NEW ZEALAND CONSUMER MEDICINE INFORMATION

CANDESTAR

Candesartan cilexetil 4 mg, 8 mg, 16 mg and 32 mg tablets



What is in this leaflet

Please read this leaflet carefully before you start taking Candestar.

This leaflet answers some common questions about Candestar.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking Candestar against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Candestar is taken for

Candestar contains the active ingredient candesartan cilexetil. It belongs to a group of medicines called angiotensin II receptor blockers, or ARBs.

Candestar is taken to treat:

- high blood pressure (hypertension)
- heart failure patients with reduced heart muscle function

Candestar works by blocking the effects of the hormone, angiotensin II. This causes relaxation or widening of the blood vessels which results in a lowering of the blood pressure.

It also helps with heart failure by widening the blood vessels, so that the heart does not have to pump as hard to move the blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope better so you may not get short of breath as easily.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you take Candestar

When you must not take it:

Do not take Candestar if you have an allergy to:

- any medicine containing candesartan
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you have or have had any of the following medical conditions:

- severe liver problems
- diabetes (type I or II) or moderate to severe kidney problems, and also taking any aliskiren- containing medicines

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

It is not known whether the active ingredient in Candestar passes into breast milk.

Do not give Candestar to children.

Safety and effectiveness in children has not been established.

Do not take this medicine after the expiry date, or if the bottle shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it:

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- mild to moderate liver problems
- mild kidney problems
- A condition called primary hyperaldosteronism.

If you have not told your doctor about any of the above, tell him/her before you start taking Candestar.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you

get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Candestar may interfere with each other. These include:

- other medicines used to treat high blood pressure including angiotensin converting enzyme (ACE) inhibitors, other angiotensin II receptor blockers (ARBs), and thiazide diuretics.
- any medicine containing potassium, including potassium-sparing diuretics, potassium supplements, salt substitutes or medicines that may increase potassium levels (e.g. heparin or cotrimoxazole)
- lithium, a medicine used to treat mood swings and some types of depression
- non-steroidal antiinflammatory drugs (NSAIDs), used to treat pain and inflammation
- any medicine containing aliskiren used in patients with diabetes (type I or II) or who have moderate to severe kidney problems

These medicines may be affected by Candestar or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Candestar.

How to take Candestar

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

Hypertension:

The usual adult starting dose is 8 mg once daily. 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 or kidney problems, your doctor may prescribe a lower starting dose.

Heart Failure:

The usual adult starting dose is 4 mg once daily. Your doctor may increase your dose up to 32 mg once a day over intervals of at least 2 weeks.

How to take it

Swallow the tablets whole with a full glass of water.

Candestar tablets may be broken in half if required.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take Candestar with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally. Do not take a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking Candestar

Things you must do

If you are about to be started on any new medicines, remind your doctor and pharmacist that you are taking Candestar.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking Candestar.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. Candestar may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take Candestar to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Candestar affects you.

This medicine may cause dizziness or drowsiness in some people. If you feel dizzy or drowsy, do not

drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have [used/taken] too much [Trade name]. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Candestar.

Candestar helps most people but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- · dizziness, lightheadedness
- cough
- back pain

The above list includes the more mild side effects of Candestar.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- severe and sudden onset of rash, itchiness, hives (itchy swellings on the skin)
- worsening of kidney function (symptoms may include passing little or no urine, nausea or vomiting, loss of appetite and weakness)
- nausea, diarrhoea, muscle pain or weakness and changes in heart rhythm (these symptoms may indicate high potassium levels in the blood)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- jaundice (yellowing of the skin and / or eyes)
- a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects such as changes in your potassium, sodium or white blood cell levels can only be found when your doctor does tests to check your progress. It is important you keep all of your doctor's appointments so that your progress can be checked.

After taking Candestar

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Candestar or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Candestar where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Candestar 4 mg tablets are white to off white, round tablets marked with "M" over "C1" on one side, and plain with a break line on the other side.

Candestar 8 mg tablets are white to off white, round tablets marked with "M" over "C5" on one side, and plain with a break line on the other side.

Candestar 16 mg tablets are white to off white, round tablets marked with "M" over "C6" on one side, and plain with a break line on the other side.

Candestar 32 mg tablets are white to off white, round tablets marked with "M" over "C7" on one side, and plain with a break line on the other side.

Ingredients

Active ingredient:

Candestar contains 4 mg, 8 mg, 16 mg or 32 mg of candesartan cilexetil as the active ingredient.

<u>Inactive ingredients:</u>
Candestar also contains:

- lactose
- mannitol

- carmellose calcium
- hydroxypropyl cellulose
- magnesium stearate

Candestar contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Candestar is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND www.viatris.co.nz Telephone 0800 168 169

Date of Preparation

15 May 2025 (Based on datasheet dated 15 May 2025)