

Package leaflet: Information for the patient

Candesartan Mylan 4 mg Tablets
Candesartan Mylan 8 mg Tablets
Candesartan Mylan 16 mg Tablets
Candesartan Mylan 32 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 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 Mylan is and what it is used for
2. What you need to know before you take Candesartan Mylan
3. How to take Candesartan Mylan
4. Possible side effects
5. How to store Candesartan Mylan
6. Contents of the pack and other information

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

Candesartan Mylan contains the active substance candesartan which belongs to a group of medicines known as angiotensin II receptor antagonists that lower blood pressure. It works by making your blood vessels relax and widen (which helps to lower your blood pressure). It also makes it easier for your heart to pump blood to all parts of your body.

Candesartan Mylan is used for:

- treating high blood pressure (hypertension) in adult patients and in children and adolescents aged 6 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 (MRA) cannot be used. (ACE-inhibitors and MRAs are medicines used to treat heart failure).

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

Do not take Candesartan Mylan:

- if you are allergic to candesartan cilexetil or any of the other ingredients of this medicine (listed in section 6)
- if you have severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder)
- if you are more than 3 months pregnant. (It is also better to avoid Candesartan Mylan in early pregnancy - see pregnancy section)
- if the patient is a child under 1 year of age
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor or pharmacist before taking Candesartan Mylan:

- 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 gland called Conn's syndrome (also called primary hyperaldosteronism)
- if you have low blood pressure
- if you have ever had a stroke
- 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 Mylan")
- you must tell your doctor if you think you are (or might become) pregnant. Candesartan 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).

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 Mylan"

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

Children and adolescents

Candesartan has been studied in children. For more information, talk to your doctor. Candesartan must not be given to children under 1 year of age due to the potential risk to the developing kidneys.

Other medicines and Candesartan 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 Mylan can affect the way some other medicines work and some medicines can have an effect on Candesartan Mylan. Your doctor may need to change your dose and/or to take other precautions. 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 taking 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 Mylan" and "Warnings and precautions").
- 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).
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib, or etoricoxib (medicines used 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).
- Heparin (a medicine for thinning the blood)
- Diuretics (medicines known as 'water tablets')
- Lithium (a medicine used to treat mental health problems)

Candesartan Mylan with food and alcohol

- You can take Candesartan Mylan with or without food.
- When you are prescribed candesartan discuss with your doctor before drinking alcohol. Alcohol, while taking Candesartan Mylan, may make you feel faint and dizzy.

Pregnancy and breast-feeding***Pregnancy***

If you are pregnant, 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 Mylan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of this medicine. Candesartan Mylan 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

If you are breast-feeding or about to start breast-feeding ask your doctor or pharmacist for advice before taking this medicine. Candesartan 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 this medicine. If this happens to you, do not drive or use any tools or machines.

Candesartan 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 Mylan

This is a long-term treatment.

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 every day.

You can take Candesartan Mylan with or without food. Swallow the tablet with a drink of water. Try to take the tablet at the same time each day. This will help you remember to take it.

The tablet can be divided into equal doses.

To treat high blood pressure:

The recommended starting dose is 8 mg once a day. Your doctor may increase this dose up to 32 mg once a day depending on blood pressure response.

In some patients, such as those with liver problems, kidney problems or those who recently have lost body fluids, e.g. 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 given as the only treatment; these patients may need a higher dose.

To treat heart failure:

The recommended starting dose of candesartan is 4 mg once a day. Your doctor may increase your dose by doubling the dose at intervals of at least 2 weeks up to 32 mg once a day. Candesartan can be taken together with other medicines for heart failure, and your doctor will decide which treatment is suitable for you.

Use in children and adolescents with high blood pressure:

Children 6 to 18 years of age: The recommended starting dose is 4 mg once daily.

For patients weighing less than 50 kg 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 your doctor may decide the dose needs to be increased to 8 mg once daily and then to 16 mg once daily, if needed.

If you take more Candesartan Mylan than you should:

If you take more Candesartan Mylan than prescribed by your doctor, contact a doctor or pharmacist immediately for advice. Your blood pressure may become low and you may feel dizzy.

If you forget to take Candesartan 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 Mylan:

If you stop taking this medicine, your blood pressure may increase again. Therefore, do not stop taking Candesartan Mylan without 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 Mylan and contact your doctor or go to the nearest hospital emergency department if you have any of the following:

Very rare (may affect less than 1 in 10,000 people):

- swelling of the face, lips, tongue and/or throat, which may cause difficulties in breathing or swallowing.
- an increase in the number of infections you may get which causes fever, severe chills, sore throats, mouth ulcers or chesty coughs. These may be due to a low number of white blood cells.
- abnormal liver function including inflammation of the liver (hepatitis) which may be seen as feeling sick (nausea), being sick (vomiting) loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin or whites of the eyes with pale stools or dark coloured urine. These may be signs of serious problems with your liver.
- a decrease in kidney function which may be seen as producing little or no urine, cloudy urine or blood in the urine, pain when passing urine or lower back pain. These may be signs of serious kidney problems. In very rare cases kidney failure may occur.

