

FINAL PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: Atacand 8, 16 & 32 mg Tablets

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.

SCHEDULING STATUS: S3

PROPRIETARY NAME (and dosage form):

Atacand® 8 mg, Atacand® 16 mg, Atacand® 32 mg (Tablet)

The active substance is candesartan cilexetil.

1. WHAT ATACAND CONTAINS:

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 carmellose calcium, hypolose, iron oxide, magnesium stearate, maize starch and macrogol. Contains sugar (lactose monohydrate).

2. WHAT ATACAND 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.

3. BEFORE YOU TAKE ATACAND:

Do not take ATACAND:

- If you are pregnant, think you might be pregnant or considering becoming pregnant.
- If you are breast-feeding.
- If you have a severe kidney problem.
- If you are allergic to any of the ingredients in ATACAND.
- If you have a severe liver problem.
- 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 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 drug in the same class called angiotensin receptor blockers (ARB's) or ACE inhibitors (a different class of blood pressure lowering drugs).

Important: You should not take ATACAND if you have had problems in the past when taking medicines containing candesartan cilexetil.

Take special care with ATACAND:

Please talk to your doctor or pharmacist before taking this medicine:

- If you are taking other medicines to help lower your blood pressure, particularly diuretics (tablets that make you urinate).
- If you are taking any other medicines including those you have bought without a prescription.
- If you are taking lithium.
- If you are taking potassium-sparing diuretics, potassium supplements, salt substitutes or other medicines that may increase potassium levels (e.g. heparin).
- If you have any heart, liver or kidney problems.
- If you are vomiting or have diarrhoea.
- 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 suffer from lactose intolerance.

Taking ATACAND with food and drink

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

Pregnancy and breast-feeding:

If you are pregnant or breast-feeding your baby while taking this medicine please consult your doctor, pharmacist or other health care professional for advice.

ATACAND is contra-indicated (should not be used) in pregnancy and breast-feeding.

Driving and using machinery:

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.

Important information about some of the ingredients of ATACAND:

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

Taking other medicines with ATACAND:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ATACAND with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional, for advice.

4. HOW TO TAKE ATACAND:

Always take ATACAND exactly as your doctor has instructed you. You should 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.

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

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 tablet or 32 mg (two 16 mg tablets) 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 medication together with the ATACAND to treat your high blood pressure or heart failure.

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 overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

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 to make up.

5. POSSIBLE SIDE EFFECTS:

ATACAND can have side effects.

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.
- Yellowing of the skin and eyes, also called jaundice.

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. All of these side effects are very rare and may occur (in less than 0,01% of patients).

Common side effects include (in 1% or more of patients, but less than 10%):

- Dizziness.
- Worsening of your kidney function (especially in patients with existing kidney problems or heart failure), which can be detected by blood tests.

Very rare side effects that may occur (in less than 0,01% patients):

- Back pain.
- Changes to the functioning of your liver, including inflammation of the liver.

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.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

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

6. STORING AND DISPOSING OF ATACAND:

Store at or below 30 °C.

Store all medicines out of reach 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).

7. PRESENTATION OF ATACAND:

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.

Not all pack sizes may be marketed.

8. IDENTIFICATION OF ATACAND:

ATACAND 8 mg tablets are light pink round 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.

9. REGISTRATION NUMBERS:

ATACAND 8 mg: 32/7.1.3/0099

ATACAND 16 mg: 32/7.1.3/0100

ATACAND 32 mg: A39/7.1.3/0244

**10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION:**

AstraZeneca Pharmaceuticals (Pty) Limited

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

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