

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cozatan 50mg Film-coated Tablets Cozatan 100mg Film-coated Tablets

Losartan potassium

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

1. WHAT COZATAN IS AND WHAT IT IS USED FOR

Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Cozatan is used

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6–18 years of age.
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 0.5 g per day (a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilised with an ACE inhibitor you should not be switched to losartan.
- in patients with high blood pressure and a thickening of the left ventricle, Cozatan has been shown to decrease the risk of stroke (“LIFE indication”).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE COZATAN

Do not take Cozatan

- if you are allergic to losartan or any of the other ingredients of this medicine (listed in section 6)
- if your liver function is severely impaired
- if you are more than 3 months pregnant. (It is also better to avoid Cozatan in early pregnancy – see also “Pregnancy and breast-feeding”)
- 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 Cozatan.

You must tell your doctor if you think you are (or might become) pregnant. Cozatan 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 also “Pregnancy and breast-feeding”.

It is important to tell your doctor before taking **Cozatan**:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 ‘Possible side effects’),
- if you suffer from excessive vomiting or diarrhoea leading to an extreme loss of fluid and/or salt in your body,
- if you receive diuretics (medicines that increase the amount of water that you pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 ‘Dosage in special patient groups’),
- if you are known to have narrowing or blockage of the blood vessels leading to your kidneys or if you have received a kidney transplant recently,
- if your liver function is impaired (see sections 2 “Do not take Losartan” and 3 “Dosage in special patient groups”),
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a β -blocker concomitantly,
- if you have problems with your heart valves or heart muscle,
- if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain),
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- 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

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 Cozatan”

Children and adolescents

Cozatan has been studied in children. For more information, talk to your doctor.

Other medicines and Cozatan

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

Take particular care if you are taking the following medicines while under treatment with Cozatan:

- other blood pressure lowering medicines as they may additionally reduce your blood pressure. Blood pressure may also be lowered by one of the following drugs/class of drugs: tricyclic antidepressants (to treat depression), antipsychotics (to treat psychiatric disorders), baclofen (muscle relaxer), amifostine (used in cancer chemotherapy),
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamterene, spironolactone] or heparin),
- non-steroidal anti-inflammatory drugs such as indometacin, including cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan.

If your kidney function is impaired, the concomitant use of these medicines may lead to a worsening of the kidney function.

Lithium containing medicines should not be taken in combination with losartan without close

supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Cozatan” and “Warnings and precautions”)

Cozatan with food

Cozatan may be taken with or without food.

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 Cozatan before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Cozatan.

Cozatan 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. Cozatan 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

No studies on the effects on the ability to drive and use machines have been performed.

Cozatan is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities.

Cozatan contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE COZATAN

Always take Cozatan exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will decide on the appropriate dose of Cozatan, depending on your condition and whether you are taking other medicines. It is important to continue taking Cozatan for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

General dosage recommendations

Cozatan film-coated tablets are available in 2 strengths: 50 mg and 100 mg.

Cozatan 50 mg

If your doctor has told you to take a lower dose of Cozatan 50 mg, the film-coated tablets can be broken on the cross-score breaking notches into either two pieces, each of which will contain 25 mg of losartan, or four pieces, each of which will contain 12.5 mg losartan.

Cozatan 100 mg

If your doctor has told you to take a lower dose of Cozatan 100 mg, the film-coated tablets can be broken on the breaking notch into two pieces, each of which will contain 50 mg of losartan.

Adult patients with high blood pressure

Treatment usually starts with 50 mg losartan (one tablet Cozatan 50 mg) (½ tablet Cozatan 100 mg) once a day. The maximal blood pressure lowering effect should be reached 3–6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg losartan (two tablets Cozatan 50 mg) (1 tablet Cozatan 100 mg) once daily.

If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

Use in children and adolescents (6 to 18 years old)

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day (up to 25 mg of losartan). The doctor may increase the dose if blood pressure is not controlled.

Adult patients with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg losartan (one tablet Cozatan 50 mg) (½ tablet Cozatan 100 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets Cozatan 50 mg) (1 tablet Cozatan 100 mg) once daily depending on your blood pressure response.

Losartan tablets may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

Adult patients with heart failure

Treatment usually starts with 12.5 mg losartan (¼ tablet Cozatan 50 mg) once a day.

Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week) up to the usual maintenance dose of 50 mg losartan (one tablet Cozatan 50 mg) (½ tablet Cozatan 100 mg) once daily, according to your condition.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

Dosage in special patient groups

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. Losartan must not be used in patients with severe hepatic impairment (see section “Do not take Cozatan”).