Other possible side effects include:

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

- feeling dizzy/spinning sensation when standing still (vertigo)
- headache
- chest infection
- low blood pressure. This may make you feel faint or dizzy
- an increased amount of potassium in your blood which can be seen in a blood test, especially if you already have kidney problems or heart failure. If this is severe you may notice tiredness, weakness, an irregular heartbeat or pins and needles in your hands or feet

Very rare (may affect less than 1 in 10,000 people):

- skin rash, lumpy rash (hives)

- itching
- cough
- back pain, pain in joints and muscles
- feeling sick (nausea)
- changes in blood test results such as a reduced amount of sodium or an increase in liver enzymes in your blood.

Additional side effects seen in children and adolescents

In children treated for high blood pressure, side effects appear to be similar to those seen in adults, but they happen more often. A sore throat is a very common side effect seen in children and a blocked or runny nose, fever and increased heart rate are common side effects in children but none of these have been reported in 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 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 Mylan

Keep 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. After first opening the bottle, use within 100 days.

Do not store above 25°C. Store in the original package in order to protect from moisture.

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 Mylan contains

The active substance is candesartan cilexetil.

One tablet contains either 4 mg, 8 mg, 16 mg, or 32 mg of candesartan cilexetil.

The other ingredients are carmellose calcium, hydroxypropylcellulose, lactose monohydrate (see section 2 'Candesartan Mylan contains lactose'), magnesium stearate and mannitol.

What Candesartan Mylan looks like and contents of the pack

Candesartan Mylan 4 mg tablets are white to off white, round, biconvex tablet debossed with "C1" on one side and "M" on one side of the break line on the other side.

Candesartan Mylan 8 mg tablets are white to off white, round, biconvex tablet debossed with "M over C5" on one side and plain with break line on the other side.

Candesartan Mylan 16 mg tablets are white to off white, round, biconvex tablet debossed with "M over C6" on one side and plain with break line on the other side.

Candesartan Mylan 32 mg tablets are white to off white, round, biconvex tablet debossed with "M over C7" on one side and plain with break line on the other side.

Candesartan Mylan is available in blisters either inside a carton or inside a pouch of 7, 10, 14, 15, 28, 30, 50, 56, 60, 84, 90, 98 and 100 tablets, and in plastic bottles of 30, 49, 56, 90 and 98 tablets. The pouch and bottles contain a desiccant. The bottles also contain cotton wool. Do not eat the desiccant.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Ltd. T/A Gerard Laboratories, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer

Generics [UK] Ltd., Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom
McDermott Laboratories Ltd. T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland
Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary
Mylan B.V., Dieselweg 25, 3752 LB Bunschoten, the Netherlands
Mylan S.A.S., 117 Allée des Parcs, 69 800 Saint-Priest, France.

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

Austria – Candesartan cilexetil Arcana 4 mg, 8 mg, 16 mg, 32 mg Tabletten
Belgium – Candesartan Mylan 8 mg, 16 mg, 32 mg tabletten
Bulgaria – Candesagen 4 mg, 8 mg, 16 mg, 32 mg таблетки
Cyprus – Candesartan/Generics 4 mg, 8 mg, 16 mg, 32 mg Δισκία
Denmark – Kandrozid 4 mg, 8 mg, 16 mg, 32 mg tabletter
Finland – Kandrozid 4 mg, 8 mg, 16 mg, 32 mg tabletit
France – Candesartan Mylan 4 mg, 8 mg, 16 mg, 32 mg Comprimés sécables
Germany – Candesartan cilexetil Mylan 4 mg, 8 mg, 16 mg, 32 mg Tabletten
Hungary – Candesartan Mylan 4 mg, 8 mg, 16 mg, 32 mg tableta
Ireland – Candesartan Mylan 4 mg, 8 mg, 16 mg, 32 mg Tablets
Luxembourg – Candesartan Mylan 8 mg, 16 mg, 32 mg comprimés
Netherlands – Candesartan cilexetil Mylan 4 mg, 8 mg, 16 mg, 32 mg tabletten
Norway – Kandrozid 4 mg, 8 mg, 16 mg, 32 mg tabletter
Poland – Kangen 8 mg, 16 mg tabletki
Portugal – Candesartan Mylan 4 mg, 8 mg, 16 mg, 32 mg comprimidos
Romania – Candegen 4 mg, 8 mg, 16 mg comprimate
Slovakia – Candesartan Mylan 8 mg, 16 mg, 32 mg tablety
Spain – Candesartan Mylan 4 mg, 8 mg, 16 mg, 32 mg comprimidos EFG
Sweden – Kandrozid 4 mg, 8 mg, 16 mg, 32 mg tabletter
United Kingdom – Candesartan cilexetil 4 mg, 8 mg, 16 mg, 32 mg Tablets

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