

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

COZAAR® 50 Tablet

COZAAR® 100 Tablet

Losartan (as losartan potassium)

Contains sugar:

Each 50 mg film-coated tablet contains 25,5 mg of lactose hydrous

Each 100 mg film-coated tablet contains 51,0 mg of lactose hydrous

Read all of this leaflet carefully before you start taking COZAAR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- COZAAR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What COZAAR is and what it is used for
2. What you need to know before you take COZAAR

3. How to take COZAAR
4. Possible side effects
5. How to store COZAAR
6. Contents of the pack and other information

1. What COZAAR is and what it is used for

COZAAR is an angiotensin II receptor antagonist which lowers blood pressure.

COZAAR also provides kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein in their urine (proteinuria). Kidney disease can be measured by testing the urine for protein.

Your doctor has prescribed COZAAR because you have a condition known as hypertension or high blood pressure, or because you have high blood pressure and type 2 diabetes with protein in the urine.

2. What you need to know before you take COZAAR

Do not take COZAAR if

- you are allergic to any of its ingredients (listed in Contents of the pack and other information)
- you have had angioedema (swelling of the face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking an ACE inhibitor or an angiotensin receptor blocker such as COZAAR
- you have hereditary or idiopathic angioedema
- you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff, and the thickened muscle blocks the flow of blood out of the heart

- you have severe kidney disease
- you have narrowing of the blood vessels to both kidneys, or to a single kidney
- you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart)
- you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride
- you have porphyria
- you take lithium therapy. Concomitant administration with COZAAR may lead to toxic blood concentrations of lithium.
- you have liver disease
- you are pregnant or breastfeeding (see Pregnancy and breastfeeding)
- if you have moderate to severe kidney disease and are prescribed a course of an antibiotic of the fluoroquinolone class for an infection. Ask your doctor what other medicines than COZAAR you should receive to control your blood pressure, or if you should receive a different antibiotic.
- if you have diabetes and are taking the medicine aliskiren to reduce blood pressure.

Warnings and precautions

Talk to your doctor or pharmacist before taking COZAAR if

- you have or have had any medical problems, and any allergies
- you have recently suffered from excessive vomiting or diarrhoea
- you have liver or kidney disease.

Tell your doctor if you are taking other medicines that may increase serum potassium (see Other medicines and COZAAR).

Taking a course of a fluoroquinolone antibiotic with COZAAR can cause acute kidney injury, especially if you have moderate to severe kidney disease, or you are elderly.

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

COZAAR has been studied in a small number of children, treated for a short period. For more information, talk to your doctor.

Other medicines and COZAAR

Always tell your doctor, pharmacist or healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

It is important to tell your doctor if you are taking:

- potassium supplements
- potassium-sparing agents
- salt substitutes containing potassium or other medicines that may increase serum potassium (e.g., trimethoprim-containing products).
- pain and arