

SCHEDULING STATUS: **S3**

ATACAND® 8 mg tablets

ATACAND® 16 mg tablets

ATACAND® 32 mg tablets

Candesartan cilexetil

Contains sugar (lactose monohydrate).

ATACAND 8 mg: Each tablet contains 89,4 mg lactose monohydrate.

ATACAND 16 mg: Each tablet contains 80,7 mg lactose monohydrate.

ATACAND 32 mg: Each tablet contains 161,5 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ATACAND

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ATACAND has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ATACAND is and what it is used for
2. What you need to know before you take ATACAND
3. How to take ATACAND
4. Possible side effects
5. How to store ATACAND
6. Contents of the pack and other information

- 1. What ATACAND is and what it is used for**

ATACAND is a type of medicine called an angiotensin II receptor antagonist, which by blocking the effects of the hormone angiotensin II causes the blood vessels to relax and widen. This results in a lowering of your blood pressure.

ATACAND is used for treating high blood pressure (hypertension). It is also used for treating a heart condition known as heart failure where the heart does not pump the blood around the body as well as it should.

2. What you need to know before you take ATACAND

Do not take ATACAND

- If you are hypersensitive (allergic) to candesartan cilexetil or any of the other ingredients of ATACAND (listed in section 6).
- If you are pregnant, think you might be pregnant or considering becoming pregnant.
- If you are breastfeeding.
- If you have a severe kidney problem.
- If you have a severe liver problem or cholestasis, a condition which impairs the flow of bile from the liver to the small intestine.
- If you have a condition known as bilateral renal artery stenosis or stenosis in the presence of a single kidney. This is a narrowing of the kidney arteries supplying blood to the kidney(s), leading to a reduced blood flow, resulting in impaired kidney function and high blood pressure.
- If you have a condition known as Hypertrophic Obstructive Cardiomyopathy. This is a condition associated with thickening of the heart muscle, leading to stiffening of the heart walls and abnormal heart valve function, both of which may hinder normal blood flow out of the heart.
- If you have a heart condition known as aortic valve stenosis, a condition where the aortic valve in the heart becomes narrowed or blocked, limiting the blood flow from the heart to the aorta and the rest of the body.
- If you previously have developed angioedema (swelling similar to hives, but the swelling is beneath the skin rather than on the surface) after taking ATACAND or any medicine in the same class called angiotensin receptor blockers (ARB's) or ACE inhibitors (a different class of blood pressure lowering medicines). You should not take ATACAND if you have had problems in the past when taking these

medicines.

- If you have hereditary or spontaneous angioedema (swelling similar to hives, but the swelling is beneath the skin rather than on the surface)
- If you are also taking medicines for water retention, known as potassium sparing diuretics such as spironolactone, triamterene and amiloride (see “Other medicines and ATACAND”).
- If you have porphyria, an inherited disorder of blood pigment metabolism,
- If you are taking a mood stabilizer known as lithium.
- If you are younger than 1 year old (children younger than 1 year).
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you are using fluoroquinolones, an antibiotic used to treat infections.

Warnings and precautions

Please talk to your doctor or pharmacist before taking ATACAND:

- If you take other blood pressure medicines including ACE inhibitors (such as enalapril, captopril, lisinopril or ramipril) or aliskiren. The effect of the treatment for high blood pressure may be increased (see “Do not take ATACAND” and “Other medicines and ATACAND”).
- If you experience abdominal pain, nausea, vomiting or diarrhoea after taking Atacand. Your doctor will decide on further treatment. Do not stop taking Atacand on your own.
- Concomitant use of fluoroquinolones (an antibiotic used to treat infections) and ATACAND may precipitate acute kidney injury (AKI), especially if you have moderate or severe kidney disease, and in the elderly (see “Do not take ATACAND” and “Other medicines and ATACAND”).
- If you have any kidney disorders, as regular monitoring must be done of certain laboratory tests (serum potassium and creatinine levels).
- If you are using cortisone (for inflammation) along with an ACE-inhibitor (for high blood pressure).

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- If you are receiving haemodialysis, a life-saving treatment for kidney failure that removes waste and extra fluid from the blood and regulates blood pressure.
 - If you have serious kidney problems (see “Do not take ATACAND”).
 - If you have had a kidney transplant, your doctor will decide whether you may take ATACAND.
 - If you have low blood pressure. You will feel like fainting, especially when you stand up or sit down quickly.
 - If you are going to have an operation, tell your doctor or dentist that you are taking ATACAND. If combined with some anaesthetics, it may cause a drop in blood pressure.
 - If you have hyperaldosteronism, a condition characterized by excessive secretion of a hormone called aldosterone.
 - If you have hyperkalaemia, a condition in which potassium levels in your blood get too high.

Children and adolescents

Do not give ATACAND to children as it is unlikely to be safe.

If your child is younger than 1 year old, you should not give him/her ATACAND (see “Do not take ATACAND”).

Other medicines and ATACAND

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines). The use of ATACAND with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider, for advice.

Tell your doctor if you are taking any of the following medicines:

- Lithium, a mood stabilizer. You should not take ATACAND if you are using lithium (see “Do not take ATACAND”).
- The effect of the treatment for high blood pressure may be increased when you take other high blood pressure medicines with ATACAND, including ACE inhibitors (such as enalapril, captopril, lisinopril or ramipril) or aliskiren (see “Do not take ATACAND” and “Take special care with ATACAND”).

- Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may cause acute kidney injury (AKI) (see section “Do not take ATACAND”).
- If you are taking other medicines to help lower your blood pressure, particularly diuretics (“water tablets” which make you urinate) (see Do not take ATACAND”).
- If you are taking potassium-sparing diuretics, potassium supplements, salt substitutes or other medicines that may increase potassium levels (e.g. heparin).
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib, or etoricoxib (medicines used to relieve pain and inflammation), especially if you have a kidney disease.
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).

ATACAND with food and drink

It does not matter whether you take your tablet with or without food.

Pregnancy and breastfeeding

ATACAND is contraindicated (should not be used) in pregnancy and breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent ATACAND may interfere with the daily activities of the patients. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ATACAND affects them.

The treatment of high blood pressure or heart failure may lead to dizziness or tiredness in some patients. Make sure you are not affected in this way before driving or operating machines.

ATACAND contains sugar (lactose monohydrate)

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ATACAND.

Please talk to your doctor or pharmacist before taking this medicine if you suffer from lactose intolerance.

3. How to take ATACAND

Do not share medicines prescribed for you with any other person.

Always take ATACAND exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure. The instructions on the label should remind you of what the doctor has said. Try to take the tablets at the same time each day. It does not matter if you take ATACAND before or after your food.

ATACAND is not recommended for children.

For high blood pressure (hypertension):

The usual adult dose is one 8 mg tablet each day. Your doctor may increase the dose to one 16 mg or 32 mg tablet each day. If you have severe kidney or severe liver problems, your doctor may prescribe a lower dose.

For heart failure:

The usual starting dose in adults including the elderly is 4 mg (half an 8 mg) tablet taken every day. The dose is doubled at intervals of at least 2 weeks to the target dose of 32 mg or the highest dose tolerated.

Your doctor may prescribe other medicines together with the ATACAND to treat your high blood pressure or heart failure.

If you have the impression that the effect of ATACAND is too strong or too weak, talk to your doctor or pharmacist.

If you take more ATACAND than you should

If you take more than the recommended number of tablets, you are likely to feel light-headed and dizzy. You should contact a doctor or pharmacist immediately.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take ATACAND

If you forget to take a dose, just carry on with the next dose as normal. Do not take an extra tablet / double dose to make up for forgotten individual doses.

4. Possible side effects

ATACAND can have side effects.

Not all side effects reported for ATACAND are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ATACAND, please consult your healthcare provider for advice.

If any of the following happen, stop taking ATACAND and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing or breathing.
- Rash, allergic skin reaction or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ATACAND. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Difficulty breathing.
- Signs of recurrent infections such as fever or sore throat.
- There may be changes to your red or white blood cells or other parts of your

blood. Your doctor may occasionally take blood samples to check whether ATACAND has had any effect on your blood. Sometimes these changes may show themselves as tiredness or a sore throat.

- Less urine than is normal for you.
- Worsening of your kidney function (especially in patients with existing kidney problems or heart failure), which can be detected by blood tests.
- Yellowing of the skin and eyes, also called jaundice.
- Changes to the functioning of your liver, including inflammation of the liver.

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

Tell your doctor if you notice any of the following:

Common side effects:

- Dizziness/vertigo.
- Headache.
- Low blood pressure (feeling faint when standing up or sitting down quickly).

Very rare side effects:

- High levels of potassium in the blood, determined by a blood test.
- Low sodium levels, determined by a blood test.
- Cough.
- Nausea (feeling sick).
- Back pain, joint stiffness, muscle pain.
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

Side effects with unknown frequency:

- Diarrhoea (loose, watery stools).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (sho-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of ATACAND.

5. How to store ATACAND

Keep your medicine stored below 30 °C.

Keep all medicines out of the reach and sight of children.

Do not use after the expiry date stated on the blister strip/bottle or carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ATACAND contains

The active substance is candesartan cilexetil.

The active substance in ATACAND 8 mg tablet is 8 mg candesartan cilexetil.

The active substance in ATACAND 16 mg tablet is 16 mg candesartan cilexetil.

The active substance in ATACAND 32 mg tablet is 32 mg candesartan cilexetil.

The other ingredients are calcium carboxymethylcellulose (carmellose calcium), hydroxypropyl cellulose (hypromellose), iron oxide reddish brown CI 77491 (E172), lactose monohydrate, magnesium stearate, maize starch and polyethylene glycol 8000 (macrogol).

What ATACAND looks like and contents of the pack

ATACAND 8 mg tablets are light pink, circular, biconvex tablets with a score and marked A/CG on one side and 008 on the other.

ATACAND 16 mg tablets are pink round tablets with a score and marked A/CH on one side and 016 on the other.

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

ATACAND 8 and 16 mg:

PVC/PVDC blister packs of 7, 14, 28, 56 or 98 tablets in strips of 7 or 30 tablets in blister strips of 10 or 15.

White HDPE bottles of 30 or 100 tablets.

ATACAND 32 mg:

PVC/PVDC blister packs of 7, 14, 28, 56 or 98 tablets in strips of 7 or 30 tablets in blister strips of 10 or 15.

White HDPE bottles of 100 tablets.

All pack sizes may not be marketed.

Holder of Certificate of Registration

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ATACAND 16 mg: 32/7.1.3/0100

ATACAND 32 mg: A39/7.1.3/0244

Access to corresponding Professional Information

An electronic copy of the Professional Information (PI) is available on the Equity website

<http://www.equitypharmaceuticals.co.za> or <http://www.sahpra.org.za>.