Package leaflet: Information for the User

Atacand plus 16/12,5 mg Tablet

candesartan cilexetil and hydrochlorothiazide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- **This medicine has been prescribed for you only**. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Atacand plus is and what it is used for

Subject to prescription by a doctor.

Atacand plus contains candesartan cilexetil and hydrochlorothiazide as active substances and is used to treat high blood pressure (hypertension). Candesartan cilexetil specifically blocks the body's own binding sites (known as angiotensin II receptors). This widens the blood vessels and thus lowers blood pressure.

Hydrochlorothiazide belongs to a group known as diuretics (water tablets). It promotes the excretion of sodium, chloride and water through the kidneys, thereby lowering blood pressure.

Atacand plus must be taken with constant monitoring by a doctor.

2. What you need to know before you take Atacand plus

Do not take Atacand plus:

- If you have a known hypersensitivity to the active substances' candesartan cilexetil, hydrochlorothiazide or any of the other ingredients.
- If you have severe liver and kidney disease, poor urine output, symptoms of low blood potassium and sodium, calcium disorders, gout or biliary obstruction.

- If you are pregnant or breast-feeding.
- If you have diabetes mellitus (type 1 or type 2) or impaired kidney function and are taking medicines containing aliskiren for high blood pressure (e.g. Rasilez®).
- If you have ever experienced swelling of the face, lips, tongue or throat (difficulty in swallowing or breathing) when taking any medicine for high blood pressure.

Warning and precautions

- It is particularly important that you tell your doctor if you have kidney or liver disease, or if you need to take certain anticoagulants (blood thinners) at the same time. You should also take special care if you have a salt imbalance (potassium) or heart valve disease.
- Atacand plus contains lactose (milk sugar). Please only take Atacand plus after consulting your doctor if you know that you are suffering from sugar intolerance.
- In patients with diabetes, the dose of their medications will need to be readjusted. Gout attacks may be triggered in patients prone to gout.
- If you have ever had skin cancer or if you notice any unexpected skin changes during treatment. Treatment with hydrochlorothiazide (one of the active substances in Atacand plus), especially over longer periods of time and at higher doses, may lead to an increased risk of certain types of skin and lip cancer (non-melanocytic, "white" skin cancer). Protect your skin from sunlight and UV rays while using Atacand plus and check your skin regularly, so that you can show any unexpected changes to your doctor.
- Furthermore, you should tell your doctor if, in addition to Atacand plus, you are taking other medicines for high blood pressure, medicines that can increase blood potassium levels (e.g. certain water tablets such as potassium-sparing diuretics, potassium preparations or heparin), lithium preparations or if you are regularly taking painkillers for rheumatic complaints (non-steroidal anti-inflammatory drugs or COX2 inhibitors) or acetylsalicylic acid (the active substance of aspirin and other painkillers). Atacand plus is not recommended for use in combination with medicines containing aliskiren as an active substance.
- Tell your doctor or dentist before any surgery that you are taking Atacand plus. If this medicine is used at the same time as certain anaesthetics, an excessive drop in blood pressure may occur.
- As with other medicines for high blood pressure, dizziness and tiredness may also occasionally occur with Atacand plus.
- If you notice loss of vision or eye pain, this may be due to a build-up of fluid in the vascular bed of the eye (choroidal effusion) or an increase in pressure within the eye. This can occur within hours to weeks after taking Atacand plus and can lead to permanent loss of vision if treatment is not started in good time. If you have an allergy to penicillin or sulphonamide, the risk of experiencing choroidal effusion may be increased.
- Please talk to your doctor or pharmacist before taking Atacand plus if you have ever had breathing or lung problems (including inflammation or fluid accumulation in the lungs) after taking hydrochlorothiazide. If you develop severe shortness of breath or difficulty breathing after taking Atacand plus, consult a doctor immediately.
- Tell your doctor or pharmacist if you
    - suffer from other illnesses,
    - have any allergies or

- are taking or applying externally any other medicines (including those you have bought yourself!).

Pregnancy and breast-feeding

- If you are pregnant, planning a pregnancy or breast-feeding your child, you must not take Atacand plus. Similar medicines are known to cause potential harm to the foetus when used during pregnancy. If you become pregnant while taking Atacand plus, tell your doctor immediately, so that a decision can be made about stopping the product.

Driving and using machines

This medicine may affect reaction times or the ability to drive and use tools or machines.

