

AURO-CANDESARTAN™ 4, 8, 16 and 32

Candesartan cilexetil tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about AURO-CANDESARTAN.

It does not contain all the information that is known about AURO-CANDESARTAN. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What AURO-CANDESARTAN is used for

Candesartan cilexetil is a type of medicine called an angiotensin II - receptor antagonist (or blocker).

AURO-CANDESARTAN is used to treat high blood pressure, also called hypertension.

AURO-CANDESARTAN is also used to treat heart failure. It is used in combination with other medicines to treat your condition.

Hypertension:

All people have blood pressure. This pressure helps to push blood

all around your body. Your blood pressure changes during the day, depending on how busy you are or how you are feeling.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

Regular blood pressure checks are the only way of knowing that you have hypertension. There are usually 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.

AURO-CANDESARTAN 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.

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

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

You must follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor may prescribe this medicine for another use.

Ask your doctor if you want more information.

AURO-CANDESARTAN is not known to be addictive.

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

Before you take it

When you must not take it

Do not take AURO-CANDESARTAN if you have an allergy to:

- any medicine containing candesartan cilexetil;
- any of the ingredients listed at the end of the leaflet; or
- any medicine containing an angiotensin II receptor antagonist (or blocker).

Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing;
- swelling of the face, lips, tongue or other parts of the body; or
- rash, itching or hives on the skin.

Do not use AURO-CANDESARTAN if you have:

- severe liver disease; or
- conditions associated with impaired bile flow (cholestasis).

Do not take AURO-CANDESARTAN if you are pregnant or are planning to become pregnant.

It may affect your baby if you take it during pregnancy.

Do not take AURO-CANDESARTAN if you are breastfeeding.

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

Do not give AURO-CANDESARTAN to children.

There is no information about its use in children.

Do not take AURO-CANDESARTAN after the use by (expiry) date printed on the pack has passed.

It may have no effect at all or an unexpected effect if you take it after the expiry date.

Do not take AURO-CANDESARTAN if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Do not use it to treat any other complaints unless your doctor tells you to.

Do not give this medicine to anyone else.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any of the following medical conditions:

- kidney problems;
- liver problems;
- heart problems; or
- a condition called primary hyperaldosteronism.

You may have to take a lower dose of AURO-CANDESARTAN if you have these conditions.

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

Taking other medicines

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

Some medicines and AURO-CANDESARTAN may interfere with each other. These include:

- any medicines containing potassium, including salt substitutes;
- diuretics (fluid tablets);
- lithium, a medicine used to treat mood swings and some types of depression;
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis; or
- angiotensin-converting-enzyme (ACE) inhibitors, medicines

used to help lower blood pressure, especially if you have diabetes-related kidney problems.

These medicines may be affected by AURO-CANDESARTAN or may affect how it works. You may need different amounts of your medicines, or may need to take different medicines.

It may be necessary to have regular blood tests done if you take any of these medicines.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines. If you have not told your doctor about any of these things, tell them before you take any AURO-CANDESARTAN.

How to take it

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one 8 mg tablet or one 16 mg tablet taken daily.

Sometimes an increase in dose to 32 mg once daily is needed. Your doctor will tell you the dose of AURO-CANDESARTAN you should take.

How and when to take it

Take AURO-CANDESARTAN once a day, at about the same time each day.

Keeping a regular time for taking AURO-CANDESARTAN will help to remind you to take it.

It does not matter whether you take AURO-CANDESARTAN with food or on an empty stomach.

How long to take it

Continue taking this medicine for as long as your doctor tells you.

This medicine controls your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If you miss a dose take it as soon as you remember, as long as it is 12 hours before the next dose is due.

Then go back to taking it as you would normally.

If it is less than 12 hours to the next dose do not take the dose you have missed.

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

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

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much AURO-CANDESARTAN. Do this even if there are no signs of discomfort or poisoning.

If you take too many AURO-CANDESARTAN tablets you may get a headache, feel sick (nausea), dizzy and very tired.

While you are taking it

Things you must do

Take AURO-CANDESARTAN exactly as your doctor has told you to.

Your blood pressure will not be well controlled if you do not.

If you are about to be started on any new medicine, tell your doctor, dentist and pharmacist that you are taking AURO-CANDESARTAN.

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

If you go into hospital, please let the medical staff know you are taking AURO-CANDESARTAN.

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

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

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking AURO-CANDESARTAN.

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 it to treat any other complaints unless your doctor says to.

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

Do not stop taking AURO-CANDESARTAN or lower the dosage, without checking with your doctor.

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

AURO-CANDESARTAN affects you.

You may feel dizzy when you start taking AURO-CANDESARTAN.

If you are taking AURO-CANDESARTAN for high blood pressure, drink plenty of water during exercise and hot weather, especially if you sweat a lot. If you do not drink enough water while taking AURO-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.

If you are taking AURO-CANDESARTAN 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 AURO-CANDESARTAN.

AURO-CANDESARTAN helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. 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 the following list of side effects. You may not experience any of them.

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

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

- headache;
- chest or throat infection;

- flu-like symptoms;
- feeling sick (nausea, vomiting); back pain; or
- dizziness.

These side effects are usually mild.

The following side effects have been reported very rarely by patients taking candesartan: 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.

Tell your doctor as soon as possible if you notice any of the following:

- aching muscles, tenderness or weakness in the muscles.

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

If any of the following happen, stop taking AURO-CANDESARTAN and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, tongue or throat;
- 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;
- yellowing of the skin and / or eyes);
- 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; or
- symptoms that may indicate high potassium levels in the blood include nausea, diarrhoea, muscle weakness and changes in heart rhythm.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking AURO-CANDESARTAN.

After taking it

Storage

Keep your tablets in the blister foil until it is time to take them.

If you take AURO-CANDESARTAN out of the blister foil, it will not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a windowsill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Disposal

Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that the expiry date has passed.

Product description

What AURO-CANDESARTAN looks like

AURO-CANDESARTAN is available as tablets containing 4, 8, 16 & 32 mg of candesartan as cilexetil.

AURO-CANDESARTAN * tablets are supplied in blister packs containing 28 or 30 tablets.

AURO-CANDESARTAN 4 White to off white biconvex uncoated round shaped tablets debossed with 'J' and '11' separated by scoreline on one side and plain on other side.

AURO-CANDESARTAN 8 Pale pink biconvex uncoated round shaped tablets debossed with 'J' and '12' separated by scoreline on one side and plain on other side.

AURO-CANDESARTAN 16 Yellow biconvex uncoated round shaped tablets debossed with 'J' and '13' separated by scoreline on one side and plain on other side.

AURO-CANDESARTAN 32 Yellow biconvex uncoated round shaped tablets debossed with 'J' and '14' separated by scoreline on one side and plain on other side.

*Some of these presentations and pack sizes may not be marketed.

Ingredients

Active ingredient:

Candesartan cilexetil.

Other ingredients:

- lactose;
- carmellose calcium;
- hydroxypropylcellulose;
- magnesium stearate;
- aluminium magnesium silicate;
- propylene glycol;
- iron oxide red (8 mg only); and
- iron oxide yellow (16 mg and 32 mg only).

Sponsor/Marketing Authorisation Holder

Aurobindo Pharma Australia Pty
Ltd
6 Eastern Road
South Melbourne
Victoria 3205
Australia

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www.eris-pharma.com.au

Toll free telephone (Australia):
1800 233 588

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AURO-CANDESARTAN™ 8
blister pack: AUST R 195373

AURO-CANDESARTAN™ 16
blister pack: AUST R 195374

AURO-CANDESARTAN™ 32
blister pack: AUST R 195371

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