# **Noumed 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 taking Noumed Candesartan?

Noumed Candesartan contains the active ingredient candesartan cilexetil. Noumed Candesartan is used to treat high blood pressure and is also used in the treatment of heart failure in combination with other medicines.

For more information, see Section 1. Why am I taking Noumed Candesartan? in the full CMI.

## 2. What should I know before I take Noumed Candesartan?

Do not use if you have ever had an allergic reaction to candesartan cilexetil 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 take Noumed Candesartan? in the full CMI.

# 3. What if I am taking other medicines?

Some medicines may interfere with Noumed 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 take Noumed Candesartan?

- Your doctor will tell you how many tablets to take each day. The standard dose is one 8 mg or 16 mg per day. This dose may be increased to 32 mg once per day.
- Swallow the tablets whole with a glass of water and take Noumed Candesartan at about the same time each day. More instructions can be found in Section 4. How do I take Noumed Candesartan? in the full CMI.

# 5. What should I know while taking Noumed Candesartan?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are taking Noumed Candesartan</li> <li>If you plan to become pregnant or breastfeed while taking Noumed Candesartan, tell your doctor immediately</li> <li>If you are to be started on any new medicine, tell your doctor and pharmacist you are taking Noumed Candesartan</li> <li>If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Noumed Candesartan</li> <li>Make sure you drink enough water during exercise and hot weather when taking Noumed Candesartan</li> <li>If you have excessive vomiting and/or diarrhoea while taking Noumed Candesartan, tell your doctor</li> <li>If you feel lightheaded or dizzy when your dose is increased, tell your doctor immediately</li> </ul>	
Things you should not do	Do not stop taking Noumed Candesartan, or lower the dosage, without checking with your doctor	
Driving or using machines	Be careful driving or operating machinery until you know how Noumed Candesartan affects you.  Noumed Candesartan may cause dizziness or tiredness in some people. If this occurs do not drive.	
Drinking alcohol	If you drink alcohol, dizziness or light-headedness may be worse	
Looking after your medicine	<ul> <li>Keep Noumed Candesartan tablets in a cool dry place where the temperature stays below 30°C</li> <li>Keep your tablets in the packaging until it is time to take them</li> </ul>	

For more information, see Section 5. What should I know while taking Noumed Candesartan? in the full CMI.

## 6. Are there any side effects?

Common side effects: headache, chest or throat infection, flu-like symptoms, 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; severe and sudden onset of pinkish, itchy swellings on the skin (hives or nettle rash). 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**

Active ingredient(s): candesartan cilexetil (kan-de-SAR-tan sil-EX-etil)

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Noumed 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 Noumed Candesartan.

#### Where to find information in this leaflet:

1. Why am I taking Noumed Candesartan?

2.What should I know before I take Noumed Candesartan?

3.What if I am taking other medicines?

4. How do I take Noumed Candesartan?

5. What should I know while taking Noumed Candesartan?

6.Are there any side effects?

7.Product details

# 1. Why am I taking Noumed Candesartan?

Noumed Candesartan contains the active ingredient candesartan cilexetil. Noumed Candesartan belongs to a group of medicines called angiotensin II receptor antagonists (or blocker). Angiotensin II is a substance produced in the body that causes blood vessels to narrow. Noumed Candesartan 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. Noumed Candesartan is also used in combination with other medicines to treat heart failure.

Noumed Candesartan is used to treat high blood pressure, which doctors call hypertension. Noumed Candesartan is also used in treatment of heart failure in combination with other medicines.

# 2. What should I know before I take Noumed Candesartan?

# Warnings

#### Do not use Noumed Candesartan if:

- you are allergic to candesartan cilexetil, 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. It is not known if Noumed Candesartan passes into breast milk, therefore it is recommended that you not take it while you are breast-feeding
- you have severe liver disease and/or conditions associated with impaired bile flow (cholestasis)

 you have diabetes or have kidney problems and are being treated with medicines that lower blood pressure such as an ACE inhibitor, any medicines containing aliskiren or medicines that belong to a group of medicines known as angiotensin II receptor antagonist (medicines also used to treat high blood pressure)

#### Check with your doctor if you:

- · have any other medical conditions
- have had recent excessive vomiting or diarrhoea
- have kidney problems, or you have had a kidney transplant or dialysis
- have heart problems
- have liver problems, or have had liver problems in the
- past
- have diabetes
- · have high levels of potassium in your blood
- are strictly restricting your salt intake
- take any medicines for any other condition
- are pregnant or intend to become pregnant
- if you are breast feeding or plan to breastfeed
- plan to have surgery (even at the dentist) that needs a
- general anaesthetic
- have allergies to any substances, such as foods,
- preservatives, or dyes.
- 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 <u>6</u>. <u>Are there any side effects?</u>

#### Use in children

Noumed Candesartan should not be given to children.

#### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Do not take Noumed Candesartan if you are pregnant or planning to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

# 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 medicines to treat high blood pressure
- potassium supplements or, potassium-containing salt
- substitutes (you may need to have regular blood tests)

- diuretics
- medicines containing lithium (you may need to have
- regular blood tests)
- non-steroidal anti- inflammatory drugs, medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis.
- Taking Noumed Candesartan and an antiinflammatory medicine alone or with a thiazide diuretic (fluid tablet) may damage your kidneys. It may also reduce the effect Noumed Candesartan has on lowering blood pressure.
- medicines taken to treat heart failure e.g. 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 Noumed Candesartan.

# 4. How do I take Noumed Candesartan?

#### How much to take

- The usual starting dose is 8 or 16 mg once a day.
   However, some patients may need a lower starting dose. Your doctor will tell you if this is necessary.
- Depending on how your blood pressure responds, your daily dose of Noumed Candesartan may need to be increased to 32 mg once daily.
- Ask your doctor of pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.
- Follow the instructions provided and use Noumed Candesartan until your doctor tells you to stop.

#### When to take Noumed Candesartan

 Noumed Candesartan should be taken at the same time each day.

#### **How to take Noumed Candesartan**

- Swallow the tablet whole with a glass of water. It does not matter whether you take Noumed Candesartan tablets before or after food.
- Continue taking Noumed Candesartan until your doctor tells you to stop.

#### If you forget to use Noumed Candesartan

Noumed Candesartan should be taken regularly at the same time each day. If you miss your dose at the usual time, take your dose 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.

#### If you use take much Noumed Candesartan

If you think that you have taken too much Noumed 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.

# 5. What should I know while taking Noumed Candesartan?

#### Things you should do

- Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Noumed Candesartan
- Tell your doctor immediately if you become pregnant while taking Noumed Candesartan
- Have your blood pressure checked when your doctor tells you to, to make sure Noumed Candesartan is working
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Noumed Candesartan
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Noumed Candesartan. Your blood pressure may drop suddenly
- Make sure you drink enough water during exercise and hot weather when you are taking Noumed Candesartan especially if you sweat a lot. If you do not drink enough water while taking Noumed Candesartan, you may faint or feel light-headed or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.
- Tell your doctor if you have excessive vomiting and/or diarrhoea while taking Noumed Candesartan. You may lose too much water and salt and your blood pressure may drop too much.
- Tell your doctor immediately If you feel lightheaded or dizzy after taking your first dose of Noumed Candesartan, or when your dose is increased

# Things you should not do

- Do not give Noumed Candesartan tablets to anyone else, even if they have the same condition as you
- Do not take Noumed Candesartan to treat any other complaints unless your doctor or pharmacist tells you to
- Do not stop taking Noumed Candesartan, or lower the dosage, without checking 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.
- 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 Noumed Candesartan affects you.

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

Make sure you know how you react to Noumed Candesartan 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 of light-headedness may be worse.

# Looking after your medicine

- Keep Noumed Candesartan tablets in a cool dry place where the temperature stays below 30°C
- Keep your tablets in the blister pack until it is time to take them

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
headache	Speak to your
<ul> <li>chest or throat infection</li> </ul>	doctor if you
<ul> <li>flu-like symptoms</li> </ul>	have any of these
<ul><li>nausea/vomiting</li></ul>	less serious side
back pain	effects and they
<ul><li>dizziness</li></ul>	worry you.
	They are
	generally mild
	and do not
	normally require
	treatment to be
	interrupted.

#### Serious side effects

Serious side effects			
Serious side effects	What to do		
<ul> <li>skin rash or itchiness</li> <li>aching muscles, not caused by exercise</li> <li>muscle pain or weakness</li> <li>symptoms that may indicate kidney disease, such as passing little or no urine, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness</li> <li>symptoms that may indicate high potassium levels in the blood, such as nausea, diarrhoea, muscle weakness, change in heart rhythm</li> <li>yellowing of the skin and/or eyes, also called jaundice</li> <li>easy bruising or bleeding more easily than normal extreme fatigue, tiredness, weakness</li> <li>swelling of hands, feet or ankles</li> <li>harsh sounds when breathing</li> <li>signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> </ul>	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.		
Allergy-related symptoms	Stop taking Noumed		

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing;
- severe and sudden onset of pinkish, itchy swellings on the skin (hives or nettle rash)

Stop taking
Noumed
Candesartan
and
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.

# 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 <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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 contains

Active ingredient (main ingredient)	Each tablet contains 4 mg, 8 mg, 16 mg or 32 mg of candesartan cilexetil
Other ingredients (inactive ingredients)	<ul> <li>Lactose monohydrate</li> <li>iron oxide red (8mg, 16mg and 32mg tablets only),</li> <li>titanium dioxide (8mg, 16mg and 32mg tablets only)</li> <li>maize starch</li> <li>povidone</li> <li>carrageenan</li> <li>croscarmellose sodium</li> <li>magnesium stearate</li> </ul>
Potential allergens	Lactose monohydrate

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

#### What Noumed Candesartan looks like

Noumed Candesartan 4mg tablets – White, round biconvex tablet, debossed with 4 on one side and scored on the other. Pack size: 30 tablets (Aust R 284335)

Noumed Candesartan 8mg tablets – Pink, mottled, round biconvex tablet, debossed with 8 on one side and scored on the other. Pack size: 30 tablets (Aust R 284336)

Noumed Candesartan 16mg tablets – Pink, mottled, round biconvex tablet, debossed with 16 on one side and scored on the other. Pack size: 30 tablets (Aust R 284337)

Noumed Candesartan 32mg tablets – Pink, mottled, round biconvex tablet, debossed with 32 on one side and scored on the other. Pack size: 30 tablets (Aust R 284338)

#### Who distributes Noumed Candesartan

Noumed Candesartan is distributed in Australia by: Noumed Pharmaceuticals Pty Ltd Adelaide, South Australia

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