Administration

The tablets should be swallowed with a glass of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take Cozatan until your doctor tells you otherwise.

If you take more Cozatan than you should

If you accidentally take too many tablets, or a child swallows some, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you forget to take Cozatan

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten tablet.

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.

If you experience the following, stop taking losartan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which may affect up to 1 in 1,000 people. You may need urgent medical attention or hospitalisation.

The following side effects have been reported with losartan:

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

- dizziness/feeling of abnormal motion (vertigo),
- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics)
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position
- debility
- fatigue
- too little sugar in the blood (hypoglycaemia)
- too much potassium in the blood (hyperkalaemia)
- changes in kidney function including kidney failure
- reduced number of red blood cells (anaemia)
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure

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

- somnolence
- headache
- sleep disorders
- feeling of increased heart rate (palpitations)
- severe chest pain (angina pectoris)
- shortness of breath (dyspnoea)
- abdominal pain
- obstipation
- diarrhoea,
- nausea
- vomiting
- hives (urticaria)
- itching (pruritus)
- rash
- localised swelling (oedema)
- cough

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

- hypersensitivity
- angioedema (serious allergic reaction which causes swelling, especially of the face, mouth, tongue or throat)
- inflammation of blood vessels (vasculitis including Henoch-Schonlein purpura)
- numbness or tingling sensation (paraesthesia)
- fainting (syncope)
- very rapid and irregular heartbeat (atrial fibrillation)
- brain attack (stroke)
- inflammation of the liver (hepatitis)
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment

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

- reduced number of thrombocytes (thrombocytopenia)
- migraine
- liver function abnormalities
- muscle and joint pain
- flu-like symptoms
- back pain and urinary tract infection
- increased sensitivity to the sun (photosensitivity)
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- impotence
- inflammation of the pancreas (pancreatitis)
- low levels of sodium in the blood (hyponatraemia)
- depression
- generally feeling unwell (malaise)
- ringing, buzzing, roaring, or clicking in the ears (tinnitus)
- disturbed taste (dysgeusia)

Side effects in children are similar to those seen in adults.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC 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 COZATAN

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

Do not store above 30°C. Store Cozatan in the original package.

Do not open the blister pack until you are ready to take the medicine.

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 Cozatan contains

The active substance is losartan potassium.

Each Cozatan 50 mg tablet contains 50 mg of losartan potassium.

Each Cozatan 100 mg tablet contains 100 mg of losartan potassium.

The other ingredients in the tablet core are lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch and colloidal anhydrous silica.

The ingredients in the tablet film-coating are hypromellose, titanium dioxide E171, macrogol 400 and carnauba wax.

What Cozatan looks like and contents of the pack

Cozatan 50 mg film-coated tablets are white round biconvex film-coated tablets with a cross-score breaking notch on both sides. The film-coated tablet can be divided into equal doses.

Cozatan 100 mg film-coated tablets are white oblong biconvex film-coated tablets with breaking notch

on both sides. The film-coated tablet can be divided into equal doses.

Cozatan is supplied in the following pack sizes:

Cozatan 50 mg - PVC/PVDC blister packs of 10, 10x1 (single dose unit), 28, 28x1 (single dose unit), 30, 30x1 (single dose unit), 50, 50x1 (single dose unit), 60, 60x1 (single dose unit), 90, 90x1 (single dose unit), 98, 98x1 (single dose unit), 120 or 120x1 (single dose unit) film-coated tablets.

Cozatan 100 mg - PVC/PVDC blister packs of 10, 10x1 (single dose unit), 28, 28x1 (single dose unit), 30, 30x1 (single dose unit), 60, 60x1 (single dose unit), 98, 98x1 (single dose unit), 120 or 120x1 (single dose unit) film-coated 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:

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

| | |
|-----------------|---|
| Austria | Losartan STADA 50 mg and 100 mg – Filmtabletten |
| Denmark | Losarstad 12.5 mg, 50 mg and 100 mg fillovertrukne tabletter |
| Finland | Losarstad 12.5 mg, 50 mg and 100 mg kalvopäällysteiset tabletit |
| Ireland | Cozatan 50 mg and 100 mg film-coated tablets |
| Slovak Republic | Losartan STADA 50 mg, filmom obalené tablety |
| Sweden | Losarstad 12.5 mg, 50 mg and 100 mg filmdragerade tabletter |

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