

ATACAND®

Candesartan cilexetil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about ATACAND. It does not contain all the information that is known about ATACAND.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking ATACAND 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 ATACAND is used for

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

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

ATACAND 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.

ATACAND 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.

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

One of the ways ATACAND 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, ATACAND 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 ATACAND and told you what dose to take.

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

Your doctor may prescribe this medicine for another reason.

ATACAND is not addictive.

Before you use ATACAND

When you must not use it

Do not use ATACAND if you have an allergy to:

- any medicine containing candesartan cilexetil
- any ingredient listed at the end of this leaflet
- 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

- rash, itching or hives on the skin

Do not use ATACAND if you have:

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

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

Do not use ATACAND if you are pregnant or planning to become pregnant.

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

Do not use ATACAND if you are breastfeeding.

It is not known if ATACAND passes into breast milk.

Do not give ATACAND to children.

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

Do not use ATACAND after the use by (expiry) date printed on the pack or if the packaging is torn or shows signs of tampering

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should take this medicine, talk to your doctor.

Before you start to use it

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

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

- kidney problems
- liver problems
- heart problems
- recent excessive vomiting or diarrhoea
- a condition called primary hyperaldosteronism

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy at the chemist, supermarket or health food shop.

Some medicines and ATACAND 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
- 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

These medicines may be affected by ATACAND or may affect the way ATACAND works. You may need different amounts of your medicines, or you 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take ATACAND

Follow all directions given to you by your doctor 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 to take it

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 ATACAND you should take.

Take ATACAND once a day, at about the same time each day.

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

It does not matter whether you take ATACAND 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 forget to take a dose, take it as soon as you remember, as long as it is at least 12 hours before your next dose is due.

Then go back to taking it as you would normally.

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

Do NOT double the dose.

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 (13 11 26) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have

taken too much ATACAND, even if there are no signs of discomfort or poisoning.

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

While you are using ATACAND

Things you must do

Take ATACAND 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, remind your doctor and pharmacist that you are taking ATACAND.

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

Tell your doctor immediately if you become pregnant or plan to become pregnant while you are taking ATACAND.

You should not use ATACAND 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 ATACAND.

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 this medicine to anyone else, even if they have the same condition as you.

Do not stop taking ATACAND unless you have discussed it 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 ATACAND affects you.

You may feel dizzy when you start taking ATACAND.

If you are taking ATACAND 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 ATACAND, you may faint or feel light-headed or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

If you are taking ATACAND 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 ATACAND.

ATACAND 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.

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
- feeling sick (nausea, vomiting)
- back pain
- dizziness

These side effects are usually mild.

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

- aching muscles, tenderness or weakness in the muscle

The above 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
- swelling of the hands, feet or ankles.
- harsh sounds when breathing
- rash, itching or hives
- yellowing of the skin and/or eyes
- easy bruising or bleeding more easily than normal
- extreme fatigue, tiredness, weakness
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- 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

The above list includes 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.

Other side effects not listed above may occur in some people.

After using ATACAND

Storage

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

If you take ATACAND out of the blister pack it will not keep well.

Keep it in a cool, dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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

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

Product description

What ATACAND looks like

ATACAND 4 mg tablets are round white tablets, 7 mm in diameter. They are scored and marked A/CF on one side with 004 on the other.

ATACAND 8 mg tablets are round light pink tablets 7 mm in diameter. They are scored and marked A/CG on one side with 008 on the other.

ATACAND 16 mg tablets are round pink tablets 7 mm in diameter. They are scored and marked A/CH on one side with 016 on the other.

ATACAND 32 mg tablets are round pink biconvex tablets. They are scored and marked A/CL on one side with 032 on the other side.

All strengths are available in blister packs of 7 or 30 tablets.

Ingredients

Each ATACAND tablet contains candesartan cilexetil 4, 8, 16 or 32 mg as the active ingredient, plus:

Carmellose calcium

Hyprolose

Iron oxide red (E 172)

(8 mg, 16 mg and 32 mg tablets only)

Lactose monohydrate

Magnesium stearate (E 572)

Maize starch

Macrogol 8000

ATACAND does not contain gluten.

Sponsor

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ATACAND 8 mg - AUST R 64107

ATACAND 16 mg - AUST R 64108

ATACAND 32 mg - AUST R 117341

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