

Package leaflet: Information for the User

Atacand 8 mg Tablet

Atacand 16 mg Tablet

candesartan cilexetil

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 is and what it is used for
2. What you need to know before you take Atacand
3. How to take Atacand
4. Possible side effects
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1. What Atacand is and what it is used for

Atacand contains candesartan cilexetil as an active substance and is used to treat high blood pressure (hypertension) in adults, children and adolescents aged 1 - 17 years, as well as heart failure (weak heart) in adults. Atacand specifically blocks the body's own binding sites (known as angiotensin II receptors). This widens the blood vessels and thus lowers blood pressure and improves the heart's performance. Your doctor may use Atacand to improve your heart's performance in combination with other medicines or to replace medicines that are not suitable due to certain undesirable effects.

Atacand must only be used on prescription by a doctor.

2. What you need to know before you take Atacand

Do not take Atacand

Atacand must not be taken in cases of known hypersensitivity to the active substance candesartan cilexetil or any of the other ingredients, in patients with severe liver disease and/or biliary obstruction or during pregnancy and breast-feeding. Atacand must not be taken by children under 1 year old.

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[®]), you must not take Atacand.

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, you must not take Atacand.

Be careful when taking Atacand

This medicine may affect your ability to react, drive and use tools or machines. 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 heart valve disease.

Furthermore, you should tell your doctor if, in addition to Atacand, 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 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. If this medicine is used at the same time as certain anaesthetics, a drop in blood pressure may occur.

Tell your doctor or pharmacist if you

- suffer from other illnesses,

- have any allergies or
- are taking/using medicines (including those for external use or bought with a prescription).

Atacand contains lactose. If you have been told that you have a sugar intolerance, do not take Atacand without first consulting your doctor.

Can Atacand be taken during pregnancy or breast-feeding?

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

3. How to take Atacand

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

Atacand can be taken with or without food. It is best to always take the tablets at the same time of day, e.g. in the morning.

High blood pressure in adults

For treatment of high blood pressure, the recommended dosage is 8 mg once daily. If needed, your doctor may increase the dose to 16 mg once daily. If your blood pressure cannot be lowered sufficiently after 4 weeks of treatment with 16 mg once daily, the dose can be further increased to a maximum of 32 mg once daily.

High blood pressure in children and adolescents aged 1 - 17 years

The doctor will determine the exact dosage.

For children unable to swallow tablets, there is a possibility of suspending Atacand tablets. Your doctor may issue you with a prescription for the specially reconstituted suspension.

Heart failure in adults

For treatment of heart failure, the usual starting dosage is 4 mg Atacand once daily. Subsequently, the dosage is slowly increased over a period of several

weeks to a maximum of 32 mg once daily. It is important that you follow your doctor's prescription exactly.

Its effectiveness in children and adolescents with heart failure has not been studied. For this reason, Atacand must not be taken by children and adolescents with heart failure.

In elderly patients or patients with mild to moderately impaired kidney or liver function, no dose adjustment is necessary. If you suffer from severe kidney disease, your doctor may prescribe you a lower starting dosage.

There is no experience with the use of Atacand in children under 1 year old.

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.

Do not change the prescribed dosage on your own. If you feel that the effect of this medicine is too weak or too strong, talk to your doctor or pharmacist.

4. Possible side effects of Atacand

The following side effects may occur when taking Atacand:

Common: There have been reports of respiratory infections, light-headedness and dizziness, headache, back pain and low blood pressure (often in heart failure patients). Very rarely, swelling of the skin (especially of the face, lips, tongue, eyes) and/or mucous membranes (angioedema), itching or hives may occur. In this case, you must stop taking Atacand immediately and consult a doctor. Very rarely, there have also been reports of dizziness, cough, nausea, liver disease (e.g. hepatitis), rash, hives, itching, impaired kidney function or joint and muscle pain.

Other possible side effects are: fever, faster pulse, palpitations, chest pain, angina (symptoms such as pain in the chest and/or shoulder-arm area, shortness of breath), heart attack, tingling in the hands and feet, nosebleeds, anxiety, depression, shortness of breath and tissue fluid accumulation.

These side effects are not necessarily caused by Atacand, 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

Shelf life - 36 MONTHS

Do not use this medicine after the date stated on the container after “EXP”. If you have any out-of-date medicines, please return them to your pharmacy for disposal.

Storage instructions

Do not store above 30 °C and keep out of the reach of children.

Further information can be obtained from your doctor or pharmacist. These persons have the full prescribing information at their disposal.

6. Contents of the pack and other information

What Atacand contains

Active substances

Atacand 8 mg tablets contain 8 mg candesartan cilexetil

Atacand 16 mg tablets contain 16 mg candesartan cilexetil

Excipients

Atacand 8 mg, tablets:

Calcium carboxymethylcellulose, hydroxypropyl cellulose, iron oxide E 172, lactose monohydrate, magnesium stearate, maize starch and Polyethylene glycol 8000.

Atacand 16 mg, tablets:

Calcium carboxymethylcellulose, hydroxypropyl cellulose, iron oxide E 172, lactose monohydrate, magnesium stearate, maize starch and Polyethylene glycol 8000.

What Atacand looks like and contents of the pack

Atacand can be obtained at pharmacies on medical prescription only.

Atacand 8 mg (diameter: approx. 7mm): A light pink, circular, biconvex tablet with a score and engraved A/CG on one side and 008 on the other side.

Atacand 16 mg (diameter: approx. 7mm): A pink, circular, biconvex tablet with a score and engraved A/CH on one side and 016 on the other side.

The following packs are available:

28, 30 and 98 tablets Atacand 8 mg. Not all pack sizes may be marketed

28, 30 and 98 tablets Atacand 16 mg. Not all pack sizes may be marketed

Marketing Authorisation Holder

AstraZeneca AG, Neuhofstrasse 34, 6340 Baar, Switzerland

Manufacturer

AstraZeneca AB, Gärtunavägen, SE-151 57, Södertälje, Sweden.

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