

## Package leaflet: Information for the patient

### **Candesartan/ Hydrochlorothiazide 8 mg/ 12.5 mg tablets** **Candesartan/ Hydrochlorothiazide 16 mg/12.5 mg tablets**

Candesartan/Hydrochlorothiazide

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

#### **1. What Candesartan/ Hydrochlorothiazide is and what it is used for**

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

- Candesartan 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 if your blood pressure has not been properly controlled by candesartan or hydrochlorothiazide alone.

Candesartan/ Hydrochlorothiazide 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 receptors antagonists (MRA) cannot be used.

(ACE-inhibitors and MRAs are medicines used to treat heart failure).

You must talk to a doctor immediately if you do not feel better or if you feel worse.

## **2. What you need to know before you take Candesartan/ Hydrochlorothiazide**

### **Do not take Candesartan/ Hydrochlorothiazide:**

- you are allergic (hypersensitive) to candesartan or hydrochlorothiazide or any of the other ingredients of Candesartan/ Hydrochlorothiazide (listed in 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 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 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/ Hydrochlorothiazide.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Candesartan/ Hydrochlorothiazide 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 erythaematosus (SLE)
- you have low blood pressure
- you have ever had a stroke.
- you have ever had allergy or asthma.
- 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
- you are taking an ACE-inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptors antagonist (MRA). These medicines are for the treatment of heart failure (see "Other medicines and Candesartan/ Hydrochlorothiazide).

You must tell your doctor if you think you are (or might become) pregnant. Candesartan/ Hydrochlorothiazide 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.

Your doctor may want to see you more often and do some tests if you have any of these conditions.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e. g. potassium) in your blood at regular intervals.

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

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

See also information under the headline “Do not take Candesartan/ Hydrochlorothiazide”

### **Children and adolescents**

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

### **Other medicines and Candesartan/ Hydrochlorothiazide**

Please 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 can affect the way some other medicines work and some medicines can have an effect on Candesartan/ Hydrochlorothiazide. 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, 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.
- Cyclosporine, 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.

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/ Hydrochlorothiazide 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/ Hydrochlorothiazide with food, drink and alcohol**

- You can take Candesartan/ Hydrochlorothiazide with or without food.
- When you are prescribed Candesartan/ Hydrochlorothiazide, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint or dizzy.

### **Pregnancy, breast-feeding and fertility**

#### Pregnancy

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. Your doctor will normally advise you to stop taking Candesartan/ Hydrochlorothiazide 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. Candesartan/ Hydrochlorothiazide 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 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

#### Fertility

No data on the potential effects of the active substances Candesartan cilexetil/ Hydrochlorothiazide on the human fertility are available.

### **Driving and using machines**

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

### **3. How to take Candesartan/ Hydrochlorothiazide**

Always take Candesartan/ Hydrochlorothiazide 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 every day.

The usual dose of Candesartan/ Hydrochlorothiazide 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 than you should**

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

#### **If you forget to take Candesartan/ Hydrochlorothiazide**

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**

If you stop taking Candesartan/ Hydrochlorothiazide, your blood pressure may increase again. Therefore do not stop taking Candesartan/ Hydrochlorothiazide 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 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 are caused by candesartan cilexetil and some are caused by hydrochlorothiazide

#### **Stop taking Candesartan/ Hydrochlorothiazide 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 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 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 erythaematosus-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 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.

### **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 any side effects directly to the national reporting system via the internet at {insert link to the relevant 'national reporting system website' - *details will be defined at national level*}; or you can report via {insert alternative ways of reporting - *details will be defined at national level*}. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Candesartan/ Hydrochlorothiazide**

- Keep out of the reach and sight of children.
- This medicinal product does not require any special storage conditions.
- Do not use Candesartan/ Hydrochlorothiazide after the expiry date which is stated on the carton, blister pack or bottle. 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 throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Candesartan/ Hydrochlorothiazide contains:**

One Candesartan/ Hydrochlorothiazide 8 mg/12.5 mg tablet contains 8 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide as active substances.

One Candesartan/ Hydrochlorothiazide 16 mg/12.5 mg tablet contains 16 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide as active substances.

The other excipients are: Mannitol, Maize Starch, Copovidone (K25-31), Glycerol, Magnesium Stearate

Candesartan/ Hydrochlorothiazide 16 mg/12.5 mg tablet contains also Ferric oxide, yellow (E172) and Ferric oxide, red (E172).

### **What Candesartan/ Hydrochlorothiazide looks like and contents of the pack:**

**Candesartan/ Hydrochlorothiazide 8/12.5 mg tablets** are white or off white, oval, biconvex (~9,5 x 4,5 mm), uncoated tablets, with a score line on one side.

**Candesartan/ Hydrochlorothiazide 16/12.5 mg tablets** are peach, oval, biconvex (~9,5 x 4,5 mm), uncoated tablets, with a score line on one side.

The tablet can be divided into equal doses.

Candesartan/ Hydrochlorothiazide is packaged in OPA/Alu/PVC-Aluminium blisters.

Number of tablets 30.

**Marketing Authorisation Holder:**

Tchaikapharma High Quality Medicines Inc.  
One G.M. Dimitrov Blvd.,  
1172 Sofia, Bulgaria  
Tel. +359 2 962 5454  
Fax: + 359 2 9625 839  
E-mail: info@tchaikapharma.com

**Manufacturer:**

Tchaikapharma High Quality Medicines Inc.  
53 Sankt Peterburg Blvd.,  
4000 Plovdiv, Bulgaria  
Tel: +359 2 9603 746  
fax: +359 2 9603 703  
e-mail: k.kaneva.hq@tchaikapharma.com

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

Name	Member State
Cardesart-Co	Bulgaria
CANDESARTAN+HCTZ/TCHAIKAPHARMA	Greece
Candesartan+Hidroclorotiazida Tchaikapharma	Portugal
Candesartan/Hydrochlorothiazide Tchaikapharma 8 mg/12.5 mg	Czech Republic
Candesartan/Hydrochlorothiazide Tchaikapharma 16 mg/12.5 mg	
Candesartan HCT Tchaikapharma	Romania
Candesartan HCT Tchaikapharma	Poland
Kandesartan HCT Tchaikapharma 8 mg/12,5 mg	Slovak Republic
Kandesartan HCT Tchaikapharma 16 mg/12,5 mg	

This leaflet was last revised in: (MM/YYYY)