

Candesartan Sandoz®

Candesartan cilexetil tablets

Candesartan cilexetil (kan-de-SAR-tan sil-EX-etil)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Candesartan Sandoz.

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 has weighed the risks of you taking this medicine 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 Candesartan Sandoz is used for

Candesartan cilexetil belongs to a group of medicines called angiotensin II receptor antagonists (or blocker).

This medicine is used to treat:

- high blood pressure, also called hypertension.
- heart failure. It is used in combination with other medicines to treat your condition.

It contains the active ingredient candesartan cilexetil.

When taking this medicine for hypertension, it works by:

Lowering blood pressure by dilating (expanding) small blood vessels

from the heart, letting the blood be pumped around the body more easily.

All people have blood pressure. This pressure helps to push blood all around your body. Your blood pressure changes during the day, depending on how busy you are or how you are feeling. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

Regular blood pressure checks are the only way of knowing that you have hypertension. There are usually no symptoms of hypertension and you may feel fine. If hypertension is not treated, serious health problems such as stroke or heart attack and heart or kidney failure may occur.

When taking this medicine for heart failure, it works 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.

When used to treat heart failure, this medicine is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney to get rid of excess fluid from the body.

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart

attack and does not mean that the heart stops working. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. This medicine helps to treat heart failure and may improve your symptoms.

Your doctor will have explained why you are being treated with this medicine and told you what dose to take.

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 not addictive.

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

There is not enough information to recommend the use of this medicine for children.

Before you take Candesartan Sandoz

When you must not take it

Do not take this medicine if you have an allergy to:

- candesartan cilexetil, the active ingredient or to any of the other ingredients listed at the end of

this leaflet under Product Description.

- any medicine containing an angiotensin II receptor antagonist (blocker).

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 use Candesartan Sandoz if you have:

- severe liver disease and/or conditions associated with impaired bile flow (cholestasis)

Do not use Candesartan Sandoz if you are taking blood pressure medicine containing aliskiren, especially if you have diabetes mellitus or have kidney problems.

Do not take this medicine if you are pregnant or planning to become 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 if this medicine passes into breast milk.

Do not give this medicine to children.

There is no information about its use in children, so Candesartan Sandoz is not recommended for children.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or 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:

- kidney problems
- liver problems
- heart problems
- recent excessive vomiting or diarrhoea
- a condition called primary hyperaldosteronism.

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

You may have to take a lower dose of Candesartan Sandoz if you have these conditions.

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 Candesartan Sandoz may interfere with each other. These include:

- any medicines containing potassium, including salt substitutes
- diuretics (fluid tablets)
- lithium, a medicine used to treat mood swings and some types of depression
- Non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis.
- Angiotensin-converting-enzyme (ACE) inhibitors, medicines used to help lower blood pressure, especially if you have diabetes related kidney problems
- Mineralocorticoid receptor antagonists (MRAs), such as spironolactone and eplerenone, medicines used to treat heart failure.

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

It may be necessary to have regular blood tests done if you take any of these medicines.

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

How to take Candesartan Sandoz

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, ask your doctor or pharmacist for help.

How much to take

The usual dose is 8 or 16 mg taken once daily. Sometimes an increase in dose to 32 mg once daily is needed.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Candesartan Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

It does not matter whether you take this medicine with food or on an empty stomach.

When to take Candesartan Sandoz

Take your medicine once a day, 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.

How long to take Candesartan Sandoz

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

Take your dose as soon as you remember (as long as it is at least 12 hours before your next dose is due), and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Candesartan Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include a headache, feel sick (nausea), dizziness and tiredness.

While you are taking Candesartan Sandoz

Things you must do

Take Candesartan Sandoz exactly as your doctor has told you to.

Your blood pressure will not be well controlled if you do not.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Candesartan Sandoz.

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

If you are going to have surgery (even at the dentist) that needs a general anaesthetic, tell the surgeon or anaesthetist that you are taking this medicine.

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

You should not take this medicine if you are pregnant or thinking about becoming pregnant. Your doctor can discuss different treatment options with you.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some test (eg blood tests, blood pressure) from time to time. These tests may help to prevent side effects.

Things you must not do

Do not take Candesartan Sandoz 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

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

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

This medicine may cause nausea, dizziness and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you are taking this medicine for high blood pressure, drink plenty of water during exercise and hot weather, especially if you sweat a lot.

If you do not drink enough water while taking this medicine, you may faint or feel light-headed or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

If you are taking this medicine for heart failure, restricted fluid intake is generally recommended. Speak with your doctor about how much water you should drink.

Side effects

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

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:

- headache

- chest or throat infection
- flu-like symptoms
- feeling sick (nausea, vomiting)
- back pain
- dizziness

These are all mild side effects of candesartan cilexetil. Tell your doctor as soon as possible if you notice any of the following:

- aching muscles, tenderness or weakness in the muscle

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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
- swelling of the hands, feet or ankles
- harsh sounds when breathing
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- jaundice (yellowing of the skin and /or eyes).
- unusual skin reactions (severe and sudden onset of rash, itchiness, hives (itchy swellings on the skin))
- easy bruising or bleeding more easily than normal
- extreme fatigue, tiredness, weakness
- worsening of the kidney function (including passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness (especially in patients with existing kidney problems or heart failure))
- changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test.

- symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm.

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

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.

After taking Candesartan Sandoz

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Candesartan Sandoz 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 it where children cannot reach it.

A locked cupboard at least one-and-a-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

Candesartan Sandoz comes in four types of tablets:

Candesartan Sandoz 4 mg - white, round biconvex tablet, debossed with 4 on one side and scored on the other side.

Candesartan Sandoz 8 mg - pink, mottled, round biconvex tablet, debossed with 8 on one side and scored on the other side.

Candesartan Sandoz 16 mg - pink, mottled, round biconvex tablet, debossed with 16 on one side and scored on the other side.

Candesartan Sandoz 32 mg - pink, mottled, round biconvex tablet, debossed with 32 on one side and scored on the other side.

Available in blisters of 30 tablets.

Ingredients

Active ingredients:

- Candesartan Sandoz 4 mg - 4 mg candesartan cilexetil
- Candesartan Sandoz 8 mg - 8 mg candesartan cilexetil
- Candesartan Sandoz 16 mg - 16 mg candesartan cilexetil
- Candesartan Sandoz 32 mg - 32 mg candesartan cilexetil

Inactive ingredients:

- Lactose monohydrate
- iron oxide red (8 mg, 16 mg and 32 mg tablets only)
- titanium dioxide (8 mg, 16 mg and 32 mg tablets only)
- maize starch
- povidone
- carrageenan
- croscarmellose sodium
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Candesartan Sandoz is supplied in Australia by:

Sandoz Pty Ltd
ABN 60 075 449 553
54 Waterloo Road
Macquarie Park NSW 2113
Tel: 1800 726 369

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- Candesartan Sandoz 4mg tablets
- AUST R 147497
- Candesartan Sandoz 8mg tablets
- AUST R 147493
- Candesartan Sandoz 16mg tablets - AUST R 147498
- Candesartan Sandoz 32mg tablets - AUST R 147496