

Package leaflet: Information for the patient

Atacand® 16mg tablets

(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.
- 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. This includes any possible side effects not listed in this leaflet.

The name of your medicine is Atacand 16mg tablets but will be referred to as Atacand throughout this leaflet. Please note that this leaflet also contains information about the other strengths such as Atacand 4mg and 8mg tablets.

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
5. How to store Atacand
6. Contents of the pack and other information

1. What Atacand is and what it is used for

The name of your medicine is Atacand. The active ingredient is candesartan cilexetil. This belongs to a group of medicines called angiotensin II receptor antagonists. It works by making your blood vessels relax and widen. This helps to lower your blood pressure. It also makes it easier for your heart to pump blood to all parts of your body.

Atacand can be used to:

- treat high blood pressure (hypertension) in adult patients and in children and adolescents aged 6 to <18 years.
- treat adult heart failure patients with reduced heart muscle function when Angiotensin Converting Enzyme (ACE) inhibitors cannot be used or in addition to ACE-inhibitors when symptoms persist despite treatment and mineralocorticoid receptor antagonists (MRA) cannot be used (ACE-inhibitors and MRAs are medicines used to treat heart failure).

2. What you need to know before you take Atacand

Do not take Atacand:

- if you are allergic (hypersensitive) to candesartan cilexetil or any of the other ingredients of this medicine (listed section 6).
- if you are more than 3 months pregnant (it is also better to avoid Atacand in early pregnancy – see 'Pregnancy' section.)
- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if the patient is a child under 1 year of age.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Atacand.

Warnings and precautions

Talk to your doctor before taking Atacand.

- if you have heart, liver or kidney problems, or are on dialysis.
- if you have recently had a kidney transplant.
- if you are vomiting, have recently had severe vomiting, or have diarrhoea.
- if you have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- if you have low blood pressure.
- if you have ever had a stroke.
- you must tell your doctor if you think you are (or might become) pregnant. Atacand is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see 'Pregnancy' section).
- if 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.

- if you are taking an ACE-inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptor antagonists (MRA). These medicines are for the treatment of heart failure (see 'Other medicines and Atacand').

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

See also information under the heading 'Do not take Atacand'.

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

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

Children and adolescents

Atacand has been studied in children. For more information, talk to your doctor. Atacand must not be given to children under 1 year of age due to the potential risk to the developing kidneys.

Other medicines and Atacand

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Atacand can affect the way some other medicines work and some medicines can have an effect on Atacand. If you are using certain medicines, your doctor may need to do blood tests from time to time.

In particular, tell your doctor if you are using any of the following medicines as your doctor may need to change your dose and/or take other precautions:

- Other medicines to help lower your blood pressure, including beta-blockers, diazoxide and ACE-inhibitors such as enalapril, captopril, lisinopril or ramipril.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3g each day) (medicine to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Heparin (a medicine for thinning the blood).
- Water tablets (diuretics).
- Lithium (a medicine for mental health problems).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take Atacand' and 'Warnings and precautions').
- If you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example: spironolactone, eplerenone).

Atacand with food and drink and alcohol

You can take Atacand with or without food.

- When you are prescribed Atacand, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Atacand before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Atacand. Atacand is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Atacand is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Some people may feel tired or dizzy when taking Atacand. If this happens to you, do not drive or use any tools or machines.

Atacand contains lactose. Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Atacand

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important to keep taking Atacand every day. You can take Atacand with or without food. Swallow the tablet with a drink of water. Try to take the tablet at the same time each day. This will help you to remember to take it.

High blood pressure:

- The recommended dose of Atacand is 8mg once a day. Your doctor may increase this dose to 16mg once a day and further up to 32mg once a day depending on blood pressure response.
- In some patients, such as those with liver problems, kidney problems or those who recently have lost body fluids, e.g. through vomiting or diarrhoea or by using water tablets, the doctor may prescribe a lower starting dose.
- Some black patients may have a reduced response to this type of medicine, when given as the only treatment, and these patients may need a higher dose.

Use in children and adolescents with high blood pressure:

Children 6 to <18 years of age:

The recommended starting dose is 4mg once daily.

For patients weighing < 50kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to a maximum of 8mg once daily.

For patients weighing ≥ 50kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to 8mg once daily and to 16mg once daily.

Heart failure in adults:

- The recommended starting dose of Atacand is 4mg once a day. Your doctor may increase your dose by doubling the dose at intervals of at least 2 weeks up to 32mg once a day. Atacand can be taken together with other medicines for heart failure, and your doctor will decide which treatment is suitable for you.

If you take more Atacand than you should

If you take more Atacand than prescribed by your doctor, contact a doctor or pharmacist immediately for advice.

If you forget to take Atacand

Do not take a double dose to make up for a forgotten tablet. Just take the next dose as normal.

