

Package leaflet: Information for the patient

COZAAR® COMP 50 mg/12.5 mg film-coated tablets COZAAR® COMP 100 mg/12.5 mg film-coated tablets COZAAR® COMP 100 mg/25 mg 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, pharmacist or nurse.
- 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, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What COZAAR COMP is and what it is used for

Cozaar 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.

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

2. What you need to know before you take COZAAR COMP

Do not take Cozaar Comp

- if you are allergic to losartan, hydrochlorothiazide or to 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 Cozaar 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 you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cozaar 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 Cozaar 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.

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

- 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 Cozaar Comp, seek medical attention immediately.
- if you have previously suffered from swelling of the face, lips, throat or tongue;
- 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 Cozaar 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.

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 Cozaar Comp**".

- if you are taking other medicines that may increase serum potassium (see section 2 "Other medicines and Cozaar Comp");
- 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 Cozaar Comp.

Children and adolescents

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

Other medicines and Cozaar Comp

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

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines, or other medicines that may increase serum potassium (e.g., trimethoprim-containing medicines), as the combination with Cozaar Comp is not advisable.

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

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

Special precautionary measures (e.g. blood tests) may be appropriate if you take 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 Cozaar Comp**" and "**Warnings and precautions**")

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

Cozaar Comp with food and drink

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

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

Cozaar Comp tablets may be taken with or without food.

Grapefruit juice should be avoided while taking Cozaar Comp tablets.

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

Cozaar 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.

Cozaar 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 COZAAR COMP

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the appropriate dose of Cozaar Comp depending on your condition and whether you are taking other medicines. It is important to continue taking Cozaar 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 Cozaar Comp for most patients with high blood pressure is 1 tablet of Cozaar Comp 50 mg/12.5 mg per day to control blood pressure over the 24-hour period. This can be increased to 2 tablets once daily of Losartan / Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or changed to 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets (a stronger strength) per day. The maximum daily dose is 2 tablets per day of Losartan / Hydrochlorothiazide 50 mg/12.5 mg Film-Coated Tablets or 1 tablet daily of Losartan / Hydrochlorothiazide 100 mg/25 mg Film-Coated Tablets.

Administration

The tablets should be swallowed whole with a glass of water.

If you take more Cozaar Comp than you should

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

If you forget to take Cozaar Comp

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

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 Cozaar 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 affects more than 1 out of 10,000 patients but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

Very rare (may affect up to 1 in 10,000 people):

acute respiratory distress (signs include severe shortness of breath, fever, weakness, and confusion).

Other side effects that may occur:

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 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, reduced number of platelets;
- loss of appetite, increased uric acid 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, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion;
- constipation, obstipation, wind, stomach upsets, 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;
- pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness;
- 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.

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

- 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, pharmacist or nurse. 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 COZAAR 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 blister and outer carton after EXP.

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

Do not store above 30 °C.

Store in the original package in order to protect from light and 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 COZAAR COMP contains:

The active substances are losartan potassium and hydrochlorothiazide.

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

Cozaar Comp 100 mg/12.5 mg contains 100 mg of losartan potassium and 12.5 mg of hydrochlorothiazide as the active ingredients.

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

Cozaar Comp 50 mg/12.5 mg and Cozaar Comp 100 mg/25 mg also contain the following excipients: hydroxypropyl cellulose (E463), hypromellose (E464), lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), pregelatinised maize starch, titanium dioxide (E171), quinoline yellow aluminum lake (E104) and carnauba wax (E903).

Cozaar Comp 100 mg/12.5 mg also contain the following excipients: hydroxypropyl cellulose (E463), hypromellose (E464), lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), pregelatinised maize starch, titanium dioxide (E171) and carnauba wax (E903).

What Cozaar Comp looks like and contents of the pack

Cozaar Comp 50 mg/ 12.5 mg are yellow, oval-shaped, film-coated tablets marked '717' on one side and plain or scored on the other side. The score line is not intended for breaking the tablet.

