

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH
THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

Atacand® 4 mg

Tablets

Atacand® 8 mg

Tablets

Atacand® 16 mg

Tablets

Composition

Each tablet contains:

Candesartan cilexetil 4 mg

Candesartan cilexetil 8 mg

Candesartan cilexetil 16 mg

For inactive ingredients please see section 6 – “Further information”.

Read this leaflet carefully in its entirety before using this medicine.

Keep this leaflet; you may need it again.

This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

For treatment of hypertension and treatment of heart failure.

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 of blood pressure. It also assists the heart with blood flow to all parts of the body.

2. BEFORE USING THE MEDICINE

X 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 have a known sensitivity to the active ingredient - candesartan cilexetil or to any of the ingredients of the medicine (see section 6 “Further Information” below).
- 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 regarding use of Atacand

I 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.
- if you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.

- Aliskiren
- if you are taking an ACE inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptor antagonists (MRAs).

In this case 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.

⚠ If you are taking other medicines

If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- 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.

It is especially important to notify the doctor or pharmacist if you are taking:

- other antihypertensives - including diuretics, beta blockers, diazoxide, ACE inhibitors such as enalapril, captopril, lisinopril and ramipril.
- diuretics, used to remove fluids from the body.
- If you are being treated with an ACE inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRAs) for example - spironolactone, eplerenone.
- non-prescription preparations.
- 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).

⚠ Use of the medicine and food

The medicine can be taken with or without food.

! Use of the medicine and alcohol consumption

Talk to your doctor about alcohol consumption habits. Some people who drink alcohol and take Atacand may feel faint and 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 the 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 the ingredients of the medicine

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 SHOULD YOU USE THE MEDICINE?

- Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure.
- The dosage and treatment regimen will be determined by the doctor only.
- Do not exceed the recommended dose.
- This medicine is intended for adults above 18 years of age.

Directions for use:

- Do not chew or crush the tablet. The tablet can be halved to ease swallowing, take the two halves together.
- 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 forget to take the medicine at the scheduled time, take the next dose as usual, but under no circumstances should two doses be taken together!
- **If you have taken an overdose** or if a child has accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
- Complete the full course of treatment recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
- Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them.
- If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

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 dose to 16 mg once a day depending on blood pressure response. In some patients who have liver problems, kidney problems or those who recently have lost body fluids (e.g. through vomiting or diarrhoea or by using diuretics) the doctor may prescribe a lower starting dose. Some black patients may have a reduced response to this type of 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 2 mg once a day. Your doctor may increase your dose by doubling the dose at intervals of 2 weeks up to 32 mg once a day.

4. SIDE EFFECTS

As with any medicine, use of Atacand may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Side effects requiring special attention (rare)

Stop taking the medicine and contact the 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 number of white blood cells. 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, occurring frequently (affects less than 1 in every 10 patients):

- Feeling dizzy
- Headache
- Respiratory tract infection
- Low blood pressure (may cause dizziness and fainting)
- 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 (affects less than 1 in every 10,000 patients):

- Swelling of the face, lips, tongue and throat
- A reduction in red or white blood cells - you may notice tiredness, an infection or fever
- Rash, urticaria
- Itching
- Pains in the back, joints and muscles
- Changes in liver function, including inflammation (hepatitis), tiredness, yellowing of the skin and whites of the eyes, and flu 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):

- Diarrhoea

If the above side effects worsen, or if you notice side effects not listed above, please contact the doctor or pharmacist.

If a side effects occurs, if any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects can be reported to the Ministry of Health by clicking on the link “Report Side Effects of Drug Treatment” found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package/bottle/carton/label. The expiry date refers to the last day of that month. In case of doubt, consult the pharmacist who dispensed the medicine to you.
- Do not store above 30°C.
- Do not store different medicines in the same package.

6. FURTHER INFORMATION

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

Hydroxypropyl cellulose, carmellose calcium, polyethylene glycol (macrogol), magnesium stearate, maize starch, iron oxide reddish-brown (E172) (only 8 mg and 16 mg tablets).

Each 4 mg tablet contains 93.4 mg lactose

Each 8 mg tablet contains 89.4 mg lactose

Each 16 mg tablet contains 81.4 mg lactose

What the medicine looks like:

Atacand 4 mg tablets are round, biconvex, white to cream in color, with a groove, A/CF is engraved on one side and 004 on the other.

Atacand 8 mg tablets are round, biconvex, pale pink in color, with a groove, A/CG is engraved on one side and 008 on the other.

Atacand 16 mg tablets are round, biconvex, pink in color, with a groove, A/CH is engraved on one side and 016 on the other.

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

4 mg: 109 08 29183

8 mg: 109 09 29184

16 mg: 109 10 29185

Manufacturer:

AstraZeneca AB, Sodertalje, Sweden

License Holder:

AstraZeneca (Israel) Ltd.,

P.O.B 1455, Hod Hasharon 4524075

This leaflet was checked and approved by the Ministry of Health in April 2017 and was updated according to Ministry of Health guidelines in December 2019.