

Candesartan/ HCT Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Candesartan/ HCT Sandoz?

Candesartan/ HCT Sandoz contains the active ingredient candesartan cilexetil and hydrochlorothiazide. Candesartan/ HCT Sandoz is used to treat high blood pressure.

For more information, see Section [1. Why am I using Candesartan/ HCT Sandoz?](#) in the full CMI.

2. What should I know before I use Candesartan/ HCT Sandoz?

Do not use if you have ever had an allergic reaction to any medicine containing candesartan cilexetil or hydrochlorothiazide, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Candesartan/ HCT Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Candesartan/ HCT Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Candesartan/ HCT Sandoz?

- Candesartan/ HCT Sandoz should be taken once daily with a glass of water, at about the same time each day.
- It does not matter whether you take Candesartan/ HCT Sandoz with food or on an empty stomach.

More instructions can be found in Section [4. How do I use Candesartan/ HCT Sandoz?](#) in the full CMI.

5. What should I know while using Candesartan/ HCT Sandoz?

Things you should do	<ul style="list-style-type: none">• Call your doctor straight away if you become pregnant or plan to become pregnant while you are taking Candesartan/ HCT Sandoz.• If you develop any severe shortness of breath or difficulty breathing after taking Candesartan/ HCT Sandoz, seek medical attention immediately.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Candesartan/ HCT Sandoz unless you have discussed it with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Candesartan/ HCT Sandoz affects you.
Drinking alcohol	<ul style="list-style-type: none">• Alcohol may interfere with Candesartan/ HCT Sandoz .
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the blister pack until it is time to take them.• Store tablets below 25°C.

For more information, see Section [5. What should I know while using Candesartan/ HCT Sandoz?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. These include headache, nausea, flu-like symptoms, back pain, feeling tired or stomach ache. However, some side effects may need medical attention. These include rapid heartbeats, aching muscles, suspicious skin lesions, passing little urine, loss of appetite, decrease in vision or pain in your eyes or shortness of breath, fever, weakness and confusion. Serious side effects are rare.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Candesartan/ HCT Sandoz®

Active ingredient(s): *candesartan cilexetil and hydrochlorothiazide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Candesartan/ HCT Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Candesartan/ HCT Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Candesartan/ HCT Sandoz?](#)
- [2. What should I know before I use Candesartan/ HCT Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Candesartan/ HCT Sandoz?](#)
- [5. What should I know while using Candesartan/ HCT Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Candesartan/ HCT Sandoz?

Candesartan/ HCT Sandoz contains the active ingredient **candesartan cilexetil and hydrochlorothiazide**.

Candesartan/ HCT Sandoz is used to treat **high blood pressure**.

Candesartan cilexetil is a type of medicine called an angiotensin II - receptor antagonists (or blocker). It mainly works by causing relaxation of blood vessels.

Hydrochlorothiazide is a type of medicine called a diuretic. 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.

2. What should I know before I use Candesartan/ HCT Sandoz?

Warnings

Do not use Candesartan/ HCT Sandoz if:

- you are allergic to candesartan cilexetil and hydrochlorothiazide or any of the ingredients listed at the end of this leaflet, or any medicine containing an angiotensin II receptor antagonist (or blocker), or any sulphur drugs (sulphonamides) such as some antibiotics or some medicines to treat diabetes. Always check the ingredients to make sure you can use this medicine.

- you have severe kidney or liver disease and/or conditions associated with impaired bile flow (cholestasis)
- you have gout
- you are taking blood pressure medicine containing aliskiren, especially if you have diabetes mellitus or have kidney problems**

Check with your doctor if you:

- have any allergies to any other medicines or foods.
- have any other 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 condition called primary hyperaldosteronism
 - 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 have an earlier penicillin or sulphonamide allergy, you can be at higher risk of developing this.
 - a salt restricted diet
 - a past operation known as sympathectomy
- experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past.
- have any questions about how you should be using your Candesartan/ HCT Sandoz

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant or planning to become pregnant.

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

Do not use Candesartan/ HCT Sandoz if you are breastfeeding.

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

Use in Children

Do not give this medicine to children.

There is no information about its use in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Candesartan/ HCT Sandoz and affect how it works. These include:

- other blood pressure lowering medicines, particularly diuretics (fluid tablets) and ACE-inhibitors, especially if you have diabetes-related kidney problems
- medicines 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, 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 it works. You may need different amounts of your medicines or may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Candesartan/ HCT Sandoz.

4. How do I use Candesartan/ HCT Sandoz?

How much to take

- The usual dose is one tablet once daily, taken whole with a glass of water.

When to take Candesartan/ HCT Sandoz

- **Candesartan/ HCT Sandoz should be taken once daily, at about the same time each day.**
- Keeping a regular time for taking Candesartan/ HCT Sandoz will help to remind you to take it. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How to take Candesartan/ HCT Sandoz

- It does not matter whether you take Candesartan/ HCT Sandoz with food or on an empty stomach.

How to long to take Candesartan/ HCT Sandoz

Candesartan/ HCT Sandoz helps to control your condition, but does not cure it. Therefore, you must take Candesartan/ HCT Sandoz every day. Continue taking the tablets for as long as your doctor tells you to.

If you forget to use Candesartan/ HCT Sandoz

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 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 use too much Candesartan/ HCT Sandoz

If you think that you have used too much Candesartan/ HCT Sandoz, 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.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Candesartan/ HCT Sandoz?

Things you should do

- **Take Candesartan/ HCT Sandoz exactly as your doctor has told you.** 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 or 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.
- **If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell the surgeon or anaesthetist that you are taking this medicine.**
- **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 Candesartan/ HCT Sandoz.
- **If you develop any severe shortness of breath or difficulty breathing after taking Candesartan/ HCT Sandoz, seek medical attention immediately**

Call your doctor straight away if you:

- **Become pregnant while you are taking Candesartan/ HCT Sandoz. 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.**
Remind any doctor, dentist or pharmacist you visit that you are using Candesartan/ HCT Sandoz.

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 tests (e.g. blood tests, blood pressure) from time to time. These tests may help to prevent side effects.

Things you should not do

- Do not take use it 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

- **Move slowly when getting out of bed or standing up if you feel faint, dizzy or light-headed.**
- **Drink plenty of water while you are taking 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Candesartan/ HCT Sandoz affects you.

Candesartan/ HCT Sandoz may cause dizziness when you start taking it due to the drop in your blood pressure.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may interfere with Candesartan/ HCT Sandoz.

Looking after your medicine

- Keep your medicine in the blister pack until it is time to take them.
- If you take it out of the blister pack, it may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date, packaging is torn or shows signs of tampering.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gut or Gastrointestinal related:</p> <ul style="list-style-type: none"> feeling sick (nausea) or vomiting stomach ache <p>General Disorders:</p> <ul style="list-style-type: none"> headache or dizziness feeling tired <p>Infection related:</p> <ul style="list-style-type: none"> flu-like symptoms or infections chest, throat or sinus infections urinary tract infection <p>Muscle-joint related:</p> <ul style="list-style-type: none"> back pain <p>Skin related:</p> <ul style="list-style-type: none"> symptoms of sunburn which happens more quickly than normal 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>They are generally mild and do not cause patients to stop taking Candesartan/HCT Sandoz.</p>

Serious side effects

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> rapid heartbeats <p>Muscle-joint related:</p> <ul style="list-style-type: none"> aching muscles, tenderness or weakness in the muscle <p>Skin related:</p> <ul style="list-style-type: none"> suspicious skin lesions <p>Allergy related:</p> <ul style="list-style-type: none"> swelling of the face, lips, tongue or throat swelling of the hands, feet or ankles rash, itching or hives <p>Lungs related:</p> <ul style="list-style-type: none"> harsh sounds when breathing acute respiratory distress (very rare): signs include severe shortness of breath, fever, weakness and confusion <p>Blood related:</p> <ul style="list-style-type: none"> easy bruising or bleeding more easily than normal <p>Liver related:</p> <ul style="list-style-type: none"> yellowing of the skin and eyes 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<p>Infection related:</p> <ul style="list-style-type: none"> signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers <p>Kidney related:</p> <ul style="list-style-type: none"> 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)). <p>Electrolytes related:</p> <ul style="list-style-type: none"> 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. <p>Eyes related:</p> <ul style="list-style-type: none"> 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] <p>Others:</p> <ul style="list-style-type: none"> feel extremely tired 	
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Candesartan/ HCT Sandoz contains

Active ingredient (main ingredient)	<ul style="list-style-type: none">• candesartan cilexetil• hydrochlorothiazide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• iron oxide red• iron oxide yellow• maize starch• lactose monohydrate• povidone• carrageenan• croscarmellose sodium• magnesium stearate• iron oxide black (32mg/12.5mg and 32mg/25mg only)
Potential allergens	<ul style="list-style-type: none">• sugars as lactose <p>This medicine does not contain gluten, tartrazine or any other azo dyes.</p>

Do not take this medicine if you are allergic to any of these ingredients.

What Candesartan/ HCT Sandoz looks like

Candesartan/ HCT Sandoz 16mg/12.5 mg - apricot, mottled, oval biconvex scored on both sides (Aust R 157942).

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 (Aust R 195279).

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 (Aust R 195278).

Available in blister packs of 30 tablets.

Who distributes Candesartan/ HCT Sandoz

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

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