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**CANDESARTAN
TEVA PHARMA**
**4 mg, 8 mg, 16 mg &
32 mg TABLETS**
candesartan cilexetil

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

WHAT IS IN THIS LEAFLET:

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

1 WHAT CANDESARTAN TEVA PHARMA IS AND WHAT IT IS USED FOR

The name of your medicine is Candesartan Teva Pharma. 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 WHAT YOU NEED TO KNOW BEFORE YOU TAKE CANDESARTAN TEVA PHARMA

**Do NOT take Candesartan Teva
Pharma**

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Candesartan Teva Pharma:

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

Use in children

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

Other medicines and Candesartan

Teva Pharma

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

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

Candesartan Teva Pharma with food, drink and alcohol

- You can take Candesartan Teva Pharma with or without food.
- When you are prescribed Candesartan Teva Pharma, 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 Candesartan Teva Pharma 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 Pharma.

Candesartan Teva Pharma 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 Pharma 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

Driving and using machines
Some people may feel tired or dizzy when taking Candesartan Teva Pharma. If this happens to you, do not drive or use any tools or machines.

Candesartan Teva Pharma contains lactose

Candesartan Teva Pharma 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 PHARMA

Always take Candesartan Teva Pharma 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 Teva Pharma every day.

You can take Candesartan Teva Pharma 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 Pharma 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 Pharma 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 Pharma 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 Teva Pharma than you should

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

If you forget to take Candesartan Teva Pharma

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 Pharma

If you stop taking Candesartan Teva Pharma, your blood pressure may increase again. Therefore do not stop taking Candesartan Teva Pharma 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 Teva Pharma 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 Pharma 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 Pharma 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 Pharma has had an 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 you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5 HOW TO STORE CANDESARTAN TEVA PHARMA

- Keep this medicine out of the sight and reach of children.
- Do not use Candesartan Teva Pharma after the expiry date which is stated on the carton after {EXP}. The expiry date refers to the last day of that month.
- Do not store above 25 °C (4 mg, 8 mg). This medicinal product does not require any special storage conditions. (16 mg, 32 mg).

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 Pharma contains

The active substance is candesartan cilexetil.
Each Candesartan Teva Pharma 4 mg Tablet contains 4 mg candesartan cilexetil.
Each Candesartan Teva Pharma 8 mg Tablet contains 8 mg candesartan cilexetil.
Each Candesartan Teva Pharma 16 mg Tablet contains 16 mg candesartan cilexetil.
Each Candesartan Teva Pharma 32 mg Tablet contains 32 mg candesartan cilexetil.

The other ingredients are docusate sodium, sodium laurilsulphate, carmellose calcium, pregelatinised maize starch, hydroxypropylcellulose, lactose monohydrate, magnesium stearate (E572), iron oxide red (E172) (16 mg and 32 mg tablets only).

What Candesartan Teva Pharma looks like and contents of the pack
Candesartan Teva Pharma 4 mg is supplied in the following pack sizes:

Blister packages with 7, [10, 14, 15, 20, 28, 30, 50, 50x1 unit dose, 56, 60, 84, 90, 98, 100] white, round biconvex tablets, marked CC on one face and 04 on the other face and scored on both faces.

Candesartan Teva Pharma 8 mg is supplied in the following pack sizes:

Blister packages with 7, [10, 14, 15, 20, 28, 30, 50, 50x1 unit dose, 56, 60, 84, 90, 98, 100] white, round biconvex tablets, marked CC on one face and 08 on the other face and are scored on both faces.

Candesartan Teva Pharma 16 mg is supplied in the following pack sizes:

Blister packages with 7, [10, 14, 15, 20, 28, 30, 50, 50x1 unit dose, 56, 60, 84, 90, 98, 100] light red, round biconvex tablets, marked CC on one face and 16 on the other face and are scored on both faces.

Candesartan Teva Pharma 32 mg is supplied in the following pack sizes:

Blister packages with 7, [10, 14, 15, 20, 28, 30, 50, 50x1 unit dose, 56, 60, 84, 90, 98, 100] 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 and Manufacturer

Marketing Authorisation Holder:

Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer(s) (responsible for batch release):

Bluepharma Indústria
Farmacêutica, S.A.
S. Martinho do Bispo, 3045-016
Coimbra
Portugal

Cemelog-BRS Ltd.
Vasút u. 13, 2040 Budaörs
Hungary

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

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

Pharmachemie B.V.
Swensweg 5, 2031 GA Haarlem
The Netherlands

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

Bulgaria:	ACRUX 8 mg, 16 mg and 32 mg tablets
Estonia:	Candesartan Teva 4 mg, 8 mg, 16 mg and 32 mg tabletid
Hungary:	Candesartan-Teva 4 mg, 8 mg, 16 mg and 32 mg tabletta
Ireland:	Candesartan Teva Pharma 4 mg, 8 mg, 16 mg and 32 mg Tablets
Lithuania:	Candesartan Teva 4 mg, 8 mg, 16 mg and 32 mg tabletes
Latvia:	Candesartan Teva 4 mg, 8 mg, 16 mg and 32 mg tabletes
Romania:	HIPOSTYN 4 mg, 8 mg, 16 mg and 32 mg comprimate
The Netherlands:	Candesartan cilexetil 4 mg, 8 mg, 16 mg and 32 mg Teva, tabletten

This leaflet was last revised in November 2013.