

Patient Leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Atacand® 8 mg
Tablets

Atacand® 16 mg
Tablets

Active ingredient

Each tablet contains:

Atacand 8 mg: candesartan cilexetil 8 mg

Atacand 16 mg: candesartan cilexetil 16 mg

Inactive ingredients and allergens in this medicine: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

The medicine is intended for adults above the age of 18.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For treatment of hypertension.

For treatment of patients with heart failure and impaired left ventricle systolic function (left ventricular ejection fraction < or = 40%) as add-on therapy to ACE inhibitors or when ACE inhibitors are not tolerated.

Therapeutic group:

Angiotensin II receptor antagonist which blocks the effects of the hormone angiotensin II, thereby causing the blood vessels to relax, resulting in lowering blood pressure. It also assists the heart with blood flow to all parts of the body.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are more than 3 months pregnant (it is also better to avoid using the medicine in early pregnancy, for further information see 'Pregnancy and breastfeeding' section below).
- you are sensitive (allergic) to the active ingredient (candesartan cilexetil) or to any of the other ingredients in this medicine (see section 6 'Further Information').
- you have severe liver function impairment or biliary tract obstruction.
- you are taking a medicine to lower blood pressure containing aliskiren and you have diabetes.
- you are taking a medicine to lower blood pressure containing aliskiren and you have kidney function problems.

Special warnings about using this medicine

Before treatment with Atacand, tell your doctor if:

- you are suffering, or have suffered in the past, from impaired function of the heart, the liver, the kidney or are on dialysis.
- you have recently undergone a kidney transplantation, if you suffer from diarrhea and vomiting or have recently had severe vomiting, if you have a disease called primary hyperaldosteronism, if you have an adrenal gland disease called Conn's syndrome, if you have low blood pressure, if you have ever had a stroke.
- tell the doctor if you are pregnant, think you might be pregnant or are planning to become pregnant. Atacand is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your unborn baby (for further information see "pregnancy and breastfeeding" section).
- you are about to undergo surgery, tell the doctor or dentist that you are taking Atacand. Atacand in combination with anesthetics may cause a drop in blood pressure.
- you are taking any of the following medicines used to treat high blood pressure:
 - ACE inhibitors (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - Aliskiren.
 - you are being treated with medicines of the ACE inhibitor class together with medicines to treat heart failure, known as mineralocorticoid receptor antagonists (MRAs).

Tell your doctor if you experience abdominal pain, nausea, vomiting or diarrhea after taking Atacand. Your doctor will decide on further treatment. Do not stop taking Atacand on your own.

Your doctor may need to check and monitor the following parameters – your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Interactions with other medicines

If you are taking or have recently taken other medicines including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

- Do not use Atacand if you are taking a medicine to lower blood pressure containing aliskiren and you have diabetes.
- Do not use Atacand if you are taking a medicine to lower blood pressure containing aliskiren and you have kidney function problems.

In particular, tell your doctor or pharmacist if you are taking:

- other medicines to help lower your blood pressure– including diuretics, beta-blockers, diazoxide, ACE inhibitors such as enalapril, captopril, lisinopril and ramipril.
- diuretics, used to remove fluids from the body.
- medicines of the ACE inhibitor class together with medicines to treat heart failure, known as mineralocorticoid receptor antagonists (MRAs), for example – spironolactone, eplerenone.
- Co-trimoxazole (an antibiotic) also known as trimethoprim/sulfamethoxazole.
- non-steroidal anti-inflammatory drugs (NSAIDs) also used to relieve pain such as ibuprofen, naproxen, diclofenac, aspirin (if you are taking more than 3 g each day), etoricoxib, celecoxib.
- potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium or other medicines that might raise the potassium level.
- heparin - a medicine for thinning the blood.
- lithium (a medicine for mental health problems).

Using this medicine and food

The medicine can be taken with or without food.

Using this medicine and alcohol consumption

Talk to your doctor about your alcohol consumption habits. Some people who drink alcohol and take Atacand may feel faint or dizzy.

Pregnancy and breastfeeding

- You must tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant. Your doctor will normally advise you to stop taking Atacand before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead. Atacand is not recommended for use in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your unborn baby if used after the third month of pregnancy.
- If you are breastfeeding or intend to breastfeed, please notify your doctor. Atacand is not recommended for nursing mothers especially if your baby is newborn or was born prematurely. If you wish to breastfeed your doctor may recommend an alternative treatment.

