

Package leaflet: Information for the user

Cozatan Comp 50mg/12.5mg Film-coated Tablets Cozatan Comp 100mg/25mg Film-coated Tablets

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

1. What Cozatan Comp is and what it is used for

Cozatan Comp is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). 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. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

Cozatan Comp is indicated for the treatment of essential hypertension (high blood pressure).

2. What you need to know before you take Cozatan Comp

DO NOT take Cozatan Comp

- if you are allergic to losartan, hydrochlorothiazide or any of the other ingredients of this medicine (listed in section 6),
- if you are allergic to other sulfonamide-derived substances (e.g. other thiazides, some antibacterial drugs such as co-trimoxazole, ask your doctor if you are not sure),
- if you have severely impaired liver function,
- if you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment,
- if you are suffering from gout,
- if you are more than 3 months pregnant. (It is also better to avoid Cozatan Comp in early pregnancy - see Pregnancy section),
- if you have severely impaired kidney function or your kidneys are not producing any urine,
- if you have diabetes or impaired kidney function and are taking a medicine called aliskiren to reduce blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cozatan Comp.

You must tell your doctor if you think you are (or might become) pregnant. Cozatan Comp 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).

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

- if you have previously suffered from swelling of the face, lips, throat or tongue (angioedema)
- if you take diuretics (water pills)
- if you are on a salt-restricted diet
- if you have or have had severe vomiting and/or diarrhoea
- if you have heart failure
- if your liver function is impaired (see section 2 “Do not take Cozatan Comp)
- if you have narrow arteries to your kidneys (renal artery stenosis) or only have one functioning kidney, or you have recently had a kidney transplant
- if you have narrowing of the arteries (atherosclerosis), angina pectoris (chest pain due to poor heart function)
- if you have ‘aortic or mitral valve stenosis’ (narrowing of the valves of the heart) or ‘hypertrophic cardiomyopathy’ (a disease causing thickening of heart muscle)
- if you are diabetic
- if you have had gout
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus).
- if you have high calcium or low potassium levels or you are on a low potassium diet
- if you need to have an anaesthetic (even at the dentist) or before surgery, or if you are going to have tests to check your parathyroid function, you must tell the doctor or medical staff that you are taking losartan potassium and hydrochlorothiazide tablets.
- 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
- if 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 Cozatan Comp.
- if 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 Cozatan Comp. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.
- if 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 Cozatan Comp, seek medical attention immediately.

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 Comp”.

Children and adolescents

There is no experience with the use of Cozatan Comp in children. Therefore, Cozatan Comp should not be given to children.

Other medicines and Cozatan Comp

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

Diuretic agents such as the hydrochlorothiazide contained in Cozatan Comp may interact with other medicines.

Preparations containing lithium should not be taken with Cozatan Comp without close supervision by your doctor.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics (“water tablets”), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking:

- other medicines to reduce your blood pressure,
- steroids,
- medicines to treat cancer,
- pain killers,
- drugs for treatment of fungal infections,
- arthritis medicines,
- resins used for high cholesterol, such as colestyramine,
- medicines which relax your muscles,
- sleeping tablets,
- opioid medicines such as morphine,
- ‘pressor amines’ such as adrenaline or other drugs from the same group,
- oral agents for diabetes or insulins.

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 Comp” and “Warnings and precautions”)

Please also inform your doctor you are taking Cozatan Comp if you will be undergoing a radiographic procedure and will be given iodine contrast media.

Cozatan Comp with food, drink and alcohol

You are advised not to drink alcohol whilst taking these tablets: alcohol and Cozatan Comp tablets may increase each other’s effects.

Dietary salt in excessive quantities may counteract the effect of Cozatan Comp tablets.

Cozatan Comp tablets 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 Comp before you become **pregnant** or as soon as you know you are pregnant and will advise you to take another medicine instead of Cozatan Comp. Cozatan Comp 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. Cozatan Comp is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed.

Use in elderly patients

Cozatan Comp works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

Driving and using machines

When you begin treatment with this medication, you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how

you tolerate your medicine.

Cozatan Comp 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 Comp

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

High Blood Pressure

The usual dose of Cozatan Comp for most patients with high blood pressure is 1 tablet of Cozatan Comp 50 mg/12.5 mg once daily to control blood pressure over 24-hour period. This can be increased to 2 tablets once daily of Cozatan Comp 50 mg/12.5 mg or changed to 1 tablet daily of Cozatan Comp 100 mg/25 mg (a stronger strength) daily. The maximum daily dose is 2 tablets per day of Cozatan Comp 50 mg/12.5 mg or 1 tablet daily of Cozatan Comp 100 mg/25 mg.

You should swallow the tablets or tablet halves whole, not chewed, with a glass of water. You may take the tablets with or without food.

Cozatan Comp film-coated tablets are available in 2 strengths: Cozatan Comp 50 mg/12.5 mg and 100 mg/25 mg.

If you take more Cozatan Comp than you should

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdosage can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take Cozatan Comp

Try to take Cozatan Comp daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

If you stop taking Cozatan Comp

You should never stop the treatment on your own initiative unless you suspect a serious side effect. In any case, you should immediately consult 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.

If you experience the following, stop taking Cozatan Comp 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.

