

CANDESAN

contains the active ingredient candesartan cilexetil

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CANDESAN.

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 CANDESAN 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 CANDESAN is used for

CANDESAN belongs to a group of medicines known as angiotensin-II receptor antagonists.

CANDESAN is used to treat:

- high blood pressure, also called hypertension
- heart failure, usually in combination with other medicines.

Hypertension

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or

worried you are. You have hypertension (high blood pressure) which means your blood pressure stays high, even when you are calm and relaxed.

Regular blood pressure checks are the only way of knowing that you have hypertension. There are no symptoms of hypertension and you may feel fine. If hypertension is not treated, serious health problems such as stroke or heart attack and heart or kidney failure may occur.

CANDESAN lowers blood pressure by dilating (expanding) small blood vessels from the heart, letting the blood be pumped around the body more easily.

Heart Failure

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working.

Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

CANDESAN helps to treat heart failure and may improve your symptoms.

One of the ways CANDESAN helps heart failure is that it widens the blood vessels, so that the heart does not have to pump as hard to move the blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope better so you may not get short of breath as easily.

When used to treat heart failure, CANDESAN is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body.

Your doctor will have explained why you are being treated with CANDESAN and told you what dose to take.

Your doctor may have prescribed CANDESAN for another reason.

Ask your doctor if you have any questions about why CANDESAN has been prescribed for you.

CANDESAN is available only with a doctor's prescription.

Before you take CANDESAN

When you must not take it

Do not take CANDESAN if you are allergic to medicines containing candesartan cilexetil, other angiotensin II receptor antagonists, or 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, rash, itching or hives on the skin

Do not use CANDESAN if you have:

- severe liver disease and/or conditions associated with impaired bile flow (cholestasis)

Do not use CANDESAN if you are taking blood pressure medicine containing aliskiren, especially if you have diabetes mellitus or have kidney problems.

Do not take CANDESAN if you are pregnant. CANDESAN may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking CANDESAN. It is not known if CANDESAN passes into breast milk.

Do not give CANDESAN to children. There is no information about its use in children, so CANDESAN is not recommended for children.

Do not take CANDESAN if the expiry date (Exp.) printed on the pack has passed.

Do not take CANDESAN 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
- recent excessive vomiting or diarrhoea
- a condition called primary hyperaldosteronism.

You may have to take a lower dose of CANDESAN if you have these conditions.

If you have not told your doctor about any of the above, tell them before you start taking CANDESAN.

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 CANDESAN, or may affect how well it works. These include:

- fluid tablets or diuretics
- lithium or lithium containing medicines (e.g. Lithicarb)
- potassium containing salt substitutes (e.g. Pressor-K)
- anti-inflammatory medicines, used to relieve pain, swelling and other symptoms of inflammation, including arthritis. These include nonsteroidal anti-inflammatory agents – NSAIDs (e.g. Voltaren, Indocid) and COX-2 inhibitors (e.g. Celebrex).
- 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

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 CANDESAN.

How to take CANDESAN

How much to take

The usual dose is one 8 mg tablet or one 16 mg tablet taken daily. Sometimes, this may need to be increased to 32 mg taken daily.

Take CANDESAN 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 CANDESAN

Swallow the tablets with a glass of water.

It does not matter whether you take CANDESAN tablets before or after food.

If you forget to take it

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 it for

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

Keep taking CANDESAN for as long as your doctor recommends.

If you take too much (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 CANDESAN. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much CANDESAN, you may get a headache and feel sick, dizzy and very tired.

While you are taking CANDESAN

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking CANDESAN.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking CANDESAN.

Tell your doctor immediately if you become pregnant or plan to become pregnant while taking CANDESAN. You should not use CANDESAN 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 CANDESAN.

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 CANDESAN to treat any other conditions unless your doctor tells you to.

Do not give CANDESAN to anyone else, even if they have the same condition as you.

Do not stop taking CANDESAN unless you have discussed it with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how CANDESAN affects you.

CANDESAN 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 CANDESAN for high blood pressure, make sure you drink enough water during exercise and hot weather when you are taking CANDESAN, especially if you sweat a lot. If you do not drink enough water while taking CANDESAN, 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 CANDESAN 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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CANDESAN.

Like all other medicines, CANDESAN 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
- chest or throat infection
- flu-like symptoms
- nausea/vomiting
- back pain
- dizziness.

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 CANDESAN: 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 CANDESAN.

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

- 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

- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
 - jaundice (yellowing of the skin and /or eyes)
 - unusual skin reactions (severe and sudden onset of rash, itchiness, hives (itchy swellings on the skin))
 - easy bruising or bleeding more easily than normal
 - extreme fatigue, tiredness, weakness
 - 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.
- These are very rare but serious side effects. 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.

After using CANDESAN

Storage

Keep CANDESAN 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 CANDESAN or any other medicine in the bathroom or near a sink.

Do not leave CANDESAN in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product Description

What it looks like

CANDESAN comes in 4 strengths of tablets:

- CANDESAN 4mg – Light pink, round, biconvex tablet with '291' on one side and a break line on the other side
- CANDESAN 8mg – Light pink, round, biconvex tablet with '292' on one side and a break line on the other side
- CANDESAN 16mg – Light pink, round, biconvex tablet with 'L293' on one side and a break line on the other side
- CANDESAN 32mg – Light pink, round, biconvex tablet with 'L294' on one side and a break line on the other side.

Each PVC/PE/PVDC/Aluminium or Aluminium/Aluminium blister pack contains 30 tablets.

Ingredients

The active ingredient in CANDESAN is candesartan cilexetil.

- each CANDESAN 4mg tablet contains 4 mg of candesartan cilexetil
- each CANDESAN 8mg tablet contains 8 mg of candesartan cilexetil
- each CANDESAN 16mg tablet contains 16 mg of candesartan cilexetil
- each CANDESAN 32mg tablet contains 32 mg of candesartan cilexetil.

The tablets also contain:

- lactose monohydrate
- carmellose calcium
- maize starch
- macrogol 8000
- hyprolose
- magnesium stearate
- Pigment Blend PB-24880 Pink (iron oxide red and lactose monohydrate).

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Australian registration numbers:

CANDESAN 4mg - AUST R 195483
CANDESAN 8mg - AUST R 195509
CANDESAN 16mg - AUST R 195443
CANDESAN 32mg - AUST R 195459

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