

BTC Candesartan

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?

BTC Candesartan contains the active ingredient candesartan cilexetil. BTC Candesartan is used to treat high blood pressure (hypertension) and heart failure (in combination with other medicines to treat your condition).

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

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

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

3. What if I am taking other medicines?

Some medicines may interfere with BTC Candesartan 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?

- Your doctor will tell you how many tablets to take each day. The usual dose is 8 mg or 16 mg once daily. This dose may be increased to 32 mg once daily.
- Swallow the tablets whole with a glass of water at about the same time each day

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

5. What should I know while using BTC Candesartan?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist, or pharmacist you visit that you are taking BTC Candesartan.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 are taking BTC Candesartan for heart failure, restricted fluid intake is generally recommended. Speak with your doctor about how much water you should drink.Move slowly when getting out of bed or standing up if you feel faint, dizzy or light-headed.
Things you should not do	<ul style="list-style-type: none">Do not stop taking BTC Candesartan or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how BTC Candesartan affects you. BTC Candesartan may cause nausea, dizziness and tiredness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">Keep BTC Candesartan below 30°C.Keep your tablets in the original packaging until it is time to take them.

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

6. Are there any side effects?

Common side effects: headache, chest or throat infection, flu-like symptoms, feeling sick (nausea, vomiting), back pain or dizziness.

Serious side effects: swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing; swelling of the hands, feet or ankles; aching muscles, tenderness or weakness in the muscles, 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).

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

Active ingredient(s): *Candesartan cilexetil*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

[1. Why am I using BTC Candesartan?](#)

[2. What should I know before I use BTC Candesartan?](#)

[3. What if I am taking other medicines?](#)

[4. How do I use BTC Candesartan?](#)

[5. What should I know while using BTC Candesartan?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using BTC Candesartan?

BTC Candesartan contains the active ingredient candesartan cilexetil.

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

BTC Candesartan is used to treat

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

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

Warnings

Do not use BTC Candesartan if:

- you are allergic to candesartan cilexetil, any medicine containing an angiotensin II receptor antagonist (blocker) or any of the ingredients listed at the end of this leaflet. 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.
- you have severe liver disease and/or conditions associated with impaired bile flow (cholestasis)

- 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 other medical conditions
 - kidney problems
 - liver problems
 - heart problems
 - recent excessive vomiting or diarrhoea
 - a condition called primary hyperaldosteronism.
- take 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?](#)

Use in Children

BTC Candesartan should not be given to children. There is not enough information to recommend the use of this medicine for children.

Pregnancy and breastfeeding

Do not take BTC Candesartan 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.

Talk to your doctor if you intend to breastfeed. It is not known if this medicine passes into breast milk.

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 and affect how it works. 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.

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.

4. How do I use BTC Candesartan?

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.
- Follow the instructions your doctor or pharmacist give you. If you take the wrong dose, BTC Candesartan may not work as well, and your problem may not improve.

When to take BTC Candesartan

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

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.

How to long to take BTC Candesartan

Continue taking BTC Candesartan 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

If you miss your dose at the usual time, take it 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 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

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

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.

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

5. What should I know while using BTC Candesartan?

Things you should do

- Take BTC Candesartan 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 or pharmacist that you are taking BTC Candesartan
- 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.
- 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 (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:

- become pregnant while taking this medicine. You should not take this medicine 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 BTC Candesartan.

Things you should not do

- Do not take BTC Candesartan 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.
- 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BTC Candesartan 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep BTC Candesartan in the original container.

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

Store it in a cool dry place below 30°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 or if the 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
Infection related: <ul style="list-style-type: none"> • chest or throat infection • flu-like symptoms 	Speak to your doctor if you have any of these less serious side effects and they worry you. They are generally mild and do not cause patients to stop taking BTC Candesartan.
Gut or Gastrointestinal related: <ul style="list-style-type: none"> • feeling sick (nausea/vomiting) 	
Muscle-joint related: <ul style="list-style-type: none"> • back pain 	
General disorders: <ul style="list-style-type: none"> • headache • dizziness 	

Serious side effects

Serious side effects	What to do
Allergy related: <ul style="list-style-type: none"> • swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing 	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.
General disorders: <ul style="list-style-type: none"> • extreme fatigue, tiredness, weakness 	
Skin related: <ul style="list-style-type: none"> • Unusual skin reactions (severe and sudden onset of rash, itchiness, hives (itchy swellings on the skin)) 	
Muscle-joint related: <ul style="list-style-type: none"> • aching muscles, not caused by exercise, tenderness in the muscle • muscle pain or weakness 	
Kidney related: <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) 	
Electrolytes related: <ul style="list-style-type: none"> • symptoms that may indicate high potassium levels in the blood, include nausea, diarrhoea, muscle weakness, change in heart rhythm • changes in your potassium, sodium and red or white blood cell levels may occur. Such changes are usually detected by a blood test. 	
Liver related: <ul style="list-style-type: none"> • jaundice (yellowing of the skin and/or eyes) 	
Infection related: <ul style="list-style-type: none"> • signs of frequent infections such as fever, severe chills, sore throat, or mouth ulcers. 	
Blood related: <ul style="list-style-type: none"> • easy bruising or bleeding more easily than normal 	

<p>Lungs related:</p> <ul style="list-style-type: none"> • harsh sounds when breathing <p>Others:</p> <ul style="list-style-type: none"> • swelling of hands, feet, or ankles 	
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BTC Candesartan 32 mg - pink, mottled, round biconvex tablet, debossed with 32 on one side and scored on the other side (AUST R 396087).

Available in blisters of 30 tablets.

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.

Who distributes BTC Candesartan

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

This leaflet was prepared in January 2023.

7. Product details

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

What BTC Candesartan contains

Active ingredient (main ingredient)	candesartan cilexetil
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • iron oxide red (8 mg, 16 mg, and 32 mg tablets only) • titanium dioxide (8 mg, 16 mg, and 32 mg tablets only) • lactose monohydrate • maize starch • povidone • carrageenan • croscarmellose sodium • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • sugars as lactose <p>This medicine does not contain sucrose, 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 looks like

BTC Candesartan 4 mg - white, round biconvex tablet, debossed with 4 on one side and scored on the other side (AUST R 396088).

BTC Candesartan 8 mg - pink, mottled, round biconvex tablet, debossed with 8 on one side and scored on the other side (AUST R 396085).

BTC Candesartan 16 mg - pink, mottled, round biconvex tablet, debossed with 16 on one side and scored on the other side (AUST R 396089).