If you stop taking Atacand

If you stop taking Atacand, your blood pressure may increase again. Therefore do not stop taking Atacand without first talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

Stop taking Atacand and seek medical help immediately if you have any of the following allergic reactions:

- difficulties in 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 difficulties in swallowing.
- severe itching of the skin (with raised lumps).

Atacand may cause a reduction in the number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Atacand has had any effect on your blood (agranulocytosis).

Other possible side effects include:

Common (affects 1 to 10 users in 100)

- Feeling dizzy/spinning sensation.
- Headache.
- Respiratory infection.

- Low blood pressure. This may make you feel faint or dizzy.
- Changes in blood test results:
 - An increased amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe you may notice tiredness, weakness, irregular heart beat or pins and needles.
- Effects on how your kidneys work, especially if you already have kidney problems or heart failure. In very rare cases, kidney failure may occur.

Very rare (affects less than 1 user in 10,000)

- Swelling of the face, lips, tongue and/or throat.
- A reduction in your red or white blood cells. You may notice tiredness, an infection or a fever.
- Skin rash, lumpy rash (hives).
- Itching.
- Back pain, pain in joints and muscles.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu-like symptoms.
- Nausea.
- Changes in blood test results:
 - A reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps.
- Cough.

In children treated for high blood pressure, side effects appear to be similar to those seen in adults, but they happen more often. Sore throat is a very common side effect in children but not reported in adults and runny nose, fever and increased heart rate are common in children but not reported in adults.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.hpra.ie e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atacand

Keep out of the sight and reach of children.

Do not store above 30°C.

Do not use after the expiry date which is stated on the carton and blister label after 'Exp'. The expiry date refers to the last day of that month.

Return any unused medicine to your pharmacist for safe 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.

If your tablets become discoloured or show any other signs of deterioration seek the advice of your pharmacist.

6. Contents of the pack and other information

What Atacand contains

- The active ingredient is candesartan cilexetil. The tablets contain 16mg candesartan cilexetil.
- The other ingredients are carmellose calcium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, maize starch, macrogol, and iron oxide (E172).

What Atacand looks like and contents of the pack

Atacand 16mg are available as pink, round tablets with one convex side embossed '16' and one flat side with a score-line. They are available in blister packs of 28 tablets. The name of this product in the UK is AMIAS.

Manufactured by:

Takeda Italia Farmaceutici S.p.A., Via Crosa 86, 28065 Cerano (No), Italy or Takeda Ireland Ltd., Bray Business Park, Kilruddery, Co. Wicklow, Ireland.

Procured from within the EU and repackaged by PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Atacand 16mg tablets; PPA No: 1328/18/3

Leaflet date: 13.02.2015

Atacand is a trademark of the AstraZeneca group of companies.

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1. What Atacand is and what it is used for

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- treat adult heart failure patients with reduced heart muscle function when Angiotensin Converting Enzyme (ACE) inhibitors cannot be used or in addition to ACE-inhibitors when symptoms persist despite treatment and mineralocorticoid receptor antagonists (MRA) cannot be used (ACE-inhibitors and MRAs are medicines used to treat heart failure).

2. What you need to know before you take Atacand

Do not take Atacand

- If you are allergic (hypersensitive) to candesartan cilexetil or any of the other ingredients of this medicine (listed section 6).
- If you are more than 3 months pregnant (it is also better to avoid Atacand in early pregnancy – see 'Pregnancy' section.)
- If you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if the patient is a child under 1 year of age.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Atacand.

Warnings and precautions

Talk to your doctor before taking Atacand.

- if you have heart, liver or kidney problems, or are on dialysis.
- if you have recently had a kidney transplant.
- if you are vomiting, have recently had severe vomiting, or have diarrhoea.
- if you have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- if you have low blood pressure.
- if you have ever had a stroke.
- you must tell your doctor if you think you are (or might become) pregnant. Atacand is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see 'Pregnancy' section).
- if 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.

- if you are taking an ACE-inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptor antagonists (MRA). These medicines are for the treatment of heart failure (see 'Other medicines and Atacand').

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

See also information under the heading 'Do not take Atacand'.

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

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

Children and adolescents

Atacand has been studied in children. For more information, talk to your doctor. Atacand must not be given to children under 1 year of age due to the potential risk to the developing kidneys.

Other medicines and Atacand

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Atacand can affect the way some other medicines work and some medicines can have an effect on Atacand. If you are using certain medicines, your doctor may need to do blood tests from time to time.

