Package leaflet: Information for the patient.

Candesartan Clonmel 4 mg tablets
Candesartan Clonmel 8 mg tablets
Candesartan Clonmel 16 mg tablets
candesartan cilexetil

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

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

The name of the medicine is Candesartan Clonmel. The active substance is candesartan cilexetil. It 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.

Candesartan Clonmel can be used for:
- treatment of high blood pressure (hypertension) in adult patients and in children and adolescents aged from 6 up to 18 years.
- treating 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 receptor antagonists (MRAs) cannot be used (ACE inhibitors and MRAs are medicines used to treat heart failure).

2. What you need to know before you take Candesartan Clonmel

Do not take Candesartan Clonmel
- if you are allergic to candesartan cilexetil or any of the other ingredients of this medicine (listed in section 6).
- if you are more than 3 months pregnant (it is also better to avoid *Candesartan Clonmel* in early pregnancy, see the section on pregnancy).
- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- if the patient is a child under 1 year of age.
- if you have diabetes or impaired kidney function and you are also 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 Clonmel

Warnings and precautions

Talk to your doctor or pharmacist before taking Candesartan Clonmel
- 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 glands 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 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 the pregnancy section).
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE inhibitor (e.g., enalapril, lisinopril, ramipril), in particular if you have kidney diabetes-related kidney problems
  - aliskiren
- if you are taking an ACE inhibitor together with a medicine that belongs to a class of medicines known as mineralocorticoid receptor antagonists (MRAs). These medicines are used for the treatment of heart failure (see "Other medicines and Candesartan Clonmel").

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Candesartan Clonmel. Your doctor will decide on further treatment. Do not stop taking Candesartan Clonmel on your own.

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

See also information under the heading "Do not take Candesartan Clonmel"

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 the doctor or dentist that you are taking Candesartan Clonmel. This is because Candesartan Clonmel, when combined with some anaesthetic, may cause an exessive drop in blood pressure.

Children and adolescents
Candesartan Clonmel has been studied in children. Contact your doctor for more information. Candesartan Clonmel should not be given to children under 1 year of age due to the potential risk to developing kidneys.

Other medicines and Candesartan Clonmel
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Candesartan Clonmel can affect the way some other medicines work, and some medicines can have an effect on Candesartan Clonmel. If you are using certain medicines, your doctor may need to do blood tests from time to time.

In particular, tell the doctor if you are taking any of the following medicines: the doctor may need to change your dose and/or take other precautions:

- Other medicines to help lower 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 that relieve pain and inflammation-like conditions).
- Acetylsalicylic acid (if you take more than 3 g a day) (medicine that relieves pain and

inflammation-like conditions).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Heparin (blood-thinning medicine).
- CoTrimoxazole (antibiotic), also called trimethoprim/sulfamethoxazole.
- Water tablets (diuretics).
- Lithium (medicine for mental disorders).
- If you are also taking an ACE inhibitor or aliskiren (see also information under the headings "Do not take Candesartan Clonmel" and "Warnings and precautions").
- If you are being treated with an ACE inhibitor together with certain other heart failure medicines called mineralocorticoid receptor antagonists (e.g. spironolactone, eplerenone).

Candesartan Clonmel with food, drink and alcohol

- You can take Candesartan Clonmel with or without food.
- When you are prescribed Candesartan Clonmel, talk to your doctor before drinking alcohol. Alcohol can make you feel unwell 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 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 Clonmel. Candesartan 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 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, especially if your baby is newborn, or was born prematurely.

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

Candesartan Clonmel contains lactose
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 Clonmel

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important to take Candesartan Clonmel every day.
You can take Candesartan Clonmel with or without food. Swallow the tablet with water.
Try to take the tablet at the same time each day. This will help you to remember to take the tablet.
The 4 mg, 8 mg, 16 mg tablet can be divided into equal doses.

High blood pressure:
- The recommended dose of Candesartan Clonmel is 8 mg once daily. 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.
- In some patients, such as those with liver or kidney problems or those who have recently lost body fluid, for example 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 it is given as the only treatment, and these patients may need a higher dose.

Use in children and adolescents:
Children and adolescents aged from 6 to 18 years:
The recommended starting dose is 4 mg once daily.

For patients weighing less than 50 kg: in some patients whose blood pressure is not adequately controlled your doctor may decide the dose needs to be increased to a maximum of 8 mg once daily.

For patients weighing 50 kg or more: in some patients whose blood pressure is not adequately controlled, your doctor may decide the dose needs to be increased to 8 mg once daily and to 16 mg once daily.

Heart failure in adults:
- The recommended starting dose of Candesartan Clonmel is 4 mg once daily. The doctor may increase the dose by doubling it at intervals of at least 2 weeks up to 32 mg once daily. Candesartan Clonmel 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 Clonmel than you should
If you take more Candesartan Clonmel than prescribed by your doctor, contact a doctor or pharmacist immediately for advice

If you forget to take Candesartan Clonmel
Do not take a double dose to make up for a forgotten tablet. Just take the next dose at the usual time.

If you stop taking Candesartan Clonmel
If you stop taking Candesartan Clonmel your blood pressure may increase again. Therefore, do not stop taking Candesartan Clonmel without first talking to your doctor first.

