

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### **Candesartan cilexetil/Hydrochloorthiazide Torrent 8 mg/12,5 mg tabletten Candesartan cilexetil/Hydrochloorthiazide Torrent 16 mg/12,5 mg tabletten Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/12,5 mg tabletten Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/25 mg tabletten**

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

### **1. WHAT CANDESARTAN CILEXETIL/HYDROCHLOORTHIAZIDE TORRENT IS AND WHAT IT IS USED FOR**

The name of your medicine is Candesartan cilexetil/Hydrochloorthiazide Torrent. 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 cilexetil/Hydrochloorthiazide Torrent 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 CILEXETIL/HYDROCHLOORTHIAZIDE TORRENT**

#### **Do not take Candesartan cilexetil/Hydrochloorthiazide Torrent:**

- if you are allergic to candesartan cilexetil or hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- if you are more than 3 months pregnant (it is also better to avoid Candesartan cilexetil/Hydrochloorthiazide Torrent in early pregnancy – see pregnancy section).
- if you have severe kidney problems.

- if you have severe liver disease or biliary obstruction (a problem with the drainage of bile from the gall bladder).
- if you have persistently low levels of potassium in your blood.
- if you have persistently high levels of calcium in your blood.
- if 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 cilexetil/Hydrochlorothiazide Torrent.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Candesartan cilexetil/Hydrochlorothiazide Torrent 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 experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Candesartan cilexetil/Hydrochlorothiazide Torrent. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- you have ever had allergy or asthma.
- you must tell your doctor if you think you are (or might become) pregnant. Candesartan cilexetil/Hydrochlorothiazide Torrent 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 have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Candesartan cilexetil/Hydrochlorothiazide Torrent.
- If you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Candesartan cilexetil/Hydrochlorothiazide Torrent, seek medical attention immediately.
- If you experience abdominal pain, nausea, vomiting or diarrhoea after taking Candesartan cilexetil/Hydrochlorothiazide Torrent. Your doctor will decide on further treatment. Do not stop taking Candesartan cilexetil/Hydrochlorothiazide Torrent on your own.

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 cilexetil/Hydrochlorothiazide Torrent".

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 cilexetil/Hydrochlorothiazide Torrent. This is because Candesartan cilexetil/Hydrochlorothiazide Torrent, when combined with some anaesthetics, may cause an excessive drop in blood pressure.

Candesartan cilexetil/Hydrochloorthiazide Torrent may cause increased sensitivity of the skin to sun.

### **Children**

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

### **Other medicines and Candesartan cilexetil/Hydrochloorthiazide Torrent**

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Candesartan cilexetil/Hydrochloorthiazide Torrent can affect the way some other medicines work and some medicines can have an effect on Candesartan cilexetil/Hydrochloorthiazide Torrent. 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 as your doctor may need to change your dose and/or take other precautions:

- Other medicines to help lower your blood pressure, including beta-blockers, aliskiren- containing medicines, 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.
- certain antibiotic medicine (e. g. Penicillin or co-trimoxazole also known as trimethoprim/sulfamethoxazole).
- 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.
- ACE-inhibitor or aliskiren (see also information under the headings "Do not take Candesartan cilexetil/Hydrochloorthiazide Torrent" and "Warnings and precautions")

### **Candesartan cilexetil/Hydrochloorthiazide Torrent with food and alcohol**

You can take cilexetil/Hydrochloorthiazide Torrent with or without food.

When you are prescribed Candesartan cilexetil/Hydrochloorthiazide Torrent, 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 cilexetil/Hydrochloorthiazide Torrent before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Candesartan cilexetil/Hydrochloorthiazide Torrent. Candesartan cilexetil/Hydrochloorthiazide Torrent 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 cilexetil/Hydrochloorthiazide Torrent 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 cilexetil/Hydrochloorthiazide Torrent. If this happens to you, do not drive or use any tools or machines.

### **Candesartan cilexetil/Hydrochloorthiazide Torrent contains lactose and natrium**

Candesartan cilexetil/Hydrochloorthiazide Torrent contains lactose which is a type of sugar. If you have been told by doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium-free’.

## **3. HOW TO TAKE CANDESARTAN CILEXETIL/HYDROCHLOORTHAZIDE TORRENT**

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 cilexetil/Hydrochloorthiazide Torrent every day. The recommended dose of Candesartan cilexetil/Hydrochloorthiazide Torrent is one tablet once a day.

You can take Candesartan cilexetil/Hydrochloorthiazide Torrent with or without food.

Take the tablet with a glass of water.

The tablets can be divided into equal doses.

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 cilexetil/Hydrochloorthiazide Torrent than you should**

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

### **If you forget to take Candesartan cilexetil/Hydrochloorthiazide Torrent**

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 cilexetil/Hydrochloorthiazide Torrent**

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

**Stop taking Candesartan cilexetil/Hydrochlorothiazide Torrent and seek medical help immediately if you have any of the following allergic reactions:**

1. difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat
2. swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing
3. severe itching of the skin (with raised lumps)

Candesartan cilexetil/Hydrochlorothiazide Torrent 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 cilexetil/Hydrochlorothiazide Torrent has had any effect on your blood (agranulocytosis).

Other possible side effects include:

**Common (may affect up to 1 in 10 people)**

- 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 (may affect up to 1 in 100 people)**

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

- 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.

