

Noumed 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 Noumed Candesartan/ HCT?

Noumed Candesartan/ HCT contains the active ingredients candesartan cilexetil and hydrochlorothiazide. Noumed Candesartan/ HCT is used to treat high blood pressure, which doctors call hypertension. For more information, see Section [1. Why am I using Noumed Candesartan/ HCT?](#) in the full CMI.

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

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

3. What if I am taking other medicines?

Some medicines may interfere with Noumed 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 Noumed Candesartan/ HCT?

- The standard dose for this medicine is one tablet once daily. Your doctor may have prescribed a different dose. Swallow the tablet whole with a glass of water and take at about the same time each day.

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

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

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using Noumed Candesartan/HCT.Before being started on any new medicine, tell your doctor and pharmacist you are taking Noumed Candesartan/HCT.Tell your doctor if you have excessive vomiting or diarrhoea while taking Noumed Candesartan/HCT.If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.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 Noumed Candesartan/HCT.If you become pregnant while taking this medicine or plan to become pregnant, tell your doctor immediately.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 Noumed Candesartan/HCT.Be sure to keep all your doctor's appointment so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">Do not take Noumed Candesartan/HCT to treat any other complaints unless your doctor tells you to.Do not stop taking Noumed Candesartan/HCT unless you have discussed it with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Noumed Candesartan/HCT affects you.This medicine may cause dizziness when you start taking it. If this occurs, do not drive.
Drinking alcohol	<ul style="list-style-type: none">If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">Keep your medicine in a cool dry place where the temperature stays below 25°C.Keep your tablets in the packaging until it is time to take them.

For more information, see Section [5. What should I know while using Noumed 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, urinary tract infection, rapid heartbeats, feeling tired, stomach ache. Serious side effects: rapid heartbeats, aching muscles, tenderness or weakness in the muscle, 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. 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.

Noumed Candesartan/ HCT

Active ingredient(s): [Candesartan cilexetil and hydrochlorothiazide]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Noumed 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 Noumed Candesartan/ HCT.**

Where to find information in this leaflet:

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

1. Why am I using Noumed Candesartan/ HCT?

Noumed Candesartan/ HCT 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. Angiotensin II is a substance produced in the body that causes blood vessels to narrow. Candesartan cilexetil blocks angiotensin-II and therefore widens your blood vessels, making it easier for your heart to pump blood throughout your body. This helps to lower your blood pressure.

Hydrochlorothiazide belongs to the class of medicines known as diuretics. Diuretics cause an increase in the volume of urine. They also help with lowering blood pressure particularly when combined with other blood pressure reducing medicines.

Noumed Candesartan/ HCT is used to treat high blood pressure, which doctors call hypertension.

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

Warnings

Do not use Noumed Candesartan/ HCT if:

- you are allergic to candesartan cilexetil, hydrochlorothiazide, sulfonamide derived medicines (commonly known as sulfur drugs), or any of the ingredients listed at the end of this leaflet.

- Always check the ingredients to make sure you can use this medicine.
- You are pregnant (or think you may be pregnant) or are planning to become pregnant.
- you are breast-feeding
- you have diabetes or have kidney problems and you are being treated with medicines that lower blood pressure such as an ACE inhibitor, any aliskiren-containing medicines that belong to a group of medicines known as AIIRAs (medicines also used to treat high blood pressure)
- have or have had severe kidney or liver disease and/or conditions associated with impaired bile flow (cholestasis)
- have or have had gout

Check with 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.

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

Check with your doctor if you are pregnant or intend to become pregnant. It may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Your baby can take in components of Noumed Candesartan/HCT from breast milk if you are breastfeeding.

Use in children

Noumed Candesartan/ HCT should not be given to 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.

Tell your doctor if you are taking or plan to take any of the following:

- other blood pressure lowering medicines
- any 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 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 Noumed Candesartan/ HCT.

4. How do I use Noumed Candesartan/ HCT?

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, Noumed Candesartan/HCT may not work as well and your problem may not improve.

When to take Noumed Candesartan/ HCT

- 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.

How to take Noumed Candesartan/ HCT

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

- 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 Noumed 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 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 Noumed Candesartan/ HCT

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

If you take too many Noumed 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 Noumed Candesartan/ HCT?

Things you should do

- Take Noumed Candesartan/HCT 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 Noumed Candesartan/HCT.
- Tell your doctor if you have excessive vomiting or diarrhoea while taking Noumed Candesartan/HCT.
- 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.
- 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 Noumed Candesartan/HCT.
- 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 Noumed 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.

Things you should not do

- Do not take Noumed 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 Noumed 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
- Be careful driving or operating machinery until you know how Noumed Candesartan/HCT 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 Noumed Candesartan/HCT, 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 Noumed Candesartan/HCT affects you.

As with many other medicines used to treat high blood pressure, Noumed Candesartan/HCT may cause dizziness or lightheadedness in some people. If this occurs do not drive.

Make sure you know how you react to Noumed Candesartan/HCT before you drive a car, operate

machinery or do anything else that could be dangerous if you are dizzy or light-headed.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

- Keep your medicine in a cool dry place where the temperature stays below 25°C.
- Keep your tablets in the blister pack until it is time to take them

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

Store it in a cool dry place 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.

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.

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
<ul style="list-style-type: none"> • 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 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • rapid heartbeats • aching muscles, tenderness or weakness in the muscle 	<p>Call your doctor straight away, or go straight</p>

<ul style="list-style-type: none"> • 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. • Symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm. 	<p>to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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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 Noumed Candesartan/ HCT contains

Active ingredient (main ingredient)	Each Noumed Candesartan/ HCT 16/12.5 mg tablet contains 16 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • iron oxide yellow • iron oxide red • maize starch • povidone

	<ul style="list-style-type: none"> • carrageenan • croscarmellose sodium • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • lactose monohydrate

Active ingredient (main ingredient)	Each Noumed Candesartan/ HCT 32/12.5 mg tablet contains 32 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • iron oxide black • iron oxide yellow • iron oxide red • maize starch • povidone • carrageenan • croscarmellose sodium • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • lactose monohydrate

Active ingredient (main ingredient)	Each Noumed Candesartan/ HCT 32/25 mg tablet contains 32 mg candesartan cilexetil and 25 mg hydrochlorothiazide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • iron oxide black • iron oxide red • maize starch • povidone • carrageenan • croscarmellose sodium • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • lactose monohydrate

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

What Noumed Candesartan/ HCT looks like

Noumed Candesartan/HCT 16mg/12.5 mg – apricot or apricot-mottled, oval biconvex tablets, scored on both sides. (AUST R 285581)

Noumed Candesartan/HCT 32mg/12.5mg - light brown or light-brown mottled, oblong, biconvex tablets, debossed with 32 on one side and with score line on both sides (AUST R 285582)

Noumed Candesartan/HCT 32mg/25mg - reddish brown, or reddish-brown mottled, oblong, biconvex tablets, debossed with H 32 on one side and with score line on both sides. (AUST R 285583)

Available in blister packs (Al/Al) of 30 tablets.

Who distributes Noumed Candesartan/ HCT

Sponsor

Avallon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive,
Macquarie Park
North Ryde, NSW 2113
Phone: 1800 930 999

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