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.

Stop taking Candesartan Clonmel and seek medical help immediately if you have any of the following allergic reactions::
- difficulty 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 difficulty in swallowing
- severe itching of the skin (with raised lumps)

Candesartan Clonmel may cause a reduction in the number of white blood cell. Your resistance to infections may be decreased and you may notice tiredness, an infection or fever. If this happens contact your doctor. Your doctor may occasionally do blood tests to check whether Candesartan Clonmel has had any effect on your blood (agranulocytosis).

Other possible side effects include:
Common: may affect up to 1 in 10 people:
- Dizziness/ spinning sensation.
- Headache.
- Respiratory infection.
- Low blood pressure. May make you feel unwell or dizzy.

- Changes in blood tests 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 kidney work, especially if you already have kidney problems or heart failure. In very rare cases, kidney failure may occur.

Very rare: may affect up to 1 in 10,000 people
- Swelling of the face, lips, tongue and/or neck.
- A reduction in your red or white blood cell. You may notice tiredness, an infection or a fever.
- Skin 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 or the whites of your eyes, or flu-like symptoms.
- Nausea.
- Changes in blood tests:
  - A reduced amount of sodium in your blood. If this is severe then you may notice weakness, lack of energy or muscle cramps.
- Cough
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

Not known: frequency cannot be estimated from the available data
- Diarrhoea

Additional side effects in children
In children being treated for hypertension, the side effects seem similar to those seen in adults, but they occur more often. Sore throat is a very common side effect in children but is not reported for adults, and runny nose, fever and increased heart rate are common in children but are not reported for adults.

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:
Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie
Malta: ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Candesartan Clonmel

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

Do not use this medicine after the expiry date which is stated on the carton and blister or bottle label 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.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Candesartan Clonmel contains

The active substance is candesartan cilexetil

Candesartan Clonmel 4 mg tablets contain 4 mg of candesartan cilexetil.
Candesartan Clonmel 8 mg tablets contain 8 mg of candesartan cilexetil.
Candesartan Clonmel 16 mg tablets contain 16 mg of candesartan cilexetil.

The other excipients are:
Lactose monohydrate, Maize starch, Hydroxypropylcellulose, Carmellose calcium, Macrogol 8000, Magnesium stearate. The 8 mg, 16 mg also contain Iron Oxide Red (E172).

What Candesartan Clonmel looks like and contents of the pack
Candesartan Clonmel 4 mg: 7mm, round tablet of white to off white colour with a score line on one side and a "4" on the other side.

Candesartan Clonmel 8 mg: 6.4mm, round tablet of pink colour (not uniform with possible small spots of darker or white colour) with a score line on one side and a "8" on the other side.

Candesartan Clonmel 16 mg: 7mm, round tablet of pink colour (not uniform with possible small spots of darker or white colour) with a score line on one side and a "16" on the other side.

Tablets are available in:
4 mg pack-sizes:
Blister: 14, 20, 28, 30, 50, 56, 84, 90, 98, 100 tablets
Bottle: 100 tablets

8 mg pack-sizes:
Blister: 14, 20, 28, 30, 50, 56, 84, 90, 98, 100 tablets
Bottle: 100 tablets

16 mg pack-sizes:
Blister: 14, 20, 28, 30, 50, 56, 84, 90, 98, 100 tablets
Bottle: 100 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
Laboratorios Liconsa S.A., Avda. Miralcampo, Nº7, PI Miralcampo, 19200- Azuqueca de Henares - Guadalajara, Spain
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This medicine is authorised in the Member States of the European Economic Area under the following names

Austria:	Candesartan Aliud 4 mg, 8 mg, 16 mg, 32 mg Tabletten
Belgium:	Candesartan EG 2 mg, 4 mg, 8 mg, 16 mg, 32 mg tabletten
Denmark:	Candesartan STADA
Finland:	Candesartan STADA 4 mg, 8 mg, 16 mg, 32 mg tabletti
France:	CANDESARTAN EG LABO 4 mg, 8 mg, 16 mg, 32 mg comprimé sécable
Germany:	Candesartan STADA 2 mg, 4 mg, 8 mg, 16 mg, 32 mg Tabletten
Iceland:	Candesartan STADA 4 mg, 8 mg, 16 mg, 32 mg töflur
Ireland:	Candesartan Clonmel 4 mg, 8 mg, 16 mg tablets

Luxembourg:	Candesartan EG 2 mg, 4 mg, 8 mg, 16 mg, 32 mg comprimés
Malta:	Candesartan Clonmel 4 mg, 8 mg, 16 mg tablets
Norway:	Candesartan STADA 4 mg, 8 mg, 16 mg, 32 mg tabletter
Portugal:	Candesartan Ciclum
Slovakia:	Kandesartan STADA 8 mg, 16 mg, 32 mg tablety
Spain:	Candesartán STADAFARMA 4 mg, 8 mg, 16 mg, 32 mg comprimidos EFG
Sweden:	Candesartan STADA 4 mg, 8 mg, 16 mg, 32 mg tabletter

This leaflet was last revised in December 2025.

<Other sources of information>
<Detailed information on this medicine is available on the web site of: {name of Member State/Agency}>