

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

This medicine is dispensed with a doctor's prescription only

## **Atacand Plus<sup>®</sup>**

Tablets

### **Composition**

Each tablet contains:

Candesartan cilexetil 16 mg

Hydrochlorothiazide 12.5 mg

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

### **Read this package insert 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.

### **1. WHAT IS THE MEDICINE INTENDED FOR?**

Atacand Plus is intended for treatment of hypertension when treatment with candesartan or hydrochlorothiazide alone is not sufficient.

#### **Therapeutic Group**

Candesartan cilexetil, a medicine belonging to the angiotensin II receptor antagonists, works by blocking the effects of the hormone angiotensin II, leading to dilation of the blood vessels and to lowering of blood pressure.

Hydrochlorothiazide is a medicine that belongs to the group of preparations called diuretics. The medicine works by getting rid of sodium chloride salt and water through the urinary system and thus causes lowering of blood pressure.

### **2. BEFORE USING THE MEDICINE**

### **X Do not use the medicine if:**

- you are allergic to the active ingredients, candesartan cilexetil or hydrochlorothiazide or to any of the inactive ingredients (see section 6).
- you are more than 3 months pregnant (it is also better to avoid using the medicine in early pregnancy, for further information see section “pregnancy and breastfeeding” below).
- you have a known sensitivity to sulfonamide medicines. If you are not sure if this applies to you, consult the doctor.
- you suffer from gout.
- you suffer from severe liver or kidney problems, or from cholestasis (bile formation disturbance and/or bile secretion disturbance) .
- In case of fluid or electrolyte imbalance (e.g., low levels of potassium or high levels of calcium).
- you are taking a medicine to lower blood pressure that contains aliskiren and you have diabetes.
- you are taking a medicine to lower blood pressure that contains aliskiren and you have kidney function problems.

### **Special warnings regarding use of Atacand Plus**

#### **I Before treatment with Atacand Plus, tell your doctor if:**

- you are suffering from impaired function of the heart, the liver or the kidney.
- you have diabetes.
- you have SLE (lupus).
- you have recently undergone a kidney transplantation.
- you suffer from diarrhea and vomiting or have recently had severe vomiting.
- you have, an adrenal gland disease called Conn’s syndrome (also called primary hyperaldosteronism).
- you have low blood pressure.
- you have ever had a stroke.
- you have ever had asthma or allergy.
- you are about to undergo surgery, tell the doctor or dentist that you are taking Atacand Plus. Atacand Plus in combination with anesthetics may cause a drop in blood pressure.

- you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- 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

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.

- You have ever had a skin cancer or if you develop an unexpected skin lesion during treatment with this medicine. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk to develop skin and lip cancer (non-melanoma skin cancer).

Protect your skin from sun exposure and UV rays while taking Atacand Plus

- If you experience impaired vision or eye pain. These may be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase in eye pressure and may occur within a few hours to **weeks** from 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 this condition.

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

Atacand Plus may cause increased sensitivity of the skin to sun.

### **⚠ 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.**

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

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

- Medicines to help lower your blood pressure - 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 may increase the amount of potassium in your blood).
- Heparin (a medicine for thinning the blood).
- Diuretics, used to remove fluids from the body.
- Laxatives.
- Penicillin or a combination of two medicines to treat bacterial infection – trimethoprim and sulfamethoxazol.
- Non-steroidal anti-inflammatory drugs (NSAIDs) also used to relieve pain such as - aspirin (if you are taking more than 3 g each day), ibuprofen, naproxen, diclofenac, etoricoxib, celecoxib.
- Colestipol or cholestyramine (cholesterol-lowering medicines).
- Amphotericin (antibiotic for the treatment of fungal infections).
- Lithium (a medicine for mental health problems).
- Calcium supplements or vitamin D.
- Beta blockers, digoxin (medicines to control your heart beat).
- Anticholinergic preparations (e.g., atropine, biperiden)
- Cytotoxic preparations (e.g., cyclophosphamide, methotrexate), medicines to treat cancer.
- Steroids such as - prednisolone.
- Adrenal hormone (ACTH).
- Amantadine (for the treatment of Parkinson's disease or for serious infections caused by viruses).
- Barbiturates (a type of sedative also used to treat epilepsy).
- Antipsychotic medicines that may affect blood potassium levels.
- Carbenoxolone (for treatment of oesophageal disease or oral ulcers).
- Anti-diabetes medicines (including insulin).
- Cyclosporine (a medicine used following organ transplants to prevent rejection of the organ).
- Other medicines that may lead to enhancement of the antihypertensive effect, such as -baclofen (muscle relaxer), amifostine (used in cancer treatment) and some antipsychotic medicines.
- Contrast agents that contain iodine intended for imaging.

