

**CANDESARTAN/
HYDROCHLOROTHIAZIDE
TEVA PHARMA
8 mg/12.5 mg &
16 mg/12.5 mg TABLETS
Candesartan cilexetil/
hydrochlorothiazide**

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

**1 WHAT CANDESARTAN/
HYDROCHLOROTHIAZIDE
TEVA PHARMA IS AND
WHAT IT IS USED FOR**

The name of your medicine is Candesartan/Hydrochlorothiazide Teva Pharma Tablet. It is used for treating high blood pressure (hypertension) in adult patients. It contains two active ingredients: candesartan cilexetil and hydrochlorothiazide. These work together to lower your blood pressure.

- Candesartan cilexetil belongs to a group of medicines called angiotensin II receptor antagonists. It makes your blood vessels relax and widen. This helps to lower your blood pressure.
- Hydrochlorothiazide belongs to a group of medicines called diuretics (water tablets). It helps your body to get rid of water and salts like sodium in your urine. This helps to lower your blood pressure.

Your doctor may prescribe Candesartan/Hydrochlorothiazide Teva Pharma if your blood pressure has not been properly controlled by candesartan cilexetil or hydrochlorothiazide alone.

**2 WHAT YOU NEED TO
KNOW BEFORE YOU
TAKE CANDESARTAN/
HYDROCHLOROTHIAZIDE
TEVA PHARMA**

**Do not take Candesartan/
Hydrochlorothiazide Teva Pharma if:**

- you are allergic to candesartan cilexetil or hydrochlorothiazide or any of the other ingredients of Candesartan/Hydrochlorothiazide Teva Pharma (see section 6).
- you are allergic to sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- you are more than 3 months pregnant (it is also better to avoid Candesartan/Hydrochlorothiazide Teva Pharma in early pregnancy see – pregnancy section).
- you have severe kidney problems.
- you have severe liver disease or biliary obstruction (a problem with the drainage of bile from the gall bladder).
- you have persistently low levels of potassium in your blood.
- you have persistently high levels of calcium in your blood.
- you have ever had gout.

If you are not sure if any of these applies to you, talk to your doctor or pharmacist before taking Candesartan/Hydrochlorothiazide Teva Pharma.

**Warnings and precautions
Talk to your doctor or pharmacist
before taking Candesartan/
Hydrochlorothiazide Teva Pharma if:**

- you have diabetes.
- you have heart, liver or kidney problems.
- you have recently had a kidney transplant.
- you are vomiting, have recently had severe vomiting, or have diarrhoea.
- you have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- you have ever had a disease called systemic lupus erythematosus (SLE).
- you have low blood pressure.
- you have ever had a stroke.
- you have ever had allergy or asthma
- you must tell your doctor if you think you are (or might become) pregnant. Candesartan/
Hydrochlorothiazide 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/
Hydrochlorothiazide Teva Pharma. This is because Candesartan/
Hydrochlorothiazide Teva Pharma, when combined with some anaesthetics, may cause a drop in blood pressure.

Candesartan/Hydrochlorothiazide Teva Pharma may cause increased sensitivity of the skin to sun.

Use in children

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

**Other medicines and Candesartan/
Hydrochlorothiazide 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/
Hydrochlorothiazide Teva Pharma can affect the way some other medicines work and some medicines can have an effect on Candesartan/
Hydrochlorothiazide 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 Angiotensin Converting Enzyme (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).
- Calcium or Vitamin D supplements.
- Medicines to lower your cholesterol, such as colestipol or cholestyramine.
- Medicines for diabetes (tablets or insulin).
- Medicines to control your heart beat (antiarrhythmic agents) such as digoxin and beta-blockers.
- Medicines that can be affected by potassium blood levels such as some antipsychotic medicines.
- Heparin (a medicine for thinning the blood).
- Water tablets (diuretics).
- Laxatives.
- Penicillin (an antibiotic).
- Amphotericin (for the treatment of fungal infections).
- Lithium (a medicine for mental health problems).
- Steroids such as prednisolone.
- Pituitary hormone (ACTH).
- Medicines to treat cancer.
- Amantadine (for the treatment of Parkinson's disease or for serious infections caused by viruses).
- Barbiturates (a type of sedative also used to treat epilepsy).
- Carbenoxolone (for treatment of oesophageal disease, or oral ulcers).
- Anticholinergic agents such as atropine and biperiden.
- Ciclosporin, a medicine used for organ transplant to avoid organ rejection.
- Other medicines that may lead to enhancement of the antihypertensive effect such as baclofen (a medicine for relief of spasticity), amifostin (used in cancer treatment) and some antipsychotic medicines.

**Candesartan/Hydrochlorothiazide
Teva Pharma with food, drink and
alcohol**

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

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

Candesartan/Hydrochlorothiazide 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.

