

Package leaflet: Information for the user

Candesartan/Hydrochlorothiazide Clonmel 16 mg/12.5 mg Tablets

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 effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

The name of your medicine is Candesartan/ Hydrochlorothiazide Clonmel . 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 Clonmel 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 Clonmel

DO NOT take Candesartan/ Hydrochlorothiazide Clonmel :

- if you are allergic to candesartan cilexetil, 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/ Hydrochlorothiazide Clonmel in early pregnancy – see pregnancy section).
- if you have severe kidney problems.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- 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 are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Candesartan/ Hydrochlorothiazide Clonmel .

Warnings and precautions

Talk to your doctor or pharmacist before taking Candesartan/ Hydrochlorothiazide Clonmel :

- if you have diabetes.
- if you have heart, liver or kidney problems.
- 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 ever had a disease called systemic lupus erythematosus (SLE)
- if you have low blood pressure
- if you have ever had a stroke.
- if you have ever had allergy or asthma.
- you must tell your doctor if you think you are (or might become) pregnant. Candesartan/ Hydrochlorothiazide Clonmel 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 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/ Hydrochlorothiazide Clonmel").

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/ Hydrochlorothiazide Clonmel".

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

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

Children

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

Other medicines and Candesartan/ Hydrochlorothiazide Clonmel

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. Candesartan/ Hydrochlorothiazide Clonmel can affect the way some other medicines work and some medicines can have an effect on Candesartan/ Hydrochlorothiazide Clonmel . 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), amifostine (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 Clonmel" 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 Clonmel with food, drink and alcohol

- You can take Candesartan/ Hydrochlorothiazide Clonmel with or without food.
- When you are prescribed Candesartan/ Hydrochlorothiazide Clonmel, 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 for advice before taking this medicine.

Pregnancy

Your doctor will normally advise you to stop taking Candesartan/ Hydrochlorothiazide Clonmel 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 Clonmel. Candesartan/ Hydrochlorothiazide Clonmel 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 Clonmel is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Driving and using machines

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

3. How to take Candesartan/ Hydrochlorothiazide Clonmel

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/ Hydrochlorothiazide Clonmel every day.

The recommended dose of Candesartan/ Hydrochlorothiazide Clonmel 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.

Candesartan/ Hydrochlorothiazide Clonmel 16/12.5 mg

The score line is only to help you break the tablet if you have difficulty swallowing it whole.

If you take more Candesartan/ Hydrochlorothiazide Clonmel than you should

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

If you forget to take Candesartan/ Hydrochlorothiazide Clonmel

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 Clonmel

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

Stop taking Candesartan/ Hydrochlorothiazide Clonmel 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 Clonmel 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 Clonmel 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.
- Worsening of existing lupus erythematosis-like reactions or appearance of unusual skin reactions.

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.

Not known (frequency cannot be estimated from available data)

- Sudden shortsightedness
- Sudden eye pain (acute angle-closure glaucoma)
- 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 HPRA 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/ Hydrochlorothiazide Clonmel

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister, 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 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 Clonmel contains

- The active substances are candesartan cilexetil and hydrochlorothiazide. Each tablet contains 16 mg candesartan cilexetil and 12.5 mg hydrochlorothiazide.
- The other ingredients are mannitol (E421), maize starch, copovidone, glycerol, magnesium stearate yellow ferric oxide (E172) and red ferric oxide (E172).

What Candesartan/ Hydrochlorothiazide Clonmel looks like and contents of the pack

Candesartan/ Hydrochlorothiazide Clonmel 16/12.5 mg tablets are peach, oval, biconvex (~9.5 x 4.5 mm), uncoated tablets, with a break line on one side.

Candesartan/ Hydrochlorothiazide Clonmel 16/12.5 mg tablets are packed in blister packs of 7, 10, 14, 15, 28, 28x1 (single dose unit), 30, 50, 50x1 (single dose unit), 56, 56x1 (single dose unit), 90, 98, 98x1 (single dose unit), 100 and 300 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Delorbis Pharmaceuticals Ltd, 17, Athinon Street, Ergates Industrial Area, 2643 Nicosia, Cyprus

HBM Pharma s.r.o., Sklabinská 30, 036 80 Martin, Slovak Republic

Pharmaceutical Works Polpharma S.A., Production Solid Form Department, 19, Pelplinska Str., 83-200 Starogard Gdanski, Poland

STADA Arzneimittel AG, Stadastraße 2-18, 6118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36 / 2, 1190 Vienna, Austria

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

Portugal (RMS): Cocardax 16 mg/12.5 mg

Austria: Candesartan/HCT STADA GmbH 16 mg/12,5 mg, Tabletten

Bulgaria: Repido Plus (16 mg/12,5 mg, tablets)

Ireland: Candesartan/HCT Clonmel 16mg/12.5 mg tablets

Italy: Candesartan e Idroclorotiazide Eurogenerici 16 mg/12.5 mg compresse

This leaflet was last revised in January 2019.