Muscle pain, tenderness, weakness, or cramps. On rare occasions, these muscle problems can be serious, including muscle breakdown resulting in kidney damage.

Acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion). This is a serious but very rare side effect, which may affect up to 1 in 10,000 people.

The following side effects have been reported:

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

- Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder
- Diarrhoea, abdominal pain, nausea, indigestion
- Muscle pain or cramps, leg pain, back pain
- Insomnia, headache, dizziness
- Weakness, tiredness, chest pain
- Increased potassium levels (which can cause an abnormal heart rhythm)
- Decreased haemoglobin and haematocrit levels
- Changes in kidney function including kidney failure
- Too low sugar in the blood (hypoglycaemia)

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

- Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems and reduced number of platelets
- Loss of appetite, increased uric acid and blood urea levels or frank gout, increased blood sugar levels, abnormal blood electrolyte levels
- Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment
- Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting
- Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow
- Ringing, buzzing, roaring or clicking in the ears, vertigo
- Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, “mini-stroke”), heart attack, palpitations
- Inflammation of blood vessels, which is often associated with a skin rash or bruising
- Sore throat/inflammation of the pharynx, inflammation of the larynx, breathlessness, bronchitis, respiratory disease including pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion
- Constipation, obstipation, wind, stomach upsets and inflammation (gastritis), stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas
- Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin, flushing, sweating, hair loss, severe skin reaction characterised by blistering and peeling of the top layer of skin
- Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness, joint inflammation, chronic widespread pain (fibromyalgia)
- Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary tract infection, sugar in the urine
- Decreased sexual appetite, impotence
- Swelling of the face, localised swelling (oedema), fever

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

- Hepatitis (inflammation of the liver), abnormal liver function tests
- Severe allergic (anaphylactic) reactions

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

- Muscle breakdown
- Flu-like symptoms
- Unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- Low levels of sodium in the blood (hyponatraemia)
- Generally feeling unwell (malaise)
- Disturbed taste (dysgeusia)
- Skin and lip cancer (non-melanoma skin cancer)

- 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)

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

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cozatan Comp

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

Do not store above 30°C.

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 Comp contains

The active substances are losartan potassium and hydrochlorothiazide.

Cozatan Comp 50 mg/12.5 mg contains 50 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

Cozatan Comp 100 mg/25 mg contains 100 mg of losartan potassium and 25 mg of hydrochlorothiazide as the active ingredients.

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

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

What Cozatan Comp looks like and contents of the pack

Cozatan Comp 50 mg/12.5 mg film-coated tablets are white, round tablets.

Cozatan Comp is available in plastic/aluminium blister.

Pack sizes of 7, 7x1 (single dose unit), 14, 14x1 (single dose unit), 28, 28x1 (single dose unit), 30, 30x1 (single dose unit), 56, 56x1 (single dose unit), 60, 60x1 (single dose unit), 90, 90x1 (single dose unit), 98, 98x1 (single dose unit), 112, 112x1 (single dose unit), 120, 120x1 (single dose unit), 126, 126x1 (single dose unit), 154, 154x1 (single dose unit), 196 and 196x1 (single dose unit) film-coated tablets

Cozatan Comp 100 mg/25 mg film-coated tablets are white, oblong tablets with a score line. The tablet can be divided into two equal doses.

Cozatan Comp is available in plastic/aluminium blister.

Pack sizes of 10, 10x1 (single dose unit), 28, 28x1 (single dose unit), 30, 30x1 (single dose unit), 56, 56x1 (single dose unit), 60, 60x1 (single dose unit), 98, 98x1 (single dose unit), 112, 112x1 (single dose unit), 120 and 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 authorised in the Member States of the EEA under the following names:

Belgium:	Losartan Plus EG 50 mg/12,5 mg filmomhulde tabletten
Belgium:	Losartan Plus Forte EG 100 mg/25 mg filmomhulde tabletten
Bulgaria:	TORES
Denmark:	Losarstad Comp
Finland:	Losarstad Comp 50 mg/12.5 mg tabletti, kalvipäällysteinen
Finland:	Losarstad Comp 100 mg/25 mg tabletti, kalvipäällysteinen
Germany:	Losartan/HCT STADA 50 mg/12,5 mg Filmtabletten
Germany:	Losartan/HCT STADA 100 mg/25 mg Filmtabletten
Ireland:	Cozatan Comp 50 mg/12.5 mg film-coated tablets
Ireland:	Cozatan Comp 100 mg/25 mg film-coated tablets
Italy:	Losartan e Idroclorotiazide EG 50/12.5 mg compresse rivestite con film
Italy:	Losartan e Idroclorotiazide EG 100/25 mg compresse rivestite con film
Luxembourg:	Losartan Plus EG 50 mg/12,5 mg comprimés pelliculés
Luxembourg:	Losartan Plus Forte EG 100 mg/25 mg comprimés pelliculés
Norway:	Losarstad Comp 100/25 mg tablett, filmdrasjerte
Slovak Republic:	Losartan/Hydrochlorothiazid STADA 50 mg/12.5 mg filmom obalené tablety
Slovak Republic:	Losartan/Hydrochlorothiazid STADA 100 mg/25 mg filmom obalené tablety
Sweden:	Losarstad Comp filmdragerade tablett

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