Package leaflet: Information for the user

Cozaar® 12.5 mg film-coated tablets
Cozaar® 50 mg film-coated tablets
Cozaar® 100 mg 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, 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 is and what it is used for

Losartan (COZAAR) 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.

COZAAR 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, COZAAR has been shown to decrease the risk of stroke ("LIFE indication").

2. What you need to know before you take COZAAR

Do not take COZAAR:
- if you are allergic to losartan or to any of the other ingredients of this medicine (listed in section 6),
- if you are more than 3 months pregnant (It is also better to avoid COZAAR in early pregnancy - see Pregnancy),
- if your liver function is severely impaired,

- 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.

You must tell your doctor if you think you are (or might become) pregnant. COZAAR 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**:
- 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 COZAAR**" 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 ß-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 COZAAR**".
- if you are taking other medications that may increase serum potassium (see section 2 **"Other medicines and COZAAR"**).

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

Children and adolescents
COZAAR has been studied in children. For more information, talk to your doctor.

COZAAR is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. COZAAR is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Other medicines and COZAAR
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 such as certain diuretics (amiloride, triamteren, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with COZAAR is not advisable.

Take particular care if you are taking the following medicines while under treatment with COZAAR:
- 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, antipsychotics, baclofen, amifostine,
- non-steroidal anti-inflammatory drugs such as indomethacin, 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.

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**" and "**Warnings and precautions**").

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.

COZAAR with food and drink
COZAAR may be taken with or without food.

Grapefruit juice should be avoided while taking COZAAR.

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 before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COZAAR. COZAAR 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. COZAAR 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 a new-born, or born prematurely.

Ask your doctor or pharmacist for advice before taking this medicine.

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

COZAAR 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.

COZAAR contains lactose
COZAAR contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take COZAAR

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, depending on your condition and whether you are taking other medicines. It is important to continue taking COZAAR for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

Adult patients with High Blood Pressure
Treatment usually starts with 50 mg losartan (one tablet COZAAR 50 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 COZAAR 50 mg or one tablet of COZAAR 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

Children below 6 years of age
COZAAR is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

Children aged 6 - 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 COZAAR). The doctor may increase the dose if blood pressure is not controlled.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Adult patients with high blood pressure and Type 2 diabetes
Treatment usually starts with 50 mg losartan (one tablet COZAAR 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets COZAAR 50 mg or one tablet of COZAAR 100 mg) once daily depending on your blood pressure response.

Losartan 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 (one tablet COZAAR 12.5 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, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150 mg losartan (for example, three tablets of COZAAR 50 mg or one tablet each of COZAAR 100 mg and COZAAR 50 mg) once daily may be used.

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. The use of losartan is not recommended in patients with severe hepatic impairment (see section "Do not take COZAAR").

Administration
The tablets should be swallowed whole 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 COZAAR until your doctor tells you otherwise.

If you take more COZAAR than you should
If you accidentally take too many tablets, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

If you forget to take COZAAR
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, pharmacist, or nurse.

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 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.

The following side effects have been reported with COZAAR:

Common (may affect up to 1 in 10 people):
- dizziness,
- 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,
- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea,
- inflammation of blood vessels (vasculitis including Henoch-Schönlein 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,
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store COZAAR

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

Blisters:

Store COZAAR in the original package in order to protect from light and moisture.
Do not open the blister pack until you are ready to take the medicine.

Bottles:
Store COZAAR in the original container in order to protect from light.
Do not store above 25ºC. Keep the bottle tightly closed 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 COZAAR contains

The active substance is losartan potassium.
Each COZAAR 12.5 mg tablet contains 12.5 mg of losartan potassium.
Each COZAAR 50 mg tablet contains 50 mg of losartan potassium.
Each COZAAR 100 mg tablet contains 100 mg of losartan potassium.

The other ingredients are microcrystalline cellulose (E460), lactose monohydrate, pregelatinised maize starch, magnesium stearate (E572), hyprolose (E463), hypromellose (E464).

COZAAR 12.5 mg, 50 mg and 100 mg contain potassium in the following amounts: 1.06 mg (0.027 mEq), 4.24 mg (0.108 mEq) and 8.48 mg (0.216 mEq) respectively.

The COZAAR 12.5 mg tablets also contain carnauba wax (E903), titanium dioxide (E171) and indigo carmine (E132) aluminium lake.
The COZAAR 50 mg tablets also contain carnauba wax (E903) and titanium dioxide (E171).
The COZAAR 100 mg tablets also contain carnauba wax (E903) and titanium dioxide (E171).