In particular, tell your doctor if you are using any of the following medicines as your doctor may need to change your dose and/or take other precautions:

- Other medicines to help lower your blood pressure, including beta-blockers, diazoxide and ACE inhibitors such as enalapril, captopril, lisinopril or ramipril.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3g each day) (medicine to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Heparin (a medicine for thinning the blood).
- Water tablets (diuretics).
- Lithium (a medicine for mental health problems).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take Atacand' and 'Warnings and precautions').
- If you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example: spironolactone, eplerenone).

Taking Atacand with food and drink and alcohol

- You can take Atacand with or without food.
- When you are prescribed Atacand, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Atacand before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Atacand. Atacand is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Atacand is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Driving and using machines

Some people may feel tired or dizzy when taking Atacand. If this happens to you, do not drive or use any tools or machines.

Atacand contains lactose. Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Atacand

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important to keep taking Atacand every day. You can take Atacand with or without food. Swallow the tablet with a drink of water.

Try to take the tablet at the same time each day. This will help you to remember to take it.

High blood pressure:

- The recommended dose of Atacand is 8mg once a day. Your doctor may increase this dose to 16mg once a day and further up to 32mg once a day depending on blood pressure response.
- In some patients, such as those with liver problems, kidney problems or those who recently have lost body fluids, e.g. through vomiting or diarrhoea or by using water tablets, the doctor may prescribe a lower starting dose.
- Some black patients may have a reduced response to this type of medicine, when given as the only treatment, and these patients may need a higher dose.

Use in children and adolescents with high blood pressure:

Children 6 to <18 years of age:

The recommended starting dose is 4mg once daily.

For patients weighing < 50kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to a maximum of 8mg once daily.

For patients weighing ≥ 50kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to 8mg once daily and to 16mg once daily.

Heart failure in adults:

- The recommended starting dose of Atacand is 4mg once a day. Your doctor may increase your dose by doubling the dose at intervals of at least 2 weeks up to 32mg once a day. Atacand can be taken together with other medicines for heart failure, and your doctor will decide which treatment is suitable for you.

If you take more Atacand than you should

If you take more Atacand than prescribed by your doctor, contact a doctor or pharmacist immediately for advice.

If you forget to take Atacand

Do not take a double dose to make up for a forgotten tablet. Just take the next dose as normal.

If you stop taking Atacand

If you stop taking Atacand, your blood pressure may increase again. Therefore do not stop taking Atacand without first talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. It is important that you are aware of what these side effects may be.

Stop taking Atacand and seek medical help immediately if you have any of the following allergic reactions:

- difficulties in 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 difficulties in swallowing.
- severe itching of the skin (with raised lumps).

Atacand may cause a reduction in the number of white blood cells. Your resistance to infection may be decreased and you may notice tiredness, an infection or a fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Atacand has had any effect on your blood (agranulocytosis).

Other possible side effects include:

Common (affects 1 to 10 users in 100)

- Feeling dizzy/spinning sensation.
- Headache.

- Respiratory infection.
- Low blood pressure. This may make you feel faint or dizzy.
- Changes in blood test results:
 - An increased amount of potassium in your blood, especially if you already have kidney problems or heart failure. If this is severe you may notice tiredness, weakness, irregular heart beat or pins and needles.
- Effects on how your kidneys work, especially if you already have kidney problems or heart failure. In very rare cases, kidney failure may occur.

Very rare (affects less than 1 user in 10,000)

- Swelling of the face, lips, tongue and/or throat.
- A reduction in your red or white blood cells. You may notice tiredness, an infection or a fever.
- Skin rash, lumpy rash (hives).
- Itching.
- Back pain, pain in joints and muscles.
- Changes in how your liver is working, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes and flu like symptoms.
- Nausea.
- Changes in blood test results:
 - A reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy, or muscle cramps.
- Cough.

In children treated for high blood pressure, side effects appear to be similar to those seen in adults, but they happen more often. Sore throat is a very common side effect in children but not reported in adults and runny nose, fever and increased heart rate are common in children but not reported in adults.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie e-mail: medsafety@hpra.ie By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atacand

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

Do not take your tablets after the expiry date shown on the blister strip and carton label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 30°C.

Return any unused medicine to your pharmacist for safe disposal.

If there is a change in appearance or colour of the tablets or any other signs of deterioration, seek the advice of a pharmacist.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Atacand contains

- Each tablet contains 16mg of candesartan cilexetil as the active ingredient.
- Each tablet also contains carmellose calcium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, maize starch, macrogol and iron oxide (E172).

What Atacand looks like and contents of the pack

Atacand 16mg are available as pink and round with a score-line and markings 'A/CH' on one side and '016' on the other. Atacand 16mg are available in PVC/PVDC blister packs of 14 and 28 tablets.

Manufactured by: AstraZeneca AB, Sweden.

Procured from within the EU and repackaged by PPA

holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Atacand 16mg tablets; PPA No: 1328/18/3

Leaflet date: 13.02.2015

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