



TEVA EUROPE

Teva Pharmaceuticals Europe

Module 1.3.1

Patient Information Leaflet Text

Package leaflet: Information for the user

Candesartan Teva 4 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 of the 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 Teva is and what it is used for
2. What you need to know before you take Candesartan Teva
3. How to take Candesartan Teva
4. Possible side effects
5. How to store Candesartan Teva
6. Contents of the pack and other information

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

The name of your medicine is Candesartan Teva. 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 <18 years.
- Treating 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 Teva

Do NOT take Candesartan Teva

- 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 Teva in early pregnancy – see section 2: Pregnancy and breast-feeding).
- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

- 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 Candesartan Teva.

Warnings and precautions

Talk to your doctor or pharmacist before taking Candesartan Teva

- 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. Candesartan Teva 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 section 2: Pregnancy and breast-feeding).
- 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 Teva").

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 Teva.

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

Children and adolescents

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

Other medicines and Candesartan Teva

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Candesartan Teva can affect the way some other medicines work and some medicines can have an effect on Candesartan Teva. 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 and diazoxide.
- 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).

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 Teva” 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 Teva with food, drink and alcohol

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

Candesartan Teva 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 Candesartan Teva

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 Candesartan Teva every day.

You can take Candesartan Teva 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 Teva 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 Teva 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 Teva can be taken together with other medicines for heart failure, and your doctor will decide which treatment is suitable for you.

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 \geq 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.

If you take more Candesartan Teva than you should

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

If you forget to take Candesartan Teva

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 Teva

If you stop taking Candesartan Teva, your blood pressure may increase again. Therefore do not stop taking Candesartan Teva 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 Teva 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 Teva 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 Teva has had an effect on your blood (agranulocytosis).

Other possible side effects include:

Common (may affect up to 1 in 10 people)

- 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 (may affect up to 1 in 10,000 people)

- 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.
- Cough.
- 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.

Additional side effects in children and adolescents

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs 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 Candesartan Teva

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 blister foil and carton after {EXP}. The expiry date refers to the last day of that month.

- Tablets in Al-Al blisters: Do not store above 25°C Store in original packaging to protect from moisture.
- Tablets in Al-Al blisters with desiccant layer: Store in original packaging to protect from moisture.

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 Teva contains

- The active substance is Candesartan cilexetil.
Each Candesartan Teva 4 mg Tablet contains 4 mg of Candesartan cilexetil.
- The other ingredients are pregelatinized maize starch, povidone K-30, carmellose calcium, microcrystalline cellulose (E460), lactose monohydrate, magnesium stearate, L-leucine

What Candesartan Teva looks like and contents of the pack

Candesartan Teva 4 mg Tablet is a white to off white, capsule shaped tablet, scored on both sides. One side of the tablet is debossed with “C | 4” and the other side is debossed with “4 | C”.

Candesartan Teva Tablets are available in OPA/Aluminium/PVC – PVC/PVAC/Aluminium blisters or OPA/Aluminium/PE with desiccant agent/PE –PE/Aluminium blisters in pack sizes of 7, 14, 15, 20, 28, 30, 50, 50 x 1 unit dose blisters (hospital pack), 56, 60, 84, 90, 98, 100, 250 & 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Teva Pharma B.V.
Swensweg 5
2031 GA Haarlem
The Netherlands

Manufacturer

Teva Pharmaceutical Works Private Limited Company
Pallagi út 13,
4042 Debrecen,
Hungary

Teva UK Limited
Brampton Road,
Hampden Park,
Eastbourne,
East Sussex,
BN22 9AG,
United Kingdom

Pharmachemie B.V.

Swensweg 5,
2031 GA Haarlem
The Netherlands

Teva Santé
Rue Bellocier,
89100 Sens
France

Teva Operations Poland Sp. z.o.o.
ul. Mogilska 80,
31-546, Krakow
Poland

Teva Pharma S.L.U.
C/C, n. 4,
Poligono Industrial Malpica,
50016 Zaragoza
Spain

Teva Operations Poland Sp. z.o.o.
ul. Sienkiewicza 25,
99-300 Kutno
Poland

Merckle GmbH
Ludwig-Merckle Strasse 3,
89143 Blaubeuren-Weiler
Germany

Pliva Hrvatska d.o.o.
Prilaz baruna Filipovića 25,
10000 Zagreb
Croatia

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

Belgium Candecilteva 4 mg tabletten
Denmark Candesaratan cilexetil Teva 4 mg
Estonia Cantar 4mg
Finland Candesaratan Teva 4 mg tabletti
France Candesaratan Teva 4 mg comprimé sécable
Germany Candesaratan-ratiopharm 4 mg Tabletten
Greece Candesaratan Cilexetil/Teva Pharma B.V. 4 mg
Hungary Candesaratan-ratiopharm 4 mg tableta
Ireland Candesaratan Teva 4 mg Tablets
Italy Candesaratan Dorom 4 mg
Netherlands Candesaratan cilexetil Teva & 4 mg tabletten
Norway Candesaratan Teva 4 mg tabletter
Poland Candesaratan cilexetil Teva 4 mg
Portugal Candesaratan Teva 4 mg

Slovakia Kandesartan Teva 4 mg

Spain Candesartan Teva 4 mg comprimidos EFG

Sweden Candesartan Teva 4 mg tableter

United Kingdom Candesartan cilexetil 4 mg Tablets

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