

CANDESARTAN-GA

contains the active ingredient candesartan cilexetil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CANDESARTAN-GA.

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-GA 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-GA is used for

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

CANDESARTAN-GA 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.

CANDESARTAN-GA 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.

CANDESARTAN-GA helps to treat heart failure and may improve your symptoms.

One of the ways CANDESARTAN-GA 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, CANDESARTAN-GA 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 CANDESARTAN-GA and told you what dose to take.

Your doctor may have prescribed CANDESARTAN-GA for another reason.

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

CANDESARTAN-GA is available only with a doctor's prescription.

Before you take CANDESARTAN-GA

When you must not take it

Do not take CANDESARTAN-GA 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.

Do not take CANDESARTAN-GA if you are pregnant.

CANDESARTAN-GA may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking CANDESARTAN-GA.

It is not known if CANDESARTAN-GA passes into breast milk.

Do not give CANDESARTAN-GA to children.

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

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

Do not take CANDESARTAN-GA 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 CANDESARTAN-GA if you have these conditions.

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

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

- fluid tablets or diuretics
- lithium or lithium containing medicines (eg. Lithicarb)

- potassium tablets (eg. Span-K, Slow-K, Mag-K)
- potassium containing salt substitutes (eg. Pressor-K)
- anti-inflammatory medicines, used to relieve pain, swelling and other symptoms of inflammation, including arthritis. These include nonsteroidal anti-inflammatory agents - NSAIDs (eg. Voltaren, Indocid) and COX-2 inhibitors (eg. Celebrex).

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-GA.

How to take CANDESARTAN-GA

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 CANDESARTAN-GA 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-GA

Swallow the tablets with a glass of water.

It does not matter whether you take CANDESARTAN-GA 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

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

Keep taking CANDESARTAN-GA 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 CANDESARTAN-GA. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking CANDESARTAN-GA

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking CANDESARTAN-GA.

Tell your doctor immediately if you become pregnant or plan to become pregnant while taking CANDESARTAN-GA.

You should not use CANDESARTAN-GA 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-GA.

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 (eg 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-GA to treat any other conditions unless your doctor tells you to.

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

Do not stop taking CANDESARTAN-GA unless you have discussed it with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how CANDESARTAN-GA affects you.

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

If you do not drink enough water while taking CANDESARTAN-GA, 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-GA 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 CANDESARTAN-GA.

Like all other medicines, CANDESARTAN-GA 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 CANDESARTAN-GA: 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-GA.

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 CANDESARTAN-GA

Storage

Keep CANDESARTAN-GA 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-GA or any other medicine in the bathroom or near a sink.

Do not leave CANDESARTAN-GA in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking CANDESARTAN-GA, 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

CANDESARTAN-GA comes in 4 strengths of tablets:

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

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

Ingredients

The active ingredient in CANDESARTAN-GA is candesartan cilexetil.

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

The tablets also contain:

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

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

Distributor

Actavis Pty Ltd
Level 5, 117 Harrington St
The Rocks NSW 2000

Australian registration numbers:

- CANDESARTAN-GA 4mg -
AUST R 195506
- CANDESARTAN-GA 8mg -
AUST R 195491
- CANDESARTAN-GA 16mg -
AUST R 195513
- CANDESARTAN-GA 32mg -
AUST R 195452

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