

Package leaflet: Information for the patient

Catasart Plus 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 Catasart Plus is and what it is used for
2. What you need to know before you take Catasart Plus
3. How to take Catasart Plus
4. Possible side effects
5. How to store Catasart Plus
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1. What Catasart Plus is and what it is used for

The name of your medicine is Catasart Plus. It is used for treating high blood pressure (hypertension) in adult patients. It contains two active substances: 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 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 Catasart Plus if your blood pressure has not been properly controlled by candesartan cilexetil or hydrochlorothiazide alone.

2. What you need to know before you take Catasart Plus

Do NOT take Catasart Plus, if:

- you are **allergic** to candesartan cilexetil or hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6)
- you are allergic to sulphonamide medicines. If you are not sure if this applies to you, please ask your doctor.
- you have **severe liver disease** or **biliary obstruction** (a problem with the drainage of the bile from the gall bladder)
- you have **severe kidney problems**
- you are **more than 3 months pregnant** (it is also better to avoid Catasart Plus in early pregnancy – see pregnancy section)
- you have ever had **gout**
- you have persistently **low levels of potassium** in your blood

- you have persistently **high levels of calcium** in your blood
- 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 Catasart Plus.

Warnings and precautions

Talk to your doctor or pharmacist before taking Catasart Plus, if:

- you have **heart, liver or kidney problems**
- you have recently had a **kidney transplant**
- you **are vomiting**, have recently had **severe vomiting** or **have diarrhoea**
- you have a **disease of the adrenal gland** called Conn's syndrome (also called primary hyperaldosteronism)
- you have **diabetes**
- you have ever had a disease called **systemic lupus erythematosus (SLE)**
- you have **low blood pressure**
- you have ever had a **stroke**
- you have ever had **allergy or asthma**
- you experienced **breathing or lung problems** (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking Catasart Plus, seek medical attention immediately.
- 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**
- you have had **skin cancer** or if you develop an unexpected **skin lesion** during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking Catasart Plus.
- you experience a **decrease in vision or eye pain**. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Catasart Plus. This can lead to permanent vision loss, if not treated. If you previously have had a penicillin or sulphonamide allergy, you can be at higher risk of developing this.
- **you think you are (or might become) pregnant**. Catasart Plus 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 Plus".

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

Catasart Plus may cause increased sensitivity of the skin to sun.

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

Children and adolescents

There is no experience with the use of Catasart Plus in children and adolescents (below the age of 18 years). Therefore, Catasart Plus should not be given to children and adolescents.

Talk to your doctor if you are an **athlete taking a doping test**, as Catasart Plus contains an active substance that can cause positive results in a doping test.

Other medicines and Catasart Plus

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

Catasart Plus can affect the way some other medicines work and some medicines can have an effect on Catasart Plus. 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:

- an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Catasart Plus” and “Warnings and precautions”)
- other medicines to help lower your blood pressure, including beta-blockers, aliskiren-containing medicines, diazoxide and Angiotensin Converting Enzyme (ACE) inhibitors such as enalapril, captopril, lisinopril or ramipril
- medicines to control your heartbeat (antiarrhythmic agents) such as digoxin and beta-blockers
- 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)
- water tablets (diuretics)
- lithium (a medicine for mental health problems)
- medicines that can be affected by potassium blood levels such as some antipsychotic medicines
- medicines to lower your cholesterol, such as colestipol or cholestyramine (resin-type lipid-lowering medicines)
- calcium or vitamin D supplements
- anticholinergic agents such as atropine and biperiden
- 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)
- medicines to treat cancer
- steroids such as prednisolone
- pituitary hormone (ACTH)
- medicines for diabetes (tablets or insulin)
- laxatives
- amphotericin (for the treatment of fungal infections)
- carbenoxolone (for treatment of oesophageal disease, or oral ulcers)
- penicillin or co-trimoxazole also known as trimethoprim/sulfamethoxazole (antibiotic medicines)
- 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), amifostin (used in cancer treatment) and some antipsychotic medicines.

Catasart Plus with food and drink and alcohol

- You can take Catasart Plus with or without food.
- When you are prescribed Catasart Plus, 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 Plus before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Catasart Plus. Catasart Plus 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 Plus 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 Plus. If this happens to you, do not drive or use any tools or machines.

Catasart Plus 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 Plus 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 Plus

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 Plus every day.

The recommended dose of Catasart Plus 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.

If you take more Catasart Plus than you should

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

If you forget to take Catasart Plus

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 Plus

If you stop taking Catasart Plus, your blood pressure may increase again. Therefore, do not stop taking Catasart Plus 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 Catasart Plus are caused by candesartan cilexetil and some are caused by hydrochlorothiazide.

Stop taking Catasart Plus 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).

Also stop taking Catasart Plus and seek medical help immediately if you develop acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion) – this is a very rare side effect (may affect up to 1 in 10,000 people).

Catasart Plus 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 Plus 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 heartbeat
- 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.

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
- 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)

- sudden short-sightedness
- decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)
- systemic and cutaneous lupus erythematosus (allergic condition which causes fever, joint pain, skin rashes which may include redness, blistering, peeling and lumps)
- skin and lip cancer (non-melanoma skin cancer).

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 the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Catasart Plus

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 on the bottle/blister 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 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 Catasart Plus contains

The active substances are candesartan cilexetil and hydrochlorothiazide.

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

The other ingredients are lactose monohydrate, (maize) starch, povidone K30, carrageenan (E407), croscarmellose sodium, magnesium stearate, iron oxide, red (E172) and iron oxide, yellow (E172).

What Catasart Plus looks like and contents of the pack

Apricot, mottled, oval biconvex tablet, scored on both sides.

The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Al/Al Blister with desiccant: 7, 10, 14, 20, 28, 30, 56 or 98 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, SI-1526 Ljubljana, Slovenia.

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

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

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

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

Austria:	Candesartan-HCT Hexal 16 mg/12,5 mg – Tabletten
Germany:	Candesartan HEXAL comp
Ireland:	Catasart Plus 16 mg/12.5 mg Tablets
Italy:	CANDESARTAN CILEXETIL IDROCLOROTIAZIDE HEXAL 16 mg + 12.5 MG compresse
Spain:	Candesartan/ Hidroclorotiazida Bexal 16/12,5 mg comprimidos EFG

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