

## Candesartan HCTZ AN tablets

*Candesartan cilexetil and hydrochlorothiazide*

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about CANDESARTAN HCTZ AN.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking CANDESARTAN HCTZ AN against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.** You may need to read it again.

#### What CANDESARTAN HCTZ AN is used for

CANDESARTAN HCTZ AN is used to treat high blood pressure, also called hypertension.

CANDESARTAN HCTZ AN contains two medicines, candesartan cilexetil and hydrochlorothiazide. In combination, they lower your blood pressure more than using either one on its own.

Candesartan cilexetil belongs to a group of medicines known as angiotensin-II receptor antagonists. It works by relaxing the blood vessels.

Hydrochlorothiazide is a diuretic. It works by reducing the amount of fluid in the body.

Your doctor will have explained why you are being treated with Candesartan/hydrochlorothiazide tablets and told you what dose to take.

Your doctor may have prescribed CANDESARTAN HCTZ AN for another reason.

Ask your doctor if you have any questions about why CANDESARTAN HCTZ AN has been prescribed for you.

CANDESARTAN HCTZ AN is available only with a doctor's prescription.

#### Before you take CANDESARTAN HCTZ AN

##### *When you must not take it*

**Do not take CANDESARTAN HCTZ AN if you are allergic to:**

- medicines containing candesartan cilexetil
- other angiotensin-II receptor antagonists
- any sulphur drugs (sulphonamides) such as some antibiotics or some medicines to treat diabetes
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction can include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue, or other parts of the body.

Do not take CANDESARTAN HCTZ AN if you have:

- severe kidney or liver disease
- gout.

**Do not take CANDESARTAN HCTZ AN if you are pregnant.**

CANDESARTAN HCTZ AN may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking CANDESARTAN HCTZ AN.**

It is not known if CANDESARTAN HCTZ AN passes into breast milk.

**Do not give CANDESARTAN HCTZ AN to children.**

There is no information about its use in children, so CANDESARTAN HCTZ AN is not recommended for children.

**Do not take CANDESARTAN HCTZ AN if the expiry date (Exp.) printed on the pack has passed.**

**Do not take CANDESARTAN HCTZ AN if the packaging is torn or shows signs of tampering.**

##### *Before you start to take it*

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- kidney problems
- heart problems
- liver problems
- diabetes
- recent excessive vomiting or diarrhoea
- a salt reduced diet
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys
- a condition called primary hyperaldosteronism
- a past operation known as sympathectomy.

You may not be able to take CANDESARTAN HCTZ AN or need a lower dose, if you have these conditions.

**If you have not told your doctor about any of the above, tell them before you start taking CANDESARTAN HCTZ AN.**

##### *Taking other medicines*

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

Some medicines may be affected by CANDESARTAN HCTZ AN, or may affect how well it works.

These include:

- other blood pressure lowering medicines
- 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, used to treat epilepsy, such as phenobarbitone
- medicines like insulin that are used to treat diabetes
- calcium supplements, or medicines containing calcium

- medicines to treat irregular heart beats
- corticosteroids such as prednisone, cortisone, dexamethasone.

Your doctor can tell you what to do if you are taking any of these medicines.

**If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.**

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CANDESARTAN HCTZ AN.

##### *Things to be careful of*

**Move slowly when getting out of bed or standing up if you feel faint, dizzy or light-headed.**

**Be careful driving or operating machinery until you know how CANDESARTAN HCTZ AN affects you.**

You may feel dizzy when you start taking CANDESARTAN HCTZ AN due to the drop in your blood pressure.

Drink plenty of water while you are using CANDESARTAN HCTZ AN, especially if you sweat a lot.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

#### How to take CANDESARTAN HCTZ AN

##### *How much to take*

The usual dose is one tablet, taken once daily.

**Take CANDESARTAN HCTZ AN once a day, at about the same time each day.**

Keeping a regular time for taking your medicine will help to remind you to take it.

Follow all directions given to you by your doctor and pharmacist carefully.

##### *How to take CANDESARTAN HCTZ AN*

**Swallow the tablets with a glass of water.**

It does not matter whether you take CANDESARTAN HCTZ AN tablets before or after food.

**If you forget to take CANDESARTAN HCTZ AN**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.**

**Do not take a double dose to make up for the dose you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

##### *How long to take CANDESARTAN HCTZ AN for*

CANDESARTAN HCTZ AN helps control your high blood pressure but does not cure it. To properly control your condition, CANDESARTAN HCTZ AN must be taken every day.

**Keep taking CANDESARTAN HCTZ AN for as long as your doctor recommends.**

*If you take too much CANDESARTAN HCTZ AN (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CANDESARTAN HCTZ AN. Do this even if there are no signs of discomfort or poisoning.** You may need urgent medical attention

*If you take too much*

CANDESARTAN HCTZ AN, you may get a headache and feel sick, dizzy, thirsty and very tired.

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**While you are taking CANDESARTAN HCTZ AN**

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*Things you must do*

**Before starting any new medicine, tell your doctor or pharmacist that you are taking CANDESARTAN HCTZ AN.**

**Tell all the doctors, dentists and pharmacists who are treating you that you are taking CANDESARTAN HCTZ AN.**

**Tell your doctor if you have excess vomiting and diarrhoea while taking CANDESARTAN HCTZ AN.**

You may lose too much water and your blood pressure may become too low.

**Tell your doctor immediately if you become pregnant or plan to become pregnant while taking CANDESARTAN HCTZ AN.**

You should not use CANDESARTAN HCTZ AN if you are pregnant or thinking about becoming pregnant. Your doctor can discuss different treatment options with you.

**If you plan to have surgery, including dental surgery, that needs a general anaesthetic; tell your doctor or dentist that you are taking CANDESARTAN HCTZ AN.**

**Tell your doctor if you plan to have an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye) that you are taking CANDESARTAN HCTZ AN.**

**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 must not do*

**Do not use CANDESARTAN HCTZ AN to treat any other conditions unless your doctor tells you to.**

**Do not give CANDESARTAN HCTZ AN to anyone else, even if they have the same condition as you.**

**Do not stop taking CANDESARTAN HCTZ AN unless you have discussed it with your doctor.**

*Things to be careful of*

**Be careful driving or operating machinery until you know how CANDESARTAN HCTZ AN affects you.**

CANDESARTAN HCTZ AN may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful getting up from a sitting or lying position.**

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help. This problem can be more common if you are also taking a diuretic (fluid tablets). 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 you are taking CANDESARTAN HCTZ AN for high blood pressure, make sure you drink enough water during exercise and hot weather when you are taking CANDESARTAN HCTZ AN, especially if you sweat a lot.**

If you do not drink enough water while taking, 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.

**If you are taking CANDESARTAN HCTZ AN for heart failure, restricted fluid intake is generally recommended. Speak with your doctor about how much water you should drink.**

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

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**Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CANDESARTAN HCTZ AN.**

Like all other medicines, CANDESARTAN HCTZ AN may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor if you notice any of the following and they worry you:**

- headache or dizziness
- chest, throat or sinus infection
- flu-like symptoms or infections
- feeling sick (nausea) or vomiting
- back pain
- urinary tract infection
- feeling tired
- stomach ache.

These are common side effects.

They are generally mild and do not normally require treatment to be interrupted.

The following side effects have been reported very rarely by patients taking CANDESARTAN HCTZ AN: palpitations, agitation, anxiety, depression, trouble sleeping (insomnia), drowsiness (somnolence), nervousness, nightmare and sleep disorder. It is not known if these side effects are caused by CANDESARTAN HCTZ AN.

**Tell your doctor immediately if you notice any of the following:**

- rapid heartbeats
- aching muscles, tenderness or weakness in the muscles.

This list includes serious side effects that may require medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing
- swelling of hands, feet or ankles
- harsh sounds when breathing
- rash, itching or hives
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- jaundice (yellowing of the skin and/or eyes)
- easy bruising or bleeding more easily than normal
- extreme fatigue, tiredness, weakness
- worsening of 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.

These are very rare but serious side effects. If you have them, you may have had a serious reaction to the medicine. You may need urgent medical attention or hospitalisation.

**Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.**

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**After taking CANDESARTAN HCTZ AN**

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*Storage*

**Keep CANDESARTAN HCTZ AN where children cannot reach it.**

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

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store CANDESARTAN HCTZ AN or any other medicine in the bathroom or near a sink.**

**Do not leave CANDESARTAN HCTZ AN in the car or on window sills.**

Heat and dampness can destroy some medicines.

*Disposal*

**If your doctor tells you to stop taking CANDESARTAN HCTZ AN, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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**Product description**

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*What it looks like*

CANDESARTAN HCTZ AN comes in 3 strengths of tablets:

- CANDESARTAN HCTZ AN 16/12.5 (blister: AUST R 204586; bottle AUST R 196419)  
Light pink, oval, biconvex tablet with 'L3|02' on one side and a break line on the other side

- CANDESARTAN HCTZ AN 32/12.5  
(blister: AUST R 204587; bottle AUST R 196400)  
Light yellow, oval, biconvex tablet with 'L3|04' on one side and a break line on the other side
- CANDESARTAN HCTZ AN 32/25 (blister: AUST R 204588; bottle AUST R 196399)  
Light pink, oval, biconvex tablet with 'L3|04' on one side and a break line on the other side

Each Aluminium/Aluminium foil blister pack or HDPE bottle contains 30 tablets.

### *Ingredients*

#### **Active Ingredients:**

The active ingredients in CANDESARTAN HCTZ AN are candesartan cilexetil and hydrochlorothiazide.

- each CANDESARTAN HCTZ AN 16/12.5 tablet contains 16 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide
- each CANDESARTAN HCTZ AN 32/12.5 tablet contains 32 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide
- each CANDESARTAN HCTZ AN 32/25 tablet contains 32 mg of candesartan cilexetil and 25 mg of hydrochlorothiazide.

#### **Other Ingredients:**

- carmellose calcium
- hydroxypropylcellulose
- lactose
- macrogol 8000
- magnesium stearate
- pigment blend PB-24880 PINK (PI)
- maize starch

Please read this leaflet carefully before you start taking CANDESARTAN HCTZ AN. You may wish to keep it to read again.

### *Name and Address of the Sponsor*

#### **Scentia Pharmaceuticals Pty Ltd**

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