

# BTC Candesartan HCT

## 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 BTC Candesartan HCT?

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

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

### 2. What should I know before I use BTC Candesartan HCT?

Do not use if you have ever had an allergic reaction to BTC Candesartan HCT 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 BTC Candesartan HCT?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with BTC Candesartan HCT 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 BTC Candesartan HCT?

- The standard dose for this medicine is one tablet once daily.
- Swallow the tablet whole with a full glass of water.

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

### 5. What should I know while using BTC Candesartan HCT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using BTC Candesartan HCT.</li><li>• Tell your doctor if you have excessive vomiting or diarrhoea while taking BTC Candesartan HCT.</li><li>• 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 BTC Candesartan HCT.</li><li>• If you have had skin cancer or if you develop a suspicious skin lesion during treatment with BTC Candesartan HCT, tell your doctor or pharmacist.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine unless you have discussed it with your doctor.</li><li>• Do not take BTC Candesartan HCT to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how BTC Candesartan HCT affects you.</li><li>• This medicine may cause dizziness when you start taking it and this is due to the drop in your blood pressure.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in the original container.</li><li>• Store tablets below 25°C.</li></ul>

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

### 6. Are there any side effects?

**Common side effects:** headache or dizziness, flu-like symptoms or infections, chest, throat or sinus infections, feeling sick (nausea) or vomiting, back pain. **Serious side effects:** rapid heartbeats, aching muscles, tenderness or weakness in the muscle, swelling of the face, lips, tongue or throat.

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.

# BTC Candesartan HCT

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

## Consumer Medicine Information (CMI)

This leaflet provides important information about using BTC Candesartan HCT. **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 BTC Candesartan HCT.**

### Where to find information in this leaflet:

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

## 1. Why am I using BTC Candesartan HCT?

**BTC Candesartan HCT contains the active ingredient 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.

**BTC Candesartan HCT is used to treat high blood pressure.**

## 2. What should I know before I use BTC Candesartan HCT?

### Warnings

#### Do not use BTC Candesartan HCT if:

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

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

### Check with your doctor if you:

- 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 aldosteronism
  - 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 BTC Candesartan HCT. 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.
- have a salt restricted diet
- have had a past operation known as sympathectomy
- take any medicines for any other condition

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 developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking this medicine.**

Your baby can take in components of BTC Candesartan HCT 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 BTC Candesartan HCT 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
- 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

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

## 4. How do I use BTC Candesartan HCT?

### How much to take

- The standard dose for this medicine is one tablet once daily.
- Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.
- If you take the wrong dose, BTC Candesartan HCT may not work as well and your problem may not improve.

## When to take BTC Candesartan HCT

- BTC Candesartan HCT should be taken 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 to take BTC Candesartan HCT

- Swallow the tablet whole with a full glass of water.
- It does not matter whether you take BTC Candesartan HCT with food or on an empty stomach.

### How long to take BTC Candesartan HCT

- 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 use BTC Candesartan HCT

**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 BTC Candesartan HCT

If you think that you have used too much BTC Candesartan HCT, you may need urgent medical attention.

If you take too many BTC Candesartan HCT 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 BTC Candesartan HCT?

### Things you should do

- **Take BTC Candesartan HCT 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 BTC Candesartan HCT.**
- **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.** It may affect other medicines used during surgery.
- **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 BTC Candesartan HCT.**
- **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.

### Call your doctor straight away if you:

- **Have excessive vomiting or diarrhoea while taking BTC Candesartan HCT.** You may lose too much water and your blood pressure may become too low.
- **Become pregnant while taking this medicine or plan to become pregnant**
- **If you have had skin cancer or if you develop a suspicious skin lesion during treatment with BTC Candesartan HCT.**  
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 BTC Candesartan HCT.

Remind any doctor, dentist or pharmacist you visit that you are using BTC Candesartan HCT.

### Things you should not do

- Do not take BTC Candesartan HCT 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 BTC Candesartan HCT 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

- Drink plenty of water while you are taking BTC Candesartan HCT.