**Very rare (may affect up to 1 in 10,000 people)**

- 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.
- Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

**Not known (frequency cannot be estimated from the available data)**

- Sudden short-sightedness
- Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- Sudden eye pain (acute angle-closure glaucoma)
- Systemic and cutaneous lupus erythaematosus (allergic condition which causes fever, joint pain, skin rashes which may include redness, blistering, peeling and lumps)
- Diarrhoea
- Skin and lip cancer (Non-melanoma skin cancer)
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea

**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 [the national reporting system listed in Appendix V\\*](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE CANDESARTAN CILEXETIL/HYDROCHLOORTHIAZIDE TORRENT**

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

For Candesartan cilexetil/Hydrochloorthiazide Torrent 8 mg/12,5 mg and Candesartan cilexetil/Hydrochloorthiazide Torrent 16 mg/12,5 mg  
Do not store above 25°C.

For Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/12.5 mg and Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/25 mg>

HDPE bottle:

The shelf life after first opening of the bottle is 90 days.

Do not use this medicine after the expiry date which is stated on the carton or 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 to protect the environment.

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

### **What Candesartan cilexetil/Hydrochlorothiazide Torrent contains**

The active substances are candesartan cilexetil and hydrochlorothiazide.

Candesartan cilexetil/Hydrochlorothiazide Torrent 8 mg/12,5 mg:

One Candesartan cilexetil/Hydrochlorothiazide Torrent tablet contains 8 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.

Candesartan cilexetil/Hydrochlorothiazide Torrent 16 mg/12,5 mg:

One Candesartan cilexetil/Hydrochlorothiazide Torrent tablet contains 16 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.

Candesartan cilexetil/Hydrochlorothiazide Torrent 32 mg/12,5 mg:

One Candesartan cilexetil/Hydrochlorothiazide Torrent tablet contains 32 mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.

Candesartan cilexetil/Hydrochlorothiazide Torrent 32 mg/25 mg:

One Candesartan cilexetil/Hydrochlorothiazide Torrent tablet contains 32 mg of candesartan cilexetil and 25 mg of hydrochlorothiazide.

The other ingredients are:

Candesartan cilexetil/Hydrochlorothiazide Torrent 8 mg/12,5 mg and Candesartan cilexetil/Hydrochlorothiazide Torrent 16 mg/12,5 mg

Lactose monohydrate

Maize starch

Hypromellose 2910 (E464)

Calcium stearate

Hydroxypropyl cellulose (E463)

Disodium edetate

Microcrystalline cellulose (E460)

For Candesartan cilexetil/Hydrochlorothiazide Torrent 16 mg/12,5 mg additionally:  
ferric oxide red (E172), ferric oxide yellow (E172).

The other ingredients are:

for Candesartan cilexetil/Hydrochlorothiazide Torrent 32 mg/12,5 mg and Candesartan cilexetil/Hydrochlorothiazide Torrent 32 mg/25 mg

Lactose monohydrate

Maize starch

Calcium stearate

Hydroxypropyl cellulose (E463)

Disodium edetate

Carboxymethylcellulose calcium (E466)

Ethyl cellulose (E462)

Microcrystalline cellulose (E460)

Ferric oxide yellow (E172)

For Candesartan cilexetil/Hydrochlorothiazide Torrent 32 mg/25 mg additionally:  
ferric oxide red (E172).

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

Candesartan cilexetil/Hydrochlorothiazide Torrent 8 mg/12,5 mg:

White to off white, oval, biconvex, 9.5 x 4.5 mm, bevel edged uncoated tablets with breakline on both sides.

Candesartan cilexetil/Hydrochlorothiazide Torrent 16 mg/12,5 mg:

Peach colored to light orange colored, oval, biconvex, 9.5 x 4.5 mm, bevel edged uncoated tablets with breakline on both sides.

Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/12,5 mg:  
Light yellow colored to yellow colored, oval, biconvex, 11.0 mm x 6.5 mm, bevel edged uncoated tablets with breakline on both sides.

Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/25 mg:  
Peach colored to light orange colored, oval, biconvex, 11.0 mm x 6.5 mm, bevel edged, uncoated tablets, with breakline on both sides.

Pack sizes:

Candesartan cilexetil/Hydrochloorthiazide Torrent is available in blister packs containing 10, 14, 28, 30, 50, 56, 60, 98 or 100 tablets.

Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/12,5 mg and Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/25 mg is available in HDPE bottles containing 30, 90 or 500 (hospital pack, for use on more than one patient) tablets.

Not all pack sizes may be marketed.

### **Marketing authorisation holder**

Torrent Pharma GmbH  
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90449 Nuernberg  
Duitsland  
Tel +49 (0) 911 4302 970  
Fax +49 (0) 911 4302 971  
E-mail: mail@torrentpharma.com

### **Manufacturer**

Heumann Pharma GmbH & Co. Generica KG  
Suedwestpark 50  
90449 Nuernberg  
Duitsland

or

Interpharma Services Ltd.  
Rusalijski prohod Str. 11  
3. Stock, App. 8  
1407 Sofia  
Bulgarije

or

Torrent Pharma (Malta) Ltd  
Central Business Centre, Level 2,  
Triq Hal Tarxien,  
Il-Gudja, GDJ 1907,  
Malta

### **In het register ingeschreven onder:**

Candesartan cilexetil/Hydrochloorthiazide Torrent 8 mg/12,5 mg tabletten: RVG 107846  
Candesartan cilexetil/Hydrochloorthiazide Torrent 16 mg/12,5 mg tabletten: RVG 107847  
Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/12,5 mg tabletten: RVG 114104



Candesartan cilexetil/Hydrochloorthiazide Torrent 32 mg/25 mg tabletten: RVG 114105

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

NL: Candesartan cilexetil/Hydrochloorthiazide Torrent 8 mg/12,5 mg, 16 mg/12,5 mg, 32 mg/12,5 mg, 32 mg/25 mg tabletten

DE: Candesartan/HCT Heumann 8 mg/12,5 mg, 16 mg/12,5 mg, 32 mg/12,5 mg, 32 mg/25 mg Tabletten

**Deze bijsluiter is voor het laatst goedgekeurd in januari 2025.**