**! Use of the medicine and food:**

The medicine can be taken without regard to meals.

### **! Use of the medicine and alcohol consumption:**

Talk to your doctor about alcohol consumption habits. Some people who drink alcohol and take Atacand Plus 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 during treatment. Your doctor will normally advise you to stop taking Atacand Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead. Atacand Plus 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 Plus 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 regarding 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 not intended for children and adolescents below 18 years of age.

**Directions for use:**

- There is no available data regarding crushing/halving/chewing! Swallow the tablet with a small amount of water.
- The medicine can be taken with or without food.
- It is recommended that the tablet be taken at the same time each day, for example, in the morning.

**If you forget to take the medicine**

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

**If you have accidentally taken a higher dosage**

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.**

**4. SIDE EFFECTS**

As with any medicine, use of Atacand Plus 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; stop taking the medicine and contact the doctor immediately:**

- Difficulty breathing and swallowing, swelling of the face, tongue, lips and/or throat.
- Severe itching with raised blisters, severe rapidly developing rash, with blistering and peeling of the skin and for the most part also blistering in the mouth.

- Tendency to bruise easily, or extreme tiredness (rare).

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

Atacand Plus may cause a reduction in number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, develop an infection or a fever. If this happens, contact your doctor immediately so blood tests can be done.

**Common side effects that occur frequently (affects less than 1 in every 10 patients):**

- A reduced amount of sodium in the blood. If the reduction is severe, you may experience weakness, lack of energy, or muscle cramps.
- Increased or decreased potassium levels in the blood, especially if you have kidney problems or heart failure. If the change is severe, you may experience tiredness, weakness, heart rhythm disturbances, or prickling and tingling sensation.
- Increased levels of cholesterol, sugar or uric acid in the blood.
- Sugar in the urine.
- Dizziness and weakness.
- Headache.
- Respiratory tract infection.

**Uncommon side effects (affects less than 1 in every 100 patients):**

- Low blood pressure – may cause a feeling of faintness or dizziness.
- Loss of appetite, diarrhea, constipation, nervous stomach.
- Rash, urticaria, rash due to sensitivity to sunlight.

**Side effects that occur rarely (affects less than 1 in every 1,000 patients):**

- Jaundice (yellowing of the skin or the whites of your eyes). If this happens to you, contact your doctor immediately.
- Effect on kidney function (especially if you suffer from kidney problems or heart failure).
- Difficulties sleeping, depression, restlessness.
- Tingling or prickling sensation in the arms or legs.
- Temporary blurred vision.
- Heart rhythm disturbances.
- Difficulty breathing (including pneumonia and fluid in the lungs).
- Fever.

- Inflammation of the pancreas – causing severe abdominal pain.
- Muscle cramps.
- Damage to blood vessels, causing red or purple dots on the skin.
- Reduction in white blood cells, red blood cells and platelets – may be manifested by tiredness, infections, fever or bruising.
- A severe rash that develops quickly, with blistering or peeling of the skin or blistering in the mouth.

**Very rare side effects (affects less than 1 in every 10,000 patients):**

- Swelling of the face, tongue, lips and/or throat.
- Itching.
- Pain in the back, joints and muscles.
- Changes in liver function, including inflammation of the liver (hepatitis). You may experience tiredness, yellowing of the skin and whites of the eyes, and flu symptoms.
- Cough.
- Nausea.
- The active ingredient, hydrochlorothiazide, found in Atacand Plus, can activate or worsen lupus in some patients.

**Side effects of unknown frequency:**

- Sudden short-sightedness.
- Reduced vision or pain in the eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute narrow-angle glaucoma).
- Systemic and cutaneous lupus erythematosus (allergic condition which causes fever, joint pain, skin rashes which may include redness, blistering, peeling and lumps).
- Skin and lip cancer (non-melanoma skin cancer).
- Diarrhea.

If any of the side effects worsens, or if you notice side effects not listed above, please contact your doctor immediately.

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](http://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 and sight 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. 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.

## **6. FURTHER INFORMATION**

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

Lactose monohydrate, maize starch, calcium carboxymethylcellulose, hydroxypropyl cellulose, polyethylene glycol (macrogol) 8000, magnesium stearate, iron oxide yellow (E 172), iron oxide reddish-brown (E 172).

Each tablet contains 68 mg lactose monohydrate.

### **What the medicine look like and what is the content of the package:**

Atacand Plus tablets are oval, biconvex, peach colored, with a groove. A/CS is engraved on one side and the other side has a groove.

Each package contains 28 tablets.

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

121 44 30145

### **Manufacturer:**

AstraZeneca AB, Sodertalje, Sweden.

### **License Holder and Importer:**

AstraZeneca (Israel) Ltd.

P.O.B 1455, Hod Hasharon 4524075.

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