Package leaflet: Information for the user

Candesartan Krka 4 mg tablets
Candesartan Krka 8 mg tablets
Candesartan Krka 16 mg tablets
Candesartan Krka 32 mg 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Candesartan Krka is and what it is used for

The name of your medicine is Candesartan Krka. 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 and in children and adolescents aged 6 to under 18 years.
- Candesartan Krka can be used to 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 Candesartan Krka

Do not take Candesartan Krka
- if you are allergic to candesartan cilexetil or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant. (It is also better to avoid Candesartan Krka 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 have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Candesartan Krka.

- 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 Krka 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 receptors antagonists (MRA). These medicines are for the treatment of heart failure (see "Other medicines and Candesartan Krka").

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 Candesartan Krka".

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

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

Other medicines and Candesartan Krka
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Candesartan Krka can affect the way some other medicines work and some medicines can have an effect on Candesartan Krka. 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).

Your doctor may need to change your dose and/or to take other precautions:
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Candesartan Krka ” 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 receptors antagonists (MRA) (for example spironolactone, eplerenone).

Candesartan Krka with food and drink and alcohol
Candesartan Krka can be taken with or without food.
When you are prescribed Candesartan Krka, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this 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 Krka before you become pregnant or as soon as you know you are pregnant and will advise you to take other medicines instead of Candesartan Krka. Candesartan Krka 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 Krka 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 Krka. If this happens to you, do not drive or use any tools or machines.

Candesartan Krka contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Candesartan Krka

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important to keep taking Candesartan Krka every day.

You can take Candesartan Krka 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 Candesartan Krka 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.

Use in children and adolescents with high blood pressure
Children 6 to <18 years of age:
The recommended starting dose is 4 mg once daily.
For patients weighing < 50 kg: In some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to a maximum of 8 mg once daily.

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

Heart failure in adults
The recommended starting dose of Candesartan Krka 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 Krka 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 Krka than you should
If you take more Candesartan Krka than prescribed by your doctor, contact a doctor or a pharmacist immediately for advice.

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

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

If you have any further questions on the use of this medicine, 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 Candesartan Krka 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 Krka 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 Krka 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.
- 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.

Not known (frequency cannot be estimated from the available data):
- Diarrhoea.

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 of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
HPRA Pharmacovigilance
Website: www.hpra.ie

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

5. How to store Candesartan Krka

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

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 protect the environment.

6. Contents of the pack and other information

What Candesartan Krka 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)
  See section 2 "Candesartan Krka contains lactose and sodium".

What Candesartan Krka looks like and contents of the pack
Candesartan Krka 4 mg tablets are round, white, biconvex, scored on one side, engraved with mark 4.
Candesartan Krka 8 mg tablets are round, pink, biconvex, scored on one side, engraved with mark 8.
Candesartan Krka 16 mg tablets are round, slightly pink, biconvex, scored on one side. One side of the score line is marked with 1, the other side of the score line is marked with 6.
Candesartan Krka 32 mg tablets are round, slightly pink, biconvex, scored on one side. One side of the score line is marked with 3, the other side of the score line is marked with 2.

The score line 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.
- 250 tablets in a plastic tablet container with a tamper-evident closure (for 4 mg, 8 mg and 16 mg tablets)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Name of the member state	**Name of the medicinal product**
United Kingdom	Candesartan cilexetil
Austria, Belgium, Cyprus, Denmark, Finland, Greece, Ireland, Norway, Portugal, Sweden	Candesartan Krka
Spain	Karbis

This leaflet was last revised in