What COZAAR looks like and contents of the pack

COZAAR 12.5 mg is supplied as unscored film-coated tablets containing 12.5 mg of losartan potassium.
COZAAR 50 mg is supplied as scored film-coated tablets containing 50 mg of losartan potassium. The score line is not intended for breaking the tablet.
COZAAR 100 mg is supplied as unscored film-coated tablets containing 100 mg of losartan potassium.

COZAAR is supplied in the following pack sizes:

- COZAAR 12.5 mg - PVC/PE/PVDC blister packages with aluminium foil lidding in packs of 7, 14, 21, 28, 50, 98, 210 or 500 tablets and a unit-dose package of 28 tablets for hospital use. HDPE bottles of 100 tablets.
- COZAAR 50 mg - PVC/PE/PVDC blister packages with aluminium foil lidding in packs of 7, 10, 14, 20, 28, 30, 50, 56, 84, 90, 98, 280 or 500 tablets and unit-dose packages of 28, 56 and 98 tablets for hospital use. HDPE bottles of 100 or 300 tablets.
- COZAAR 100 mg - PVC/PE/PVDC blister packages with aluminium foil lidding in packs of 7, 10, 14, 15, 20, 28, 30, 50, 56, 84, 90, 98 or 280 tablets and unit-dose packages of 28, 56 and 98 tablets for hospital use. HDPE bottles of 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Organon Pharma (UK) Limited, Shotton Lane, Cramlington, United Kingdom, NE23 3JU.

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

Member State	Invented name
Austria	Cosaar 12,5 mg - Filmtabletten
Austria	Cosaar 50 mg - Filmtabletten
Austria	Cosaar 100 mg - Filmtabletten
Belgium	COZAAR 12,5 mg
Belgium	COZAAR 50 mg
Belgium	COZAAR 100 mg
Bulgaria	COZAAR 12,5 mg film-coated tablets
Cyprus	COZAAR
Czech Republic	COZAAR 50 mg
Czech Republic	COZAAR 100 mg
Denmark	Cozaar
Finland	Cozaar 12,5 mg kalvopäällysteiset tabletit
Finland	Cozaar 50 mg kalvopäällysteiset tabletit
Finland	Cozaar 100 mg kalvopäällysteiset tabletit
France	COZAAR 50 mg scored coated tablets
France	COZAAR 100 mg film-coated tablets
Germany	LORZAAR PROTECT 100 mg Filmtabletten
Germany	LORZAAR PROTECT 50 mg Filmtabletten
Germany	LORZAAR START 12,5 mg Filmtabletten
Greece	COZAAR
Hungary	COZAAR
Iceland	COZAAR
Ireland	COZAAR 12.5mg film-coated tablets
Ireland	COZAAR 50 mg film-coated tablets
Ireland	COZAAR 100 mg film-coated tablets
Italy	LORTAAN 12,5 mg compresse rivestite con film
Italy	LORTAAN 50 mg compresse rivestite con film
Italy	LORTAAN 100 mg compresse rivestite con film
Luxembourg	COZAAR 12,5 mg
Luxembourg	COZAAR 50 mg
Luxembourg	COZAAR 100 mg
Malta	COZAAR 12,5 mg film-coated tablets
Malta	COZAAR 50 mg film-coated tablets
Malta	COZAAR 100 mg film-coated tablets
Netherlands	COZAAR 12,5 mg
Netherlands	COZAAR 50 mg
Netherlands	COZAAR 100 mg
Norway	Cozaar
Poland	COZAAR
Portugal	Cozaar
Portugal	Cozaar 100 mg
Portugal	Cozaar IC
Spain	COZAAR 12,5 mg Inicio comprimidos recubiertos con película
Spain	COZAAR 50 mg comprimidos recubiertos con película
Spain	COZAAR 100 mg comprimidos recubiertos con película
Sweden	COZAAR 12,5 mg filmdragerade tabletter
Sweden	COZAAR 50 mg filmdragerade tabletter

Member State	**Invented name**
Sweden	COZAAR 100 mg filmdragerade tabletter
United Kingdom (Northern Ireland)	COZAAR 12,5 mg film-coated tablets
United Kingdom (Northern Ireland)	COZAAR 50 mg film-coated tablets
United Kingdom (Northern Ireland)	COZAAR 100 mg film-coated tablets

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