

ATACAND PLUS[®] TABLET

Candesartan cilexetil 16mg
Hydrochlorothiazide 12.5mg

Consumer Medication Information Leaflet (RiMUP)

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What Atacand Plus is used for

Atacand Plus is used for treating hypertension (high blood pressure), where a monotherapy is not sufficiently effective.

How Atacand Plus works

Candesartan cilexetil is a type of medicine called an angiotensin II receptor antagonist, which by blocking the effects of the hormone angiotensin II, causes relaxation of the blood vessels and results in a lowering of the blood pressure.

Hydrochlorothiazide belongs to a class of drugs called diuretics. Its effects promote the urinary excretion of sodium, chloride and water and results in a lowering of the blood pressure.

Before you use Atacand Plus

Do not take Atacand Plus if you are pregnant, think you might be pregnant or considering becoming pregnant. Atacand Plus may cause serious harm or even death to your baby if used during pregnancy (see Pregnancy section).

When you must not use it

- If you are breast feeding.
- If you are allergic to any of the ingredients in Atacand Plus or to drugs closely related to hydrochlorothiazide.
- If you have severe liver disease.

- If you have severe kidney disease.
- If you have had gout.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure medicine containing aliskiren.

Important: You should not take Atacand Plus if you have had problems in the past when taking medicines containing candesartan cilexetil or hydrochlorothiazide.

Atacand Plus is not recommended for children.

Before you start to use it

Please talk to your doctor or pharmacist before taking this medicine:

- If you are taking other medicines to help lower your blood pressure, particularly:
 - an ACE-inhibitor (for example, enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
 - aliskiren
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Atacand Plus, seek medical attention immediately.
- If you are taking any other medicines including those you have bought without a prescription.
- If you have any heart, liver or kidney problems.
- If you suffer from lactose intolerance.
- If you are taking digitalis glycosides, antiarrhythmics, non-steroidal anti-inflammatory drugs (NSAIDs), colestipol, cholestyramine, lithium, other kaliuretic diuretics, laxatives, amphotericin, carbenoxolone, salicylic acid derivatives, potassium-sparing diuretics,

potassium supplements, salt substitutes containing potassium, or other drugs that may increase potassium levels.

- If you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Atacand Plus. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- If you are diabetic.

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

Inform your healthcare providers before taking Atacand Plus if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Atacand Plus.

See also information under the heading “When you must not use it”.

Taking other medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed. Your doctor may need to change your dose and/or to take other precautions if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “When you must not use it” and “Before you start to use it”).

How to use Atacand Plus

How much to use

The dose is one tablet each day.

When to use it

It is best to take your tablet at the same time each day, e.g. in the morning.

How long to use it

Take Atacand Plus as directed by your healthcare provider. Do not stop taking your dose without talking to your healthcare provider.

If you forget to use it

If you forget to take a dose, just carry on with the next dose as normal. Do not take an extra tablet to make up.

If you use too much (overdose)

If you take more than the recommended number of tablets, contact a doctor or pharmacist (chemist) as soon as possible.

While you are using it

Things you must do

It is important to keep taking Atacand Plus every day and as your doctor has told you to. The instructions on the label should remind you of what the doctor has said.

If you have the impression that the effect of Atacand Plus is too strong or too weak, talk to your doctor or pharmacist.

Things you must not do

Do not stop taking your dose without talking to your healthcare provider.

Pregnancy

You must not take Atacand Plus if you are pregnant, might be pregnant, or are considering becoming pregnant. You must tell your doctor if you think you are (or might become) pregnant. Your doctor will ask you to stop taking Atacand Plus before you become pregnant or as soon as you know you are pregnant and may recommend another medicine instead of Atacand Plus. Atacand

Plus may cause serious harm or even death to your baby if used during pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Atacand Plus must not be used by mothers who are breast-feeding.

Things to be careful of

Taking Atacand Plus with food and drink

It does not matter whether you take your tablet with or without food.

Anaesthesia and surgery

If you are going to have an operation, tell your doctor or dentist that you are taking Atacand Plus. Atacand Plus, combined with some anaesthetics, may cause a drop in blood pressure.

Driving and using machines

The treatment of high blood pressure may lead to dizziness or weariness in some patients. Make sure you are not affected in this way before driving or operating machines.

Side effects

Most people taking Atacand Plus do not suffer any unwanted effects. Like all medicines, some people taking Atacand Plus may occasionally experience unwanted effects which are usually mild and do not last for long.

Unwanted effects reported very rarely are swelling of the face, lips, tongue and/or throat, back pain, rash, hives, itching, unusual skin reactions, easy bruising, or extreme fatigue, jaundice (yellow skin and/or eyes) or increased liver tests. If you suffer from any of these effects, or if you get any other unusual or unexpected symptoms, talk to your doctor or pharmacist (chemist). If you develop swelling of the face, lips, tongue and/or throat or jaundice, or if you get unusual skin reactions, easy bruising or feel extreme fatigue, contact your doctor immediately.

Very rarely, dizziness, cough and worsening of the kidney function (especially in patients with existing kidney problems or heart failure) have been reported. Changes in your potassium, sodium and red or white blood cell levels may occur very rarely. Such changes are usually detected by a blood test. In some patients, lupus conditions may be activated or made worse by hydrochlorothiazide, one of the medicines in this drug.

Rarely, acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion) has been reported.

Frequency 'not known':

- Skin and lip cancer (Non-melanoma skin cancer).
- Choroidal effusion: an abnormal building of liquid in your eye that may result in vision changes;
- Acute myopia: sudden nearsightedness or blurred vision;
- Acute angle-closure glaucoma: a rapid increased pressure in your eyes, eye pain. If left untreated, it may lead to permanent vision loss.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.moh.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or vaccines (AEFI)].

Storage and Disposal of Atacand Plus

Storage

Do not take your tablets after the expiry date shown on the blister strip and carton.

- Keep your medicine in a safe place where children cannot reach it.
- Keep your medicine below 30°C.
- Remember to return any unused medicine to your pharmacist.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to

dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

The tablets are peach, oval, biconvex tablets with a score on both sides and marked A/CS.

Atacand Plus tablets 16/12.5 mg will come in a blister pack of 30 tablets in strips of 10 tablets.

Ingredients

Active ingredient(s)

Atacand Plus tablets contain 16 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.

Inactive ingredients

The other ingredients are carmellose calcium, hydroxypropyl cellulose, lactose, magnesium stearate, maize starch, polyethylene glycol, iron oxide yellow (E172) and iron oxide red (E172).

MAL number:

MAL20021128ACRZ

Manufacturer

Klocke Pharma-Service GmbH
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Product Registration Holder

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