

Candesartan/ HCT Sandoz®

Candesartan cilexetil and hydrochlorothiazide tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Candesartan/HCT 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 risk of you taking Candesartan/HCT Sandoz against the benefits it is expected to 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/HCT SANDOZ IS USED FOR

This medicine is used to treat high blood pressure.

It contains the active ingredients candesartan cilexetil and hydrochlorothiazide.

Candesartan cilexetil belongs to a group of medicines called angiotensin II - receptor antagonists (or blocker). It works by causing relaxation of blood vessels.

Hydrochlorothiazide belongs to a group of medicines called diuretics. It works by reducing the amount of excess fluid in the body.

Using these two medicines together will lower your blood pressure more than using either one on its own.

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

Follow all directions given to you by your doctor carefully

Your doctor may have prescribed it for another reason.

They may differ from the information contained in this leaflet.

This medicine is not addictive.

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

BEFORE YOU TAKE CANDESARTAN/HCT SANDOZ

When you must not take it

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

- candesartan cilexetil and hydrochlorothiazide, the active ingredients, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines (such as Irbesartan), angiotensin II receptor antagonist
- any sulphur drugs (sulphonamides) such as some antibiotics or some medicines to treat diabetes.

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 kidney or liver disease and/or conditions associated with impaired bile flow (cholestasis)
- gout.

Do not use Candesartan/HCT 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 are planning to become pregnant.

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

Do not breastfeed if you are taking this medicine.

Your baby can take in components of Candesartan/HCT Sandoz from breast milk if you are breastfeeding.

Do not give this medicine to children.

There is no information about its use in 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
- diabetes
- recent excessive vomiting or diarrhoea
- systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys
- a salt restricted diet
- a condition called primary hyperaldosteronism
- a past operation known as sympathectomy.
- a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Candesartan/HCT Sandoz. This can lead to permanent vision loss, if not treated. If you earlier have a penicillin or sulphonamide allergy, you can be at higher risk of developing this.

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

Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from your

pharmacy, supermarket or health food shop.

Some medicines and Candesartan/HCT Sandoz may interfere with each other. These include:

- other blood pressure lowering medicines, particularly diuretics (fluid tablets) and ACE-inhibitors, especially if you have diabetes-related kidney problems
- any medicine containing potassium, including salt substitutes
- digoxin, a medicine used to treat heart failure
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- colestipol and cholestyramine, medicines used to treat high blood cholesterol levels
- lithium, a medicine used to treat mood swings and some types of depression
- alcohol
- strong pain killers such as codeine, morphine, dextropropoxyphene
- barbiturates, used to treat epilepsy, such as phenobarbitone
- medicines like insulin used to treat diabetes
- calcium supplements, or medicines containing calcium
- vitamin D supplements
- medicines to treat irregular heart beats
- corticosteroids such as prednisone, cortisone, dexamethasone.
- laxatives
- medicines used to treat cancer such as cyclophosphamide
- methotrexate a medicine used to treat arthritis and some cancers
- amantadine, a medicine used to treat Parkinson's Disease.
- Ciclosporin

These medicines may be affected by Candesartan/HCT Sandoz 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 this medicine.

HOW TO TAKE CANDESARTAN/HCT 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 standard dose for this medicine is one tablet once daily.

Your doctor may have prescribed a different dose.

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/HCT Sandoz may not work as well and your problem may not improve.

How to take it

Swallow the tablet whole with a full glass of water.

When to take Candesartan/HCT Sandoz**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 whether you take Candesartan/HCT Sandoz with food or on an empty stomach.**How long to take Candesartan/HCT 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**If you forget to take a dose, take it as soon as you remember, as long as it is at least 12 hours before your next dose is due.**

Then go back to taking it as you would normally.

If it is less than 12 hours to 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) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Candesartan/HCT Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many Candesartan/HCT Sandoz tablets you will probably get a headache, feel sick (nausea), dizzy, thirsty and very tired.

