

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

This medicine is dispensed with a doctor's prescription only

Atacand Plus®

Tablets

Active ingredient

Each tablet contains:

candesartan cilexetil 16 mg

hydrochlorothiazide 12.5 mg

Inactive ingredients and allergens in this medicine - see section 2 '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.

1. What is this medicine intended for?

Atacand Plus is intended for the treatment of hypertension, where monotherapy with candesartan cilexetil or hydrochlorothiazide is not sufficient.

Therapeutic group

Candesartan cilexetil belongs to a group of medicines called angiotensin II receptor antagonists, which works by blocking the effects of the hormone, angiotensin II. It makes your blood vessels relax and widen, which contributes to lowering your blood pressure.

Hydrochlorothiazide - belongs to a group of medicines called diuretics. It works to get rid of water and salts, such as sodium, through the urinary tract, and this helps lower your blood pressure.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredients candesartan cilexetil or hydrochlorothiazide or to any of the other ingredients in this medicine (see section 6).
- You are more than three months pregnant (even at the beginning of pregnancy, it is better to avoid use of the medicine. For more information, see the 'Pregnancy and breastfeeding' section).
- You have a known sensitivity to medicines in the sulphonamide class. If you are unsure whether this applies to you, consult your doctor.
- You have/have had gout.
- You have serious kidney problems.
- You have serious liver problems or biliary tract syndrome (a condition where the gallbladder has difficulty releasing bile).
- You have persistently low levels of potassium or calcium in your blood.
- You are taking a blood pressure lowering drug containing aliskiren and have diabetes or reduced kidney function.

Special warnings about using Atacand Plus

Before treatment with Atacand Plus, tell your doctor if:

- You have heart, liver or kidney problems.
- You have diabetes.

- You have ever had systemic lupus erythematosus.
- You have recently had a kidney transplant.
- You have diarrhoea and vomiting or have recently had severe vomiting.
- You have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- You have low blood pressure.
- You have ever suffered from a stroke.
- You have ever had asthma or an allergic reaction.
- You are taking any of the following drugs that are used to treat high blood pressure:
 - An ACE inhibitor (for example, enalapril, lisinopril, ramipril), especially if you have diabetic nephropathy.
 - Aliskiren.

You have had skin cancer or if you develop an unforeseen skin change during use of the medicine. Use of hydrochlorothiazide, particularly long-term use at high doses, may increase your risk of developing skin and lip cancer (non-melanoma skin cancer). Protect your skin from exposure to sunlight and ultraviolet (UV) rays while using Atacand Plus.

- You experience impaired vision or eye pain. These may be symptoms of fluid accumulation in the eye (between the choroid and retina) or an increase in eye pressure and may appear within hours of taking Atacand Plus. This may lead to permanent vision loss if not treated. If you have previously had an allergic reaction to penicillin or sulphonamide you may have a higher risk of developing these effects.
- You experienced breathing or lung problems (including inflammation or fluid in the lungs) after taking hydrochlorothiazide in the past. If you develop any shortness of breath or difficulty breathing after taking Atacand Plus, seek medical attention immediately.

Your doctor may want to see you more often if you have any of the above conditions.

If you are scheduled to have surgery, tell your doctor or dentist that you are taking Atacand Plus. Atacand Plus in combination with certain anaesthetics can cause a sharp drop in blood pressure.

Atacand Plus can make your skin more sensitive to sunlight.

Children and adolescents

There is no clinical experience of Atacand Plus being used in children (under 18 years of age). Therefore Atacand Plus is not intended for use in children.

Tests and follow-up

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

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. If you are taking certain medicines, your doctor may order blood tests.

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

- Other blood pressure lowering medicines, including beta blockers, aliskiren-containing medicines, diazoxide and ACE inhibitors such as enalapril, captopril, lisinopril or ramipril.
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in the blood).
- Heparin (to thin the blood).
- Diuretics, to remove fluids from the body.
- Laxatives.
- Penicillin or a combination of two medicines to treat a bacterial infection - trimethoprim and sulfamethoxazole.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, etoricoxib, celecoxib.
- Aspirin (if you take more than 3 g per day) (intended to relieve pain and inflammation).
- Medicines that lower cholesterol, such as colestipol or cholestyramine.
- Amphotericin (for treatment of fungal infections).

- Lithium (for treatment of mental health problems).
- Calcium or vitamin D supplements.
- Medicines to control heart rhythm such as beta blockers or digoxin.
- Anticholinergic medicines (such as atropine and biperiden).
- Medicines for treatment of cancer.
- Steroids such as prednisolone.
- Adrenocorticotrophic hormone (ACTH).
- Amantadine (for treatment of Parkinson's disease or for serious viral infections).
- Barbiturates (for the treatment of epilepsy or as a sedative).
- Drugs that may be affected by the potassium level in the blood, such as certain antipsychotic drugs.
- Carbenoxolone (for treatment of oesophageal symptoms or mouth ulcers).
- Diabetes medication (tablets or insulin).
- Cyclosporine (for treatment of transplant rejection following organ transplant).
- Other drugs that can potentiate the antihypertensive effect such as baclofen (muscle relaxant), amiphostine (for treatment of cancer) and certain antipsychotic drugs.
- ACE inhibitors or aliskiren (see information in sections 'Do not use this medicine' and 'Special warnings about using Atacand Plus').

