

Package leaflet: Information for the patient

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

1. What Catasart is and what it is used for

The name of your medicine is Catasart. The active substance is candesartan cilexetil. This 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.

This medicine is used to:

- treat high blood pressure (hypertension) in adult patients and in children and adolescents aged 6 to <18 years
- treat 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 Catasart

Do not take Catasart

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

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking Catasart.

Warnings and precautions

Talk to your doctor or pharmacist before taking Catasart

- 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 receptor antagonists (MRA). These medicines are for the treatment of heart failure (see "Other medicines and Catasart").
- you must tell your doctor if you think you are (or might become) pregnant. Catasart 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 Catasart".

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 Catasart. This is because Catasart, when combined with some anaesthetics, may cause an excessive drop in blood pressure.

Children and adolescents

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

Other medicines and Catasart

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

Catasart can affect the way some other medicines work and some medicines can have an effect on Catasart. 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, 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 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)
- Co-trimoxazole (an antibiotic medicine) also known as trimethoprim/sulfamethoxazole.
- Water tablets (diuretics)
- Lithium (a medicine for mental health problems)
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Catasart” 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 receptor antagonists (MRA) (for example spironolactone, eplerenone).

Catasart with food, drink and alcohol

- You can take Catasart with or without food
- When you are prescribed Catasart, discuss with your doctor before drinking alcohol. Alcohol may make you feel faint 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 Catasart before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Catasart. Catasart 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. Catasart 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 Catasart. If this happens to you, do not drive or use any tools or machines.

Catasart 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.

Catasart contains sodium

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

3. How to take Catasart

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 Catasart every day.

You can take Catasart 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 to remember to take it.

Dividing the tablets:

If necessary, the tablet can be divided into equal doses. Put the tablet with the score line facing up onto a hard, smooth surface (e.g. tabletop or plate). Place your index fingers (or thumbs) on either side of the score line and push simultaneously briefly and hard.



High blood pressure:

- The recommended dose of Catasart 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 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, and these patients may need a higher dose.

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 < 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 \geq 50 kg: 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:

- The recommended starting dose of Catasart 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. Catasart 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 Catasart than you should

If you take more Catasart than prescribed by your doctor, contact a doctor or pharmacist immediately for advice.

If you forget to take Catasart

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

If you stop taking Catasart

If you stop taking Catasart, your blood pressure may increase again. Therefore do not stop taking Catasart 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.

Stop taking Catasart 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).

Catasart 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 Catasart has had any effect on your blood (agranulocytosis).

Other possible side effects include:

Common (may affect up to 1 in 10 people)

- Feeling dizzy/spinning sensation
- Headache
- Respiratory infection
- Low blood pressure. This may make you feel faint or dizzy.
- Changes in blood test 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 heartbeat or pins and needles.
- Effects on how your kidneys 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 throat.
- A reduction in your red or white blood cells. You may notice tiredness, an infection or a fever.
- Skin rash, lumpy 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 and the whites of your eyes and flu like symptoms.
- Nausea
- 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.
- Cough.

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

- Diarrhoea.

Additional side effects 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. Sore throat is a very common side effect in children but not reported in adults and runny nose, fever and increased heart rate are common in children but not 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: 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 Catasart

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/bottle after "EXP". The expiry date refers to the last day of that month.

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

Shelf life after first opening of the bottle:

3 months

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 Catasart contains

The active substance is candesartan cilexetil.

Each tablet contains 4 mg of candesartan cilexetil.

Each tablet contains 8 mg of candesartan cilexetil.

Each tablet contains 16 mg of candesartan cilexetil.

4 mg tablets:

The other ingredients are lactose monohydrate, maize starch, povidone K30, carrageenan, croscarmellose sodium and magnesium stearate.

8, 16 mg tablets:

The other ingredients are lactose monohydrate, maize starch, povidone K30, carrageenan, croscarmellose sodium, magnesium stearate, ferric oxide, red (E172) and titanium dioxide (E171).

What Catasart looks like and contents of the pack

Tablet.

4 mg tablets:

White, round biconvex tablet, debossed with 4 on one side and scored on the other side.

8 mg tablets:

Pink, mottled, round biconvex tablet, debossed with 8 on one side and scored on the other side.

16 mg tablets:

Pink, mottled, round biconvex tablet, debossed with 16 on one side and scored on the other side.

Pack sizes:

4 mg, 8mg and 16 mg tablets:

Al/Al Blister 7, 10, 14, 28, 30, 56, 98, 100, 300 tablets

Al/Al perforated unit dose blister: 50 x 1 tablets

Al/Al Blister with desiccant: 7, 10, 14, 28, 30, 56, 98, 100, 300 tablets

Al/Al perforated unit dose blister with desiccant: 50 x 1 tablets

HDPE bottle with PP cap and silica gel desiccant: 30, 100, 500 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

Lek Pharmaceuticals d.d, Trimlini 2D, 9220 Lendava, Slovenia.

LEK S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

Germany:	Candesartan HEXAL 4 mg Tabletten
	Candesartan HEXAL 8 mg Tabletten
	Candesartan HEXAL 16 mg Tabletten
	Candesartan HEXAL 32 mg Tabletten
Ireland:	Catasart 4 mg Tablets
	Catasart 8 mg Tablets
	Catasart 16 mg Tablets

This leaflet was last approved in 11/2018.