

Candesan Combi

(16mg/12.mg, 32mg/12.5mg & 32mg/25mg tablets)

contains the active ingredients candesartan cilexetil and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CANDESAN COMBI.

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 COMBI against the benefits 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 COMBI is used for

CANDESAN COMBI is used to treat high blood pressure, also called hypertension.

CANDESAN COMBI 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 CANDESAN COMBI for another reason.

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

CANDESAN COMBI is available only with a doctor's prescription.

Before you take CANDESAN COMBI

When you must not take it

Do not take CANDESAN COMBI 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 CANDESAN COMBI if you have:

- severe kidney or liver disease
- gout.

Do not take CANDESAN COMBI if you are pregnant.

CANDESAN COMBI may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking CANDESAN COMBI.

It is not known if CANDESAN COMBI passes into breast milk.

Do not give CANDESAN COMBI to children.

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

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

Do not take CANDESAN COMBI 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 CANDESAN COMBI 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 CANDESAN COMBI.

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 COMBI, 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 CANDESAN COMBI.

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 CANDESAN COMBI affects you.

You may feel dizzy when you start taking CANDESAN COMBI due to the drop in your blood pressure.

Drink plenty of water while you are using CANDESAN COMBI, 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 CANDESAN COMBI

How much to take

The usual dose is one tablet, taken once daily.

Take CANDESAN COMBI 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 COMBI

Swallow the tablets with a glass of water.

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

If you forget to take CANDESAN COMBI

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 CANDESAN COMBI for

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

Keep taking CANDESAN COMBI for as long as your doctor recommends.

If you take too much CANDESAN COMBI (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 COMBI. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking CANDESAN COMBI

Things you must do

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

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

Tell your doctor if you have excess vomiting and diarrhoea while taking CANDESAN COMBI.

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 CANDESAN COMBI.

You should not use CANDESAN COMBI 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 COMBI.

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 CANDESAN COMBI.

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

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

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

Things to be careful of

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

CANDESAN COMBI 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 COMBI for high blood pressure, make sure you drink enough water during exercise and hot weather when you are taking CANDESAN COMBI, especially if you sweat a lot.

If you do not drink enough water while taking CANDESAN COMBI, 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 COMBI 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 COMBI.

Like all other medicines, CANDESAN COMBI 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 CANDESAN COMBI: 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 COMBI.

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.

After using CANDESAN COMBI

Storage

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

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

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking CANDESAN COMBI, 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 COMBI comes in 3 strengths of tablets:

- CANDESAN COMBI 16/12.5 – light pink, oval, biconvex tablet with ‘L3’ & ‘02’ on either side of break line on one side and a break line on the other side
- CANDESAN COMBI 32/12.5 – light yellow, oval, biconvex tablet with ‘L3’ & ‘04’ on either side of break line on one side and a break line on the other side
- CANDESAN COMBI 32/25 – light pink, oval, biconvex tablet with ‘L3’ & ‘04’ on either side of break line on one side and a break line on the other side

Each Aluminium/Aluminium foil blister pack contains 30 tablets.

Ingredients

The active ingredients in CANDESAN COMBI are candesartan cilexetil and hydrochlorothiazide.

- each CANDESAN COMBI 16/12.5 tablet contains 16 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide
- each CANDESAN COMBI 32/12.5 tablet contains 32 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide
- each CANDESAN COMBI 32/25 tablet contains 32 mg of candesartan cilexetil and 25 mg of hydrochlorothiazide.

The tablets also contain:

- lactose monohydrate
- carmellose calcium
- maize starch
- macrogol 8000
- hypolose
- magnesium stearate
- Pigment Blend PB-24880 Pink (16/12.5 mg and 32/25 tablet only)
- yellow colouring (iron oxide yellow and lactose monohydrate) (32/12.5 mg tablet only).

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 COMBI 16/12.5 – AUST R
204577

CANDESAN COMBI 32/12.5 – AUST R
204578

CANDESAN COMBI 32/25 – AUST R
204579

Date of Revision:

November 2016