Driving and using machines

This medicine may cause dizziness or tiredness in some people. If you feel these effects, avoid driving a vehicle, operating dangerous machines or engaging in any activity that requires alertness.

Important information about some of this medicine's ingredients

The tablets contain lactose, which is a type of sugar. If you have been told by the doctor that you suffer from an intolerance to certain sugars, consult the doctor before taking this medicine.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how you should take this medicine. Only your doctor will determine your dose and how you should take this medicine.

This medicine is intended for adults above the age of 18.

Recommended dosage unless otherwise prescribed by the doctor:

For treatment of high blood pressure:

The recommended dosage is 8 mg once a day. Your doctor may increase this dosage to 16 mg once a day depending on blood pressure response. In some patients who have kidney problems, liver problems or those who recently have lost body fluids (e.g. through vomiting or diarrhea or by using diuretics), the doctor may prescribe a lower starting dosage. Some black patients may have a reduced response to the medicine, when given as the only treatment. Therefore, these patients may need a higher dose.

For treatment of heart failure:

The recommended starting dosage is 4 mg once a day. Your doctor may increase your dose by doubling it, at intervals of at least 2 weeks, up to a total dosage of 32 mg a day.

In order to receive 4 mg you should halve a tablet of Atacand 8 mg, along the score line on the tablet.

Do not exceed the recommended dose.

Directions for use:

- Do not chew or crush the tablet. The tablet can be halved to ease swallowing. The score line on the tablets divide them into two equal halves.
- Swallow the medicine with water.
- The medicine can be taken with or without food.
- It is recommended that the tablets be taken at the same time each day (for example, in the morning).

If you have accidentally taken a higher dose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take the next dose at the usual time, but under no circumstances take two doses together!

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Atacand may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Side effects requiring special attention (rare)

Stop taking this medicine and consult your doctor immediately if you suffer from:

- difficulty breathing, with or without swelling of the face, lips, tongue and throat
- swelling of the face, lips, tongue and throat that may cause difficulty swallowing
- severe itching of the skin (with raised blisters).

Atacand may cause a reduction in the number of white blood cells. As a result, your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens, contact your doctor immediately so blood tests can be done (to rule out agranulocytosis).

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult the doctor immediately.

Common side effects - affect 1–10 in 100 users:

- Feeling dizzy.
- Headache.
- Respiratory tract infection.
- Low blood pressure (may make you feel faint or dizzy).
- Changes in blood tests: increased levels of potassium in your blood, especially if you have kidney problems or heart failure. If this is severe, you may notice tiredness, weakness, heart rhythm disturbances, and a “pins and needles” sensation.
- Problems with kidney function, and very rarely, kidney failure.

Very rare side effects - affect less than 1 in 10,000 users):

- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhea.
- Swelling of the face, lips, tongue and throat.
- A reduction in red or white blood cells - you may notice tiredness, an infection or fever.
- Skin rash, lumpy rash (hives).
- Itching.
- Pains in the back, joints and muscles.
- Changes in liver function, including inflammation of the liver (hepatitis), tiredness, yellowing of the skin and whites of the eyes, and flu-like symptoms.
- Nausea.
- Changes in blood tests: reduced amount of sodium in the blood. If the drop is severe, you may feel weakness, lack of energy, or muscle cramps.

- Cough.

Side effects of not known frequency (effects the frequency of which has not yet been determined):

- Diarrhea

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il), which opens an online form for reporting side effects, or you can also use this link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by your doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Store below 30°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, maize starch, carmellose calcium, hydroxypropyl cellulose, polyethylene glycol (macrogol), magnesium stearate, iron oxide reddish-brown (E172)

What the medicine looks like and contents of the pack:

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

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

The tablet can be divided into equal doses by breaking along the score line.

A package contains 7, 10, 14, 28, 30, 56, 98 tablets packed in a blister.

Registration holder's name and address:

Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Kiryat Matalon, Petah-Tikva.

Manufacturer's name and address:

CHEPLAPHARM Arzneimittel GmbH, Ziegelhof 24, 17489 Greifswald, Germany.

Revised in March 2025.

Registration number of the medicine in the Ministry of Health's National Drug Registry:

8 mg: 109 09 29184

16 mg: 109 10 29185