of your kidneys, especially if you already have kidney problems or suffer from heart failure. In very rare cases, kidney failure can occur.

Very rarely (occurs in less than 1 in 10,000 patients)

- swelling of your face, lips, tongue and/or throat
- fewer red blood cells or white blood cells in your blood. You may notice that you are tired, have an infection or fever
- skin rash, lumpy rash (hives)
- itching
- back pain, pain in your joints and muscles
- other function of your liver, including inflammation of your liver (hepatitis). You may notice that you are tired, that your skin or the whites of your eyes turn yellow, and that you have flu-like symptoms
- nausea
- changes in your blood values:
less sodium in your blood. If this is severe, you may notice that you feel weak, have low energy, or have muscle cramps.
- coughing.
- Intestinal angioedema: a swelling in the intestines with symptoms such as abdominal pain, nausea, vomiting, and diarrhea

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

- diarrhea.

Additional side effects that may occur in children

In children being treated for high blood pressure, the side effects are similar to those in adults, but they occur more frequently. A sore throat is a side effect that is very common in children but has not been reported in adults. A runny nose, fever, and an increased heart rate are common in children but have not been reported in adults.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (website: www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date. It can be found on the label, the box, and the bottle after "Exp.:". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

- The active substance in this medicine is candesartan cilexetil. Each tablet contains 4 mg, 8 mg, 16 mg or 32 mg candesartan cilexetil.
- The other substances in this medicine are: lactose monohydrate, hydroxypropyl cellulose, calcium carmellose, aluminium magnesium silicate, propylene glycol, magnesium stearate, red iron oxide (E172; only for the 8 mg tablets), yellow iron oxide (E172; only for the 16 mg and 32 mg tablets).

What does Candesartan cilexetil Aurobindo look like and how much is in a package?
Tablet.

Candesartan cilexetil Aurobindo 4 mg, tablets

White to off-white, biconvex, uncoated, round (diameter 7.3 mm) tablets, debossed with "CN" and "4" on either side of a score line on one side and without imprint on the other side. The tablet can be divided into equal doses.

Candesartan cilexetil Aurobindo 8 mg, tablets

Pale pink, biconvex, uncoated, round (diameter 7.3 mm) tablets, debossed with "CN" and "8" on either side of a score line on one side and without imprint on the other side. The tablet can be divided into equal doses.

Candesartan cilexetil Aurobindo 16 mg, tablets

Yellow, biconvex, uncoated, round (diameter 7.3 mm) tablets, embossed with "CN" and "16" on either side of a score line on one side and without imprint on the other side. The tablet can be divided into equal doses.

Candesartan cilexetil Aurobindo 32 mg, tablets

Yellow, biconvex, uncoated, round (diameter 10 mm) tablets, embossed with "CN" and "32" on either side of a score line on one side and without imprint on the other side. The tablet can be divided into equal doses.

Candesartan cilexetil Aurobindo tablets are available in blister packs and HDPE bottle.

Package sizes

Blister pack: 7, 14, 28, 30, 50, 56, 90, 98, and 500 tablets.

HDPE bottle pack: 30, 90, and 500 tablets.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

- Aurobindo Pharma B.V., Baarnsche Dijk 1, 3741 LN Baarn

Manufacturers

- APL Swift Services (Malta) Limited, HF26, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG 3000, Malta
- Generis Farmacêutica, S.A., Rua João de Deus, no 19, Venda Nova, Amadora 2700-487, Portugal

Registered under:

Candesartan cilexetil Aurobindo 4 mg, tablets: RVG 111811

Candesartan cilexetil Aurobindo 8 mg, tablets: RVG 111812

Candesartan cilexetil Aurobindo 16 mg, tablets: RVG 111814

Candesartan cilexetil Aurobindo 32 mg, tablets: RVG 111815

This medicine is registered in EEA member states under the following names:

Germany Candesartan Aurobindo 4 mg/8 mg/16 mg/32 mg Tablets

France CANDESARTAN ARROW LAB 4 mg/8 mg/16 mg/32 mg tablets sécable

Malta Candesartan cilexetil 2 mg/4 mg/8 mg/16 mg/32 mg tablets

Netherlands Candesartan cilexetil Aurobindo 4 mg/8 mg/16 mg/32 mg, tablets

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