

Package leaflet: Information for the patient

Candesartan/Hydrochlorothiazide Mylan 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 side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

The name of your medicine is Candesartan/Hydrochlorothiazide Mylan. It is used for treating high blood pressure (hypertension). 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 known as 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 known as 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 Mylan 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 Mylan

Do not take Candesartan/Hydrochlorothiazide Mylan if:

- you are allergic to candesartan, hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to sulfonamide medicines (such as co-trimoxazole). 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 Mylan 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 the bile from the gall bladder)
- you have persistently low levels of potassium in your blood despite treatment to increase this
- you have persistently high levels of calcium in your blood despite treatment to decrease this
- you have ever had gout
- 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 Mylan.

Warnings and precautions

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

- you have diabetes or are at risk of developing diabetes
- you have heart problems such as heart failure (a weakening of the heart muscle)
- you have a narrowing of the valves of the heart, or a thickening of the heart muscle, which can all affect the flow of blood from the heart
- you have other liver or kidney problems
- you have recently had a kidney transplant
- you have a narrowing of the kidney artery
- you have low levels of sodium in the blood, are very dehydrated or are vomiting, have recently had severe vomiting, or have diarrhoea
- you are being treated with high doses of water tablets (diuretics) or are passing large volumes of urine
- 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, heart attack or have angina (or reduced blood flow to the brain)
- you have ever had allergy or asthma
- you must tell your doctor if you think you are (or might become) pregnant.
Candesartan/Hydrochlorothiazide Mylan 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)
- **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

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 Mylan"

During treatment

This medicine can affect the result of certain blood tests. If you need any blood tests, tell the doctor or hospital staff that you are taking this medicine.

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

If you need to have surgical imagery (to see parts of your body) then tell the doctor or hospital staff that you are taking this medicine. The use of iodine in the imaging material can increase the risk of side effects occurring.

Candesartan/Hydrochlorothiazide Mylan may cause increased sensitivity of the skin to sun. If this occurs, do not use sunlamps, tanning booths and use sunscreen or cover up with clothes when in the sun.

Children and adolescents

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

Other medicines and Candesartan/Hydrochlorothiazide Mylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Candesartan/Hydrochlorothiazide Mylan can affect the way some other medicines work and some medicines can have an effect on Candesartan/Hydrochlorothiazide Mylan. If you are using certain medicines, your doctor may need to do blood tests from time to time. Your doctor may need to change your dose and/or to take other precautions.

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, ACE inhibitors such as enalapril, captopril, lisinopril or ramipril, or aliskiren (see also information under the headings “Do not take Candesartan/Hydrochlorothiazide Mylan” and “Warnings and precautions”)
- non-steroidal anti-inflammatory painkillers (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation)
- acetylsalicylic acid (aspirin) (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation)
- potassium supplements or salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin (a medicine for thinning the blood)
- medicines that may affect the amount of potassium in your blood (medicines such as water tablets (diuretics), laxatives, penicillin (an antibiotic), amphotericin (for the treatment of fungal infections), carbenoxolone (for treatment of gullet problems, or oral ulcers), steroids such as prednisolone, pituitary hormone (ACTH)
- calcium or vitamin D supplements
- medicines to lower cholesterol, such as colestipol or colestyramine
- medicines for diabetes (tablets such as metformin, or insulin)
- medicines to control your heart beat (antiarrhythmic agents) such as quinidine, disopyramide, amiodarone, sotalol, ibutilide, digoxin
- other medicines which can affect the heart rhythm such as cisapride (for stomach problems), erythromycin, sparfloxacin, pentamidine (antibiotics), halofantrin (for malaria treatment), terfenadine (antihistamine)
- some antipsychotic medicines that can be affected by potassium blood levels such as thioridazine, chlorpromazine, trifluoperazine, haloperidol, amisulpride
- lithium (a medicine for mental health problems)
- medicines to treat cancer (such as methotrexate (which can also be used for other conditions e.g. psoriasis, arthritis) and cyclophosphamide)
- amantadine, (for the treatment of Parkinson’s disease or for serious infections caused by viruses)
- barbiturates (a sedative also used to treat epilepsy)
- 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 the relief of spasticity), amifostin (used in cancer treatment) and some anti-depressant medicines (such as amitriptyline, clomipramine, dosulepin)
- adrenaline, or noradrenaline, sometimes used to help increase blood pressure or, sometimes, for treatment of severe allergic reactions

Candesartan/Hydrochlorothiazide Mylan with alcohol

When you are prescribed Candesartan/Hydrochlorothiazide Mylan, 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/Hydrochlorothiazide Mylan 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 Mylan. Candesartan/Hydrochlorothiazide Mylan is not recommended during 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 Mylan 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 Mylan. If this happens to you, do not drive or use any tools or machines.

Candesartan/ Hydrochlorothiazide Mylan contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, such as lactose, contact your doctor before taking this medicine.

3. How to take Candesartan/Hydrochlorothiazide Mylan

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 keep taking Candesartan/Hydrochlorothiazide Mylan every day. The recommended dose of Candesartan/Hydrochlorothiazide Mylan is one tablet once daily.

Swallow the tablet with a drink of water. You may take Candesartan/Hydrochlorothiazide Mylan with or without food.

Try to take the tablet at the same time each day, usually in the morning. This will help you to remember to take it.

If you take more Candesartan/Hydrochlorothiazide Mylan than you should

If you take more Candesartan/Hydrochlorothiazide Mylan than prescribed by your doctor, contact a doctor or pharmacist immediately for advice. You may experience a large drop in blood pressure, which may cause you to feel dizzy, or you may notice an increased heart rate or irregular heartbeat, muscle cramps or in some cases feel very sleepy or experience a reduced level of consciousness.

