



## PACKAGE LEAFLET: INFORMATION FOR THE USER

# Candesartan cilexetil 4 mg tablets Candesartan cilexetil 8 mg tablets Candesartan cilexetil 16 mg tablets Candesartan cilexetil 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.

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## 1. WHAT CANDESARTAN CILEXETIL IS AND WHAT IT IS USED FOR

The name of your medicine is Candesartan cilexetil. 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 CANDESARTAN CILEXETIL

### Do not take Candesartan cilexetil

- if you are allergic (hypersensitive) to candesartan cilexetil or any of the other ingredients of Candesartan cilexetil (see section 6).
- if you are more than 3 months pregnant. (It is also better to avoid Candesartan cilexetil 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 Candesartan cilexetil.

### Take special care with Candesartan cilexetil

Before you take, or whilst you are taking Candesartan cilexetil, 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 that you are (or might become) pregnant. Candesartan cilexetil 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 Candesartan cilexetil. This is because Candesartan cilexetil, 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 in children (below the age of 18 years). Therefore Candesartan cilexetil should not be given to children.

### Taking other medicines

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

Candesartan cilexetil can affect the way some other medicines work and some medicines can have an effect on Candesartan cilexetil. 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 or 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 Candesartan cilexetil with food and drink

Candesartan cilexetil can be taken with or without food.

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

### Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

#### Pregnancy

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take other medicines instead of Candesartan cilexetil. Candesartan cilexetil 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. Candesartan cilexetil 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 Candesartan cilexetil. If this happens to you, do not drive or use any tools or machines.

#### Important information about some of the ingredients of Candesartan cilexetil

Candesartan cilexetil contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

### 3. HOW TO TAKE CANDESARTAN CILEXETIL

Always take Candesartan cilexetil 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 every day.

You can take Candesartan cilexetil 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 Candesartan cilexetil 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.

#### Heart failure

The usual starting dose of Candesartan cilexetil 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 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 than you should

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

#### If you forget to take Candesartan cilexetil

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

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

Candesartan cilexetil 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 Candesartan cilexetil 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.

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.

### 5. HOW TO STORE CANDESARTAN CILEXETIL

Keep out of the reach and sight of children.

Do not use Candesartan cilexetil after the expiry date which is stated on the packaging.

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 Candesartan cilexetil contains

- The active substance is candesartan cilexetil. Each tablet contains 4 mg, 8 mg, 16 mg or 32 mg candesartan cilexetil.
- The other ingredients are lactose monohydrate, maize starch, dibutyl sebacate, sodium laurilsulfate, hydroxypropylcellulose, carmellose calcium, magnesium stearate and iron oxide red (E172) – (8 mg, 16 mg and 32 mg tablets only)

#### What Candesartan cilexetil looks like and contents of the pack

4 mg tablets are round, white, biconvex, one side scored.

8 mg tablets are round, pinkish-white, biconvex, one side scored.

16 mg tablets are round, slightly pink, biconvex, one side scored.

32 mg tablets are round, slightly pink, biconvex, one side scored.

The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Boxes of 7, 10, 14, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets in blisters are available.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder:

Krka D.D., Šmarješka cesta 6, Novo mesto, SI-8501, Slovenia

#### Manufacturer:

1. Krka D.D., Šmarješka cesta 6, Novo mesto, SI-8501, Slovenia

2. TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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