TEVA Design Department Harlow

PRODUCT: Candesartan/HCTZ Teva Pharma 18/12.5 mg & 16/12.5mg Tabs All TEI (BLU) V2	Colours: Cutter Guide PMS Process Black PMS Green	Fonts: (Artwork) Body: Univers 55 Roman/ 65 Bold/ 55 Oblique9.5pts Subhead: Univers 65 Bld 12pts Header: Univers 65 Bld 14pts	Amends: Draft: 2 Rev date: 21-3-14 Reviser: WA	Approval: Senior Artwork Co-ordinator Signed Date <input type="checkbox"/> • Subject to Reg. Agency approval <input type="checkbox"/> • Approved by Reg. Dept. for print Signed Date
Job No: 33379 Art No: X	Tints used:	Software used: Indesign CS6	Artworker's Signature:	Last amend:
Designer: SD Date: 18-3-14	Component: Leaflet	Dimensions: 148x600mm	Spellcheck: <input type="checkbox"/>	

Supplier Instructions Artwork, text and content must NOT be altered. The only exceptions to this are: bleeds, chokes, spreads or other adjustments required for print reproduction purposes only. If you have any difficulties please contact the Teva Artwork Team. We must receive a copy of the 3rd Party Vendors Proof before final approval can be made.

3 HOW TO TAKE CANDESARTAN/HYDROCHLOROTHIAZIDE TEVA PHARMA

Always take Candesartan/Hydrochlorothiazide 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/Hydrochlorothiazide Teva Pharma every day.

The usual dose of Candesartan/Hydrochlorothiazide Teva Pharma is one tablet once a day. 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.

If you take more Candesartan/Hydrochlorothiazide Teva Pharma than you should

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

If you forget to take Candesartan/Hydrochlorothiazide 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/Hydrochlorothiazide Teva Pharma

If you stop taking Candesartan/Hydrochlorothiazide Teva Pharma, your blood pressure may increase again. Therefore do not stop taking Candesartan/Hydrochlorothiazide 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/Hydrochlorothiazide 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. Some of the side effects of Candesartan/Hydrochlorothiazide Teva Pharma are caused by candesartan cilexetil and some are caused by hydrochlorothiazide.

Stop taking Candesartan/Hydrochlorothiazide 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/Hydrochlorothiazide 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/Hydrochlorothiazide Teva Pharma has had any effect on your blood (agranulocytosis).

Other possible side effects include:

Common (affects 1 to 10 users in 100)

- 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.
 - An increased or reduced 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 heartbeat or pins and needles.
 - An increased amount of cholesterol, sugar or uric acid in your blood.
- Sugar in your urine.
- Feeling dizzy/spinning sensation or weak.
- Headache.
- Respiratory infection.

Uncommon (affects less than 1 user in 100)

- Low blood pressure. This may make you feel faint or dizzy.
- Loss of appetite, diarrhoea, constipation, stomach irritation.
- Skin rash, lumpy rash (hives), rash caused by sensitivity to sunlight.

Rare (affects less than 1 user in 1,000)

- Jaundice (yellowing of the skin or the whites of your eyes). If this happens to you, contact your doctor immediately.
- Effects on how your kidneys work, especially if you have kidney problems or heart failure.
- Difficulty in sleeping, depression, being restless.
- Tingling or prickling in your arms or legs.
- Blurred vision for a short time.
- Abnormal heart beat.
- Breathing difficulties (including lung inflammation and fluid in the lungs).
- High temperature (fever).
- Inflammation of the pancreas. This causes moderate to severe pain in the stomach.
- Muscle cramps.
- Damage to blood vessels causing red or purple dots in the skin.
- A reduction in your red or white blood cells or platelets. You may notice tiredness, an infection, fever or easy bruising.
- A severe rash, that develops quickly, with blistering or peeling of the skin and possibly blistering in the mouth.
- Worsening of existing lupus erythematous-like reactions or appearance of unusual skin reactions.

Very rare (affects less than 1 user in 10,000)

- Swelling of the face, lips, tongue and/or throat.
- 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.

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/HYDROCHLOROTHIAZIDE TEVA PHARMA

- **Keep this medicine out of the sight and reach of children.**
- Do not store above 25°C.
- Do not use Candesartan/Hydrochlorothiazide 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 throw away any medicines 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 CONTENTS OF THE PACK AND OTHER INFORMATION

What Candesartan/Hydrochlorothiazide Teva Pharma contains

The active substances are candesartan cilexetil and hydrochlorothiazide.

Each Candesartan/Hydrochlorothiazide Teva Pharma Tablet contains 8 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide.

Each Candesartan/Hydrochlorothiazide Teva Pharma Tablet contains 16 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide.

The other ingredients are docusate sodium, sodium laurilsulphate, carmellose calcium, pregelatinised maize starch, hydroxypropylcellulose, lactose monohydrate, magnesium stearate (E572).

What Candesartan/Hydrochlorothiazide Teva Pharma looks like and contents of the pack

Candesartan/Hydrochlorothiazide Teva Pharma 8 mg/12.5 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, elliptic biconvex tablets, marked **CH** and **08** on the same face and scored on both faces.

Candesartan/Hydrochlorothiazide Teva Pharma 16 mg/12.5 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, elliptic biconvex tablets, marked **CH** and **16** on the same face and 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.
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Cemelog-BRS Ltd.
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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 plus tablets
Estonia:	Candesartan HCT Teva tabletid
Hungary:	Candesartan-HCT- Teva tablettá
Ireland:	Candesartan/ Hydrochlorothiazide Teva Pharma Tablets
Lithuania:	Candesartan HCT Teva tabletes
Latvia:	Candesartan HCT Teva tabletes
Romania:	Hipostyn HCT comprimat
The Netherlands:	Candesartan cilexetil/ Hydrochlorothiazide Teva tabletten

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