3. How to take Atacand plus

The doctor will determine the right dosage for you based on regular checks on your blood pressure. It is very important that you take Atacand plus every day as prescribed by your doctor.

Usually, the dosage of Atacand plus is one 16/12,5 mg tablet daily. Atacand plus can be taken with or without food. It is best to always take your tablet at the same time of day, e.g. in the morning.

If you have taken more than the prescribed dose, contact your doctor or pharmacist immediately.

If you have forgotten to take a tablet, make up for it as soon as you remember. However, if it is nearly time to take your next tablet, skip the missed tablet.

The use and safety of Atacand plus in children and adolescents have not been investigated to date.

Do not deviate from the prescribed dosage. If you believe that the effect of the medicine is too weak or too strong, talk to your doctor or pharmacist.

4. Possible side effects of Atacand plus

The following side effects may occur when taking Atacand plus:

Common (may affect 1 to 10 in 100 people)

- Dizziness, respiratory infections, metabolic disorders (e.g. increased blood sugar levels) or salt imbalances, light-headedness, headache, back pain and weakness have been observed.

Uncommon (may affect 1 to 10 in 1000 people)

- Low blood pressure, loss of appetite, nausea, vomiting, abdominal pain, diarrhoea, constipation, rash, nettle rash and increased sensitivity of the skin to light may occur.

Rare (may affect 1 to 10 in 10'000 people)

- Rarely, there have been reports of changes in the blood count, hypersensitivity reactions, worsening diabetes, sleeping disorders, dizziness, depression, restlessness, tingling in the hands and feet, transient visual disturbances, heart rhythm disorders, respiratory problems, cough,

jaundice, muscle cramps, kidney disorders, fever and lupus erythematosus (an autoimmune disease involving the skin or organs).

Very rare (may affect less than 1 in 10'000 people)

- Very rarely, liver disorders (e.g. hepatitis), itching, joint pain and muscle pain have occurred. Very rarely, swelling of the skin (especially of the face, lips, tongue, eyes) and/or mucous membranes (angioedema), itching or hives, acute short-sightedness or acute narrow angle glaucoma may occur. In this case, you must stop taking Atacand plus immediately and consult your doctor.
- Acute respiratory distress (signs include severe shortness of breath, fever, weakness and confusion).
- In addition, skin and lip cancer (non-melanocytic, "white" skin cancer) has been reported to occur. For this reason, you should immediately show any unexpected skin changes that you observe during treatment with Atacand plus to your doctor.

Other possible side effects are: palpitations, chest pain, angina (symptoms such as pain in the chest and/or shoulder-arm area, shortness of breath), heart attack, nosebleeds, anxiety and shortness of breath.

These side effects are not necessarily caused by Atacand plus, as they have also been found in patients who have not taken this medicine.

If you get any side effects, talk to your doctor or pharmacist. This particularly includes any possible side effects not listed in this leaflet.

5. How to store Atacand plus

- Do not store above 30 °C.
- Keep out of the reach of children.
- Do not use this medicine after the expiry date ("EXP") stated on the container.
- If you have any out-of-date medicines, please return them to the point where they were dispensed for proper disposal.
- Your doctor or pharmacist can give you more information. These individuals possess the comprehensive Information for healthcare professionals.

6. Contents of the pack and other information

What Atacand plus contains

- The active substances are candesartan cilexetil and hydrochlorothiazide. Each tablet (with score line) contains 16 mg candesartan cilexetil and 12,5 mg hydrochlorothiazide.
- The other ingredients are: Carboxymethylcellulose calcium (E466), hydroxypropyl cellulose (E463), lactose monohydrate (68,0 mg in 16/12,5 mg tablets), magnesium stearate (E572), maize starch, polyethylene glycol (macrogol) 8000 (E1521), Yellow iron oxide (E172), ferric oxide, pigment red (E172).

What Atacand plus looks like and contents of the pack

A peach, oval, biconvex tablet, with a score and engraved $\frac{A}{CS}$ on one side and a score on the other side.

Atacand plus 16/12,5 mg comes in packs of 28, 30 and 98 tablets (with score line). Not all pack sizes may be marketed.

Marketing Authorisation Holder

AstraZeneca AG, Neuhofstrasse 34, 6340 Baar, Switzerland

Manufacturer

AstraZeneca AB, Gärtunavägen, SE-151 85, Södertälje, Sweden.

This package leaflet was last revised in March 2022.