Using this medicine and food

The medicine can be taken regardless of meals.

Using this medicine and alcohol consumption

Discuss your alcohol consumption habits with your doctor. Some people who take Atacand Plus may feel dizzy and weak when consuming alcohol.

Pregnancy and breastfeeding

Pregnancy

- Tell your doctor if you think you are pregnant or become pregnant during the treatment. Usually your doctor will recommend that you stop taking Atacand Plus and switch to a different medicine before you become pregnant or immediately after discovering pregnancy. Atacand Plus is not recommended for use at the beginning of pregnancy and is prohibited after the first trimester, as it may harm the unborn baby.

Breastfeeding

- Please tell your doctor if you are breastfeeding or you are planning on breastfeeding. Atacand Plus is not recommended for nursing mothers, especially for newborns or preterm infants. If you would like to breastfeed, your doctor may recommend alternative treatment.

Driving and using machines

Some people may feel dizzy or tired when they take this medicine. If you feel these effects, refrain from driving a car or using dangerous machines or any other 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 your doctor that you have an intolerance to some sugars, consult your 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 to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

Instructions for use:

- Swallow the tablet with a little water. There is no information about crushing/splitting/chewing!
- The medicine can be taken with or without food.
- Try to take the tablet at the same time every day. This makes it easier to remember to take the tablet.

If you have accidentally taken a higher dose

If you have taken an overdose, 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

If you forget to take the medicine at the scheduled time, take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

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 each time you take a 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

Like all medicines, using Atacand Plus may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Stop taking the medicine and contact a doctor immediately if you experience any of the following allergic reactions:

- Difficulty breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty swallowing.
- Severe itching of the skin (with raised rash).

Atacand Plus can cause a reduction in white blood cells. Your resistance to infections may be decreased and you may feel tired, develop an infection or fever. If this happens, you should contact your doctor. Your doctor may order blood tests occasionally to check if Atacand Plus has had any effect on your blood values (agranulocytosis).

Additional side effects

Common side effects, may affect up to 1 in 10 users

- Changed results of certain blood tests:
 - Decreased level of sodium in the blood. If this decrease is severe, you may feel weakness, lack of energy or muscle cramps.
 - Increased or reduced level of potassium in the blood, especially if you have kidney problems or heart failure. If the change is severe, you may experience tiredness, weakness, irregular heartbeats or tingling and numbness in the skin.
 - Increased levels of cholesterol, sugar or uric acid in the blood.
- Sugar in the urine.
- Feeling of dizziness or weakness.
- Headaches.
- Respiratory infection.

Uncommon side effects, may affect up to 1 in 100 users

- Low blood pressure - may make you feel weak or dizzy.
- Loss of appetite, diarrhoea, constipation, stomach irritation.
- Skin rash, hives, rash that is due to sensitivity to sunlight.

Rare side effects, may affect up to 1 in 1,000 users

- Jaundice (yellow colouration of the skin or the whites of the eyes). If you develop this condition, you should contact your doctor immediately.
- Effects on renal function (especially if you have kidney problems or heart failure).
- Difficulty sleeping, depression, restlessness.
- Tingling or pins and needles in arms or legs.
- Intermittent blurred vision.
- Heart rhythm disorders.
- Breathing difficulties (including pneumonia and fluid in the lungs).
- Fever.
- Inflammation of the pancreas - causes moderate to severe stomach pain.
- Muscle cramps.

- Damage to blood vessels that causes red or purple spots on the skin.
- Reduction in the number of white blood cells, red blood cells or platelets - may be expressed as tiredness, infection, fever or easy bruising.
- Severe rash which develops rapidly, with blisters and flaking skin and possibly mouth ulcers.

Very rare side effects, may affect up to 1 in 10,000 users

- Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).
- Swelling of face, lips, tongue and/or throat.
- Itching.
- Back, joint or muscle pain.
- Changes in liver function, including inflammation of the liver (hepatitis). You may notice fatigue, yellowing of the skin and whites of the eyes and flu-like symptoms.
- Cough.
- Nausea.

Side effects with unknown frequency (effects whose frequency has not yet been determined)

- Sudden nearsightedness.
- Reduced vision or pain in the eyes due to high pressure (possible sign of fluid accumulation in the eye (between the choroid and retina) or acute narrow-angle glaucoma).
- Systemic and cutaneous lupus erythematosus (allergic condition causing fever, joint pain, skin rash that may be expressed as skin redness, blistering, scaling and lumps).
- Skin and lip cancer (non-melanoma skin cancer).
- Diarrhoea.

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 link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 30°C.

6. Additional information

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

Lactose monohydrate, maize starch, calcium carboxymethylcellulose, hydroxypropyl cellulose, polyethylene glycol 8000, magnesium stearate, iron oxide yellow, iron oxide reddish-brown.

What the medicine looks like and contents of the pack:

Atacand Plus tablets are peach-coloured, oval, biconvex tablets with a score on both sides and marked A/CS.

Each pack contains 7 or 28 tablets. Not all pack sizes may be marketed.

Registration holder's name and address:

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

Manufacturer's name and address:

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

Revised in March 2022 according to MOH guidelines.

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

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