WHILE YOU ARE USING CANDESARTAN/HCT SANDOZ

Things you must do**Take Candesartan/HCT 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/HCT Sandoz.**Tell your doctor if you have excessive vomiting or diarrhoea while taking Candesartan/HCT Sandoz.**

You may lose too much water and your blood pressure may become too low.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

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

You should not use Candesartan/HCT Sandoz if you are pregnant or thinking about becoming pregnant. Your doctor can discuss different treatment options with you.

If you plan to have a surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking Candesartan/HCT Sandoz.**Tell your doctor if you plan to have an examination such as an x-ray or a scan requiring injection of iodinated contrast (dye) that you are taking Candesartan/HCT Sandoz.****If you have had skin cancer or if you develop a suspicious skin lesion during treatment with Candesartan/HCT Sandoz, tell your doctor or pharmacist.**

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Limit exposure to sunlight and protect your skin when exposed to sun while taking Candesartan/HCT Sandoz.

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

Your doctor will check your progress and may want to take some tests (e.g. 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/HCT 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 Candesartan/HCT Sandoz unless you have discussed it with your doctor.**Things to be careful of****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

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

This medicine may cause dizziness when you start taking it and this is due to the drop in your blood pressure.

Drink plenty of water while you are using Candesartan/HCT Sandoz, especially if you sweat a lot.**Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.**

SIDE EFFECTS

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

Candesartan/HCT Sandoz helps most people with high blood pressure, 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.

Ask your doctor or pharmacist to answer any questions you may have.**Tell your doctor if you notice any of the following and they worry you:**

- headache or dizziness
- flu-like symptoms or infections
- chest, throat or sinus infections
- feeling sick (nausea) or vomiting
- back pain
- urinary tract infection
- rapid heartbeats
- feeling tired
- stomach ache
- symptoms of sunburn which happens more quickly than normal

These are all mild side effects of Candesartan/HCT Sandoz.

Tell your doctor as soon as possible if you notice any of the following:

- rapid heartbeats
- aching muscles, tenderness or weakness in the muscle
- suspicious skin lesions

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
- swelling of the hands, feet or ankles
- harsh sounds when breathing
- rash, itching or hives
- easy bruising or bleeding more easily than normal
- feel extremely tired
- yellowing of the skin and eyes
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- 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.
- decrease in vision or pain in your eye due to high pressure [possible signs of fluid accumulation in the vascular layer

of the eye (choroidal effusion) or acute angle-closure glaucoma]

- 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. If you have them, you may have had a serious reaction to Candesartan/HCT Sandoz. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

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

AFTER TAKING CANDESARTAN/HCT 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 25°C.

Do not store Candesartan/HCT 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/HCT Sandoz comes in three types of tablets:

Candesartan/HCT Sandoz 16mg/12.5 mg - apricot, mottled, oval biconvex scored on both sides.

Candesartan/HCT Sandoz 32mg/12.5mg - light brown, mottled, oblong, biconvex tablet, debossed with 32 on one side and with score line on both sides

Candesartan/HCT Sandoz 32mg/25mg - reddish brown, mottled, oblong, biconvex tablet, debossed with H 32 on one side and with score line on both sides.

Available in blister packs of 30 tablets.

Ingredients

Active ingredients:

- Candesartan cilexetil
- hydrochlorothiazide

Inactive ingredients:

- lactose monohydrate
- iron oxide red
- iron oxide yellow
- maize starch
- povidone
- carrageenan
- croscarmellose sodium
- magnesium stearate.

Additionally, Candesartan/HCT Sandoz 32mg/12.5mg and 32mg/25mg also contains iron oxide black.

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

Supplier/Distributor

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

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16mg/12.5mg tablet: AUST R 157942 (blisters)

32mg/12.5mg tablet: AUST R 195279 (blisters)

32mg/25mg tablet: AUST R 195278 (blisters)