

Amias 2 mg, 4 mg, 8 mg, 16 mg and 32 mg tablets

candesartan cilexetil

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Amias is and what it is used for
2. Before you take Amias
3. How to take Amias
4. Possible side effects
5. How to store Amias
6. Further information

1. WHAT AMIAS IS AND WHAT IT IS USED FOR

The name of your medicine is Amias. 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.

This medicine is used for:

- treating high blood pressure (hypertension) in adult patients.
- treating adult heart failure patients with reduced heart muscle function, in addition to Angiotensin Converting Enzyme (ACE) inhibitors or when ACE inhibitors cannot be used (ACE inhibitors are a group of medicines used to treat heart failure).

2. BEFORE YOU TAKE AMIAS

Do not take Amias

- if you are allergic (hypersensitive) to candesartan cilexetil or any of the other ingredients of Amias (see section 6).
- if you are more than 3 months pregnant (it is also better to avoid Amias 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 you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Amias.

Take special care with Amias

Before you take, or whilst you are taking Amias, tell your doctor.

- 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. Amias 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).

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 Amias. This is because Amias, when combined with some anaesthetics, may cause a drop in blood pressure.

Use in children

There is no experience with the use of Amias in children (below the age of 18 years). Therefore Amias should not be given to children.

Using other medicines

Please tell your doctor or pharmacist if you are using, or have recently used any other medicines, including medicines obtained without a prescription.

Amias can affect the way some other medicines work and some medicines can have an effect on Amias. 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:

- 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 3 g 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).

Taking Amias with food and drink (in particular alcohol)

- You can take Amias with or without food.
- When you are prescribed Amias, 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 Amias before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Amias. Amias 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. Amias 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 Amias. If this happens to you, do not drive or use any tools or machines.

Important information about some of the ingredients of Amias

Amias contains lactose which 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 AMIAS

Always take Amias exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. It is important to keep taking Amias every day. You can take Amias 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 usual dose of Amias is 8 mg once a day. Your doctor may increase this dose to 16 mg once a day and further up to 32 mg 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.

Please turn over →

Heart failure:

- The usual starting dose of Amias is 4 mg once a day. Your doctor may increase your dose by doubling the dose at intervals of at least 2 weeks up to 32 mg once a day. Amias 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 Amias than you should

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

If you forget to take Amias

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

If you stop taking Amias

If you stop taking Amias, your blood pressure may increase again. Therefore do not stop taking Amias 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, Amias 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 Amias 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)

Amias may cause a reduction in 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 Amias 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, an 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.
- Cough.
- 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE AMIAS

- Keep out of the reach and sight of children.
- Do not use Amias after the expiry date which is stated on the carton label and blister foil (after EXP). The expiry date refers to the last day of that month.
- Do not store above 30°C.

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.

6. FURTHER INFORMATION

What Amias contains

- The active substance is candesartan cilexetil. Each tablet contains 2 mg, 4 mg, 8 mg, 16 mg or 32 mg of candesartan cilexetil.
- The other ingredients are carmellose calcium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, maize starch and macrogol. The 8 mg, 16 mg and 32 mg tablets also contain red iron oxide (E172).

What Amias looks like and contents of the pack

- 2 mg tablets are white, round tablets.
- 4 mg tablets are white, round tablets with a score line on each side.
- 8 mg tablets are pale pink, round tablets with a score line on each side.
- 16 mg tablets are light pink, round tablets with one convex side embossed “16” and one flat side with a score line.
- 32 mg tablets are light pink, round tablets with convex faces, debossed “32” on one side and with a score line on the other.

Amias 2 mg tablets come in a blister pack containing 7 or 14 tablets.

Amias 4 mg, 8 mg and 16 mg tablets come in blister packs containing 7, 14, 20, 28, 50, 56, 98, 98x1 (single dose unit) 100 or 300 tablets.

Amias 32 mg tablets come in blister packs of 7, 10, 14, 20, 28, 50, 56, 98, 100 or 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisations for Amias are held by Takeda UK Ltd., Takeda House, Mercury Park, Wycombe Lane, Wooburn Green, High Wycombe, Buckinghamshire, HP10 0HH, United Kingdom

Your tablets are manufactured by Takeda Italia SpA, Via Crosa 86, 28065 Cerano (No), Italy (all strengths) or Takeda Ireland Ltd., Bray Business Park, Kilruddery, Co. Wicklow, Ireland (4mg, 8mg, 16mg 32mg tablets only).

This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name
Austria, Germany, Spain, Ireland, Italy, Portugal, UK	Blopress
France	Kenzen
Spain	Parapres
UK	Amias

This leaflet was last approved in January 2013.

