1. WHAT CANDESARTAN CILEXETIL TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Candesartan cilexetil Tablets. 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 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 CANDESARTAN CILEXETIL TABLETS

Do not take Candesartan cilexetil Tablets
- if you are allergic (hypersensitive) to candesartan cilexetil or any of the other ingredients of Candesartan cilexetil Tablets (see section 6).
- if you are more than 3 months pregnant (it is also better not to use Candesartan cilexetil Tablets in early pregnancy – see pregnancy section).
- if you have severe liver disease or bile duct obstruction (a problem with the drainage of the bile from the gall bladder).
- if you are allergic (hypersensitive) to any of the ingredients of Candesartan cilexetil Tablets
- if you have heart, liver or kidney problems, or are on dialysis.
- if you have recently had a kidney transplant.
- if you are taking more than 3 g each day of Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).
- if you have any of the following medicines:
  - 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).

Take special care with Candesartan cilexetil Tablets
Before you take, or whilst you are taking Candesartan cilexetil Tablets, 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 (a problem with the drainage of the bile from the gall bladder).
- if you have ever had a stroke.
- if you must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Candesartan cilexetil Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Candesartan cilexetil Tablets. Candesartan cilexetil Tablets are 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 at that stage (see pregnancy section).
- if you are breast-feeding or about to start breast-feeding. Your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.
- if you are taking more than 3 g each day of Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Candesartan cilexetil Tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Candesartan cilexetil Tablets. Candesartan cilexetil Tablets are 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 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 Candesartan cilexetil Tablets. This is because Candesartan cilexetil Tablets, when combined with some anaesthetics, may cause a drop in blood pressure.

Use in children
There is no experience with the use of Candesartan cilexetil Tablets in children (below the age of 18 years).

Therefore Candesartan cilexetil Tablets should not be given to children.

3. HOW TO TAKE CANDESARTAN CILEXETIL TABLETS

Always take Candesartan cilexetil Tablets 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 Candesartan cilexetil Tablets every day.

You can take Candesartan cilexetil Tablets 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.
• 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 CANDESARTAN CILEXETIL TABLETS

Keep out of the reach and sight of children.

Do not use Candesartan cilexetil Tablets after the expiry date which is stated on the carton and blister after (EXP). The expiry date refers to the last day of that month.

Candesartan cilexetil 4 mg and 8 mg Tablets:
Do not store above 25°C.

Candesartan cilexetil 16 mg and 32 mg Tablets:
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 Candesartan cilexetil Tablets contain
The active substance is candesartan cilexetil.
Each Candesartan cilexetil 4 mg tablet contains 4 mg candesartan cilexetil.
Each Candesartan cilexetil 8 mg tablet contains 8 mg candesartan cilexetil.
Each Candesartan cilexetil 16 mg tablet contains 16 mg candesartan cilexetil.
Each Candesartan cilexetil 32 mg tablet contains 32 mg candesartan cilexetil.

The other ingredients are docusate sodium, sodium lactulose, lactose monohydrate, magnesium stearate (E572) and iron oxide red (E172) (16 mg and 32 mg tablets only).

What Candesartan cilexetil Tablets look like and contents of the pack
Candesartan cilexetil 4 mg Tablets are supplied in the following pack sizes:
Blister packages with 7, 14, 28, 30, 50, 56, 70, 84, 90, 98, 100 and 250 white, round biconvex tablets, marked CC on one face and 04 on the other face and scored on both faces.

Candesartan cilexetil 8 mg Tablets are supplied in the following pack sizes:
Blister packages with 7, 14, 28, 30, 50, 56, 70, 84, 90, 98, 100 and 250 white, round biconvex tablets, marked CC on one face and 08 on the other face and are scored on both faces.

Candesartan cilexetil 16 mg Tablets are supplied in the following pack sizes:
Blister packages with 7, 14, 28, 30, 50, 56, 70, 84, 90, 98, 100 and 250 light red, round biconvex tablets, marked CC on one face and 16 on the other face and are scored on both faces.

Candesartan cilexetil 32 mg Tablets are supplied in the following pack sizes:
Blister packages with 7, 14, 28, 30, 50, 56, 70, 84, 90, 98, 100 and 250 light red, elliptic biconvex tablets, marked CC and 32 on the same face and are scored on both faces.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Arrow Generics Limited, Unit 2, Eastman Way, Stevenage, Hertfordshire, SG1 4SZ, United Kingdom

Manufacturer
Juta Pharma GmbH, Gutenbergstrasse 13, 24941, Flensburg, Germany

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High blood pressure:

• The usual dose of Candesartan cilexetil Tablets 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 have recently lost body fluids, e.g., through vomiting or diarrhoea or by using water tablets, your 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.

Heart failure:

• The usual starting dose of Candesartan cilexetil Tablets 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. Candesartan cilexetil Tablets 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 Candesartan cilexetil Tablets than you should

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

If you forget to take Candesartan cilexetil Tablets
Do not take a double dose to make up for a forgotten tablet. Just take the next dose as normal.

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

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