If you forget to take Candesartan/Hydrochlorothiazide Mylan

Do not take a double dose to make up for a forgotten dose. Just take the next dose as normal.

If you stop taking Candesartan/Hydrochlorothiazide Mylan

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

Stop taking Candesartan/Hydrochlorothiazide Mylan and seek medical help immediately if you have any of the following side effects:

Rare (may affect up to 1 in 1,000 people)

- difficulty breathing, swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing, severe itchy swollen skin (with raised lumps)
- liver problems, including inflammation of the liver (hepatitis). You may notice tiredness, yellowing of your skin and the whites of your eyes, dark urine, pale stools or stomach pain
- breathing difficulties (including lung inflammation and fluid in the lungs)
- inflammation of the pancreas. This causes moderate to severe pain in the stomach
- a severe rash, that develops quickly, with blistering or peeling of the skin and possibly blistering in the mouth
- occurrence or worsening of existing lupus erythematosus-like reactions (which includes appearance of unusual skin reactions, facial rash, joint pain, muscle disorder and fever)
- a reduction in your red or white blood cells or platelets. You may notice tiredness, more frequent infections (e.g. sore throat, mouth ulcers), fever, or easy bruising or bleeding. This may be due to reduced production of blood cells in the bone marrow (bone marrow depression)

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

- kidney failure, especially if you already have kidney problems or heart failure. You may notice pain in the back, pass little or no urine or have cloudy urine or blood in the urine.

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

- sudden eye pain or blurred or loss of vision (acute angle-closure glaucoma)

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 or fats, sugar, or uric acid in your blood
- sugar in your urine
- feeling dizzy/spinning sensation or weak
- headache
- lung infection (which may include signs such as common cold, flu like symptoms)

Uncommon (may affect up to 1 in 100 people):

- low blood pressure. This may make you feel faint or dizzy especially when getting up from a sitting or lying position
- loss or lack of appetite, diarrhoea, constipation, stomach irritation
- skin rash, rash caused by sensitivity to sunlight.

Rare (may affect up to 1 in 1,000 people):

- reduced functioning of kidneys, which may be seen in blood tests
- difficulty in sleeping, depression, being restless
- tingling or prickling in your arms or legs
- blurred vision for a short period
- abnormal heart beat
- high temperature (fever)
- muscle cramps
- damage to blood vessels causing red or purple dots in the skin

- increase in blood urea nitrogen or certain proteins (creatinine) in your blood which may be seen in blood tests

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

- itching
- back pain, pain in joints and muscles
- changes in how your liver is working, which may be seen in blood tests
- cough
- nausea (feeling sick)

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

- short sightedness (inability of the eye to focus on distant objects)

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: <http://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 Mylan

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, blister or bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

The in-use shelf life of the product when stored in HDPE bottles is 90 days. Do not eat or remove the desiccant contained in the bottle.

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 Mylan tablets contain

The active substances are candesartan cilexetil and hydrochlorothiazide.

Each tablet contains 16mg of candesartan cilexetil and 12.5 mg of hydrochlorothiazide.

The other ingredients are carmellose calcium, glycerol monostearate, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, maize starch, iron oxide yellow (E172) and iron oxide red (E172).

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

Candesartan/Hydrochlorothiazide Mylan 16 mg/12.5 mg tablets are peach, mottled, round, biconvex tablets marked with “M” on one side and “CH2” on the other side.

Candesartan/Hydrochlorothiazide Mylan is available in blisters of 7, 10, 14, 15, 28, 30, 50, 56, 60, 84, 90, 98, 100 tablets and in plastic bottles of 30, 90 tablets.

Not all pack sizes may be marketed.

Any unused product or waste should be disposed of in accordance with local requirements.

Marketing Authorisation Holder and Manufacturer:**Marketing Authorisation Holder:**

McDermott Laboratories Ltd t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturer:

McDermott Laboratories Ltd t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Generics [UK] Ltd., Station Close, Potters Bar, Hertfordshire EN6 1 TL, United Kingdom

Mylan Hungary Ltd. H-2900 Komárom, Mylan utca 1, Hungary

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

Austria	Candesartan/HCT Arcana 8 mg/12.5 mg, 16 mg/12.5 mg Tabletten
Belgium	Co-Candesartan Mylan 16 mg/12,5 mg tabletten
Bulgaria	CoCandesargen 8 mg/12.5 mg, 16 mg/12.5 mg tablets
Denmark	Kandrozid Comp 8 mg/12.5 mg, 16 mg/12.5 mg tablets
France	Candesartan Hydrochlorothiazide Mylan 8 mg/12,5 mg, 16 mg/12,5 mg comprimé
Germany	Candesartancilexetil HCT Mylan 8 mg/12,5 mg, 16 mg/12,5 mg Tabletten
Greece	Candesartan + HCTZ/Mylan 8 mg/12.5 mg, 16 mg/12.5 mg tablets
Ireland	Candesartan/Hydrochlorothiazide Mylan 16 mg/12.5 mg Tablets
Luxembourg	Co-Candesartan Mylan 16 mg/12,5 mg comprimés
Netherlands	Candesartan cilexetil/Hydrochlorothiazide Mylan 8 mg/12,5 mg, 16 mg/12,5 mg tabletten
Portugal	Candesartan + Hidroclorotiazida Mylan
Romania	Candesartan/Hidroclorotiazida Mylan 8 mg/12,5mg, 16 mg/12,5mg comprimate
Slovakia	Candemyl Combi 16 mg/12.5 mg
Spain	Candesartan/Hidroclorotiazida Mylan 16 mg/12.5 mg comprimidos EFG

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