Cozaar Comp 100 mg/12.5 mg are white, oval, film-coated tablets marked '745' on one side and plain on the other side.

Cozaar Comp 100 mg/ 25 mg are yellow, oval, film-coated tablets marked '747' on one side.

Cozaar Comp 50 mg/ 12.5 mg & 100 mg/12.5 mg & 100 mg/ 25 mg film-coated tablets are supplied in PVC/PE/PVDC blister packages with aluminium foil lidding in an outer carton containing 28 tablets.

Product procured within the EU, repackaged and distributed by the Parallel Product

Authorisation Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem, The Netherlands or Schering-Plough Labo NV, Industriepark 30, Heist-op-den-Berg, 2220, Belgium.

PARALLEL PRODUCT AUTHORISATION NUMBERS:

COZAAR COMP 50 mg/12.5 mg – PPA0465/109/001

COZAAR COMP 100 mg/12.5 mg – PPA0465/109/004

COZAAR COMP 100 mg/ 25 mg – PPA0465/109/002

Cozaar is a registered trademark of Merck Sharp & Dohme Corp.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium	COZAAR PLUS 50 mg/12,50 mg comprimés pelliculés; COZAAR PLUS 100 mg/12,50 mg comprimés pelliculés; COZAAR PLUS FORTE 100 mg/25 mg comprimés pelliculés,
Denmark	Cozaar Comp., Cozaar Comp Forte, Cozaar Comp 100 mg / 12,5 mg
Finland	COZAAR Comp; COZAAR Comp Forte
France	FORTZAAR 100 mg/25 mg comprimé pelliculé; HYZAAR 50 mg/12,5 mg comprimé pelliculé, FORTZAAR 100 mg/12,5 mg comprimé pelliculé
Germany	LORZAAR PLUS 50/12,5 mg Filmtabletten; FORTZAAR 100/25 mg Filmtabletten; LORZAAR PLUS forte 100/12,5 mg Filmtabletten
Greece	HYZAAR; HYZAAR Forte; HYZAAR Extra Forte
Hungary	HYZAAR
Iceland	Cozaar Comp; Cozaar Comp 100 mg/12,5 mg; Cozaar Comp Forte
Ireland	COZAAR Comp 50 mg/12.5 mg film-coated tablets; COZAAR Comp 100 mg/12.5 mg film-coated tablets; COZAAR Comp 100 mg/25 mg film-coated tablets
Italy	HIZAAR 50 mg + 12,5 mg compresse rivestite con film; HIZAAR 100 mg + 25 mg compresse rivestite con film; FORZAAR 100 mg + 25 mg compresse rivestite con film
Luxembourg	COZAAR PLUS FORTE 100 mg/25 mg comprimés pelliculés; COZAAR PLUS 50 mg/12,5 mg comprimés pelliculés; COZAAR PLUS 100 mg/12,50 mg comprimés pelliculés
Netherlands	COZAAR Plus 100/12,5; FORTZAAR 100/25; HYZAAR 50/12,5
Norway	Cozaar Comp; Cozaar Comp Forte
Poland	HYZAAR; HYZAAR FORTE
Portugal	Cozaar Plus; Fortzaar
Spain	COZAAR Plus 50 mg/12,5 mg comprimidos recubiertos con película; FORTZAAR 100 mg/25 mg comprimidos recubiertos con película
Sweden	COZAAR Comp 50 mg/12,5 mg filmdragerade tabletter; COZAAR Comp 100 mg/12,5 mg filmdragerade tabletter; COZAAR Comp Forte 100 mg/ 25 mg filmdragerade tabletter
United Kingdom (Northern Ireland)	COZAAR COMP 50 mg/12.5 mg film-coated tablets; COZAAR Comp 100 mg/25 mg film-coated tablets; COZAAR Comp 100 mg/12.5 mg film-coated tablets

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