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 BTC Candesartan HCT affects you.**

BTC Candesartan HCT may cause dizziness when you start taking it and this is due to drop in your blood pressure.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Keep your medicine in the original container. If you take it out of its original container, 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.

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
<b>Gut or Gastrointestinal related:</b> <ul style="list-style-type: none"><li>• feeling sick (nausea) or vomiting</li><li>• stomach ache</li></ul>	<b>Speak to your doctor if you have any of these less serious side</b>

<b>General Disorders:</b> <ul style="list-style-type: none"> <li>headache or dizziness</li> <li>feeling tired</li> </ul> <b>Infection related:</b> <ul style="list-style-type: none"> <li>flu-like symptoms or infections</li> <li>chest, throat or sinus infections</li> <li>urinary tract infection</li> </ul> <b>Muscle-joint related:</b> <ul style="list-style-type: none"> <li>back pain</li> </ul> <b>Heart related:</b> <ul style="list-style-type: none"> <li>rapid heartbeats</li> </ul> <b>Skin related:</b> <ul style="list-style-type: none"> <li>symptoms of sunburn which happens more quickly than normal</li> </ul>	<b>effects and they worry you.</b>  <b>They are generally mild and do not cause patients to stop taking BTC Candesartan HCT.</b>
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## Serious side effects

Serious side effects	What to do
<b>Heart related:</b> <ul style="list-style-type: none"> <li>rapid heartbeats</li> </ul> <b>Muscle-joint related:</b> <ul style="list-style-type: none"> <li>aching muscles, tenderness or weakness in the muscle</li> </ul> <b>Skin related:</b> <ul style="list-style-type: none"> <li>suspicious skin lesions</li> </ul> <b>Allergy related:</b> <ul style="list-style-type: none"> <li>swelling of the face, lips, tongue or throat</li> <li>rash, itching or hives</li> </ul> <b>Lungs related:</b> <ul style="list-style-type: none"> <li>harsh sounds when breathing</li> </ul> <b>Blood related:</b> <ul style="list-style-type: none"> <li>easy bruising or bleeding more easily than normal</li> </ul> <b>Liver related:</b> <ul style="list-style-type: none"> <li>yellowing of the skin and eyes</li> </ul> <b>Infection related:</b> <ul style="list-style-type: none"> <li>signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul> <b>Kidney related:</b> <ul style="list-style-type: none"> <li>worsening of the kidney function (including passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness)</li> </ul>	<b>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.</b>

<p>(especially in patients with existing kidney problems or heart failure).</p> <b>Electrolytes related:</b> <ul style="list-style-type: none"> <li>changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test.</li> <li>Symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm.</li> </ul> <b>Eyes related:</b> <ul style="list-style-type: none"> <li>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]</li> </ul> <b>Others:</b> <ul style="list-style-type: none"> <li>swelling of the hands, feet or ankles</li> <li>feel extremely tired</li> </ul>	
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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](http://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 BTC Candesartan HCT contains

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"> <li>candesartan cilexetil</li> <li>hydrochlorothiazide</li> </ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>iron oxide red</li> <li>iron oxide yellow</li> <li>maize starch</li> <li>lactose monohydrate</li> <li>povidone</li> <li>carrageenan</li> </ul>

	<ul style="list-style-type: none"> <li>• croscarmellose sodium</li> <li>• magnesium stearate</li> <li>• iron oxide black (32mg/12.5mg and 32mg/25mg only)</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• sugars as lactose</li> </ul> <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 BTC Candesartan HCT looks like**

**BTC Candesartan HCT 16mg/12.5 mg** - apricot, mottled, oval biconvex scored on both sides (Aust R 396084).

**BTC Candesartan HCT 32mg/12.5mg** - light brown, mottled, oblong, biconvex tablet, debossed with 32 on one side and with score line on both sides (Aust R 396086).

**BTC Candesartan HCT 32mg/25mg** - reddish brown, mottled, oblong, biconvex tablet, debossed with H 32 on one side and with score line on both sides (Aust R 396090).

Available in blister packs of 30 tablets.

### **Who distributes BTC Candesartan HCT**

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

This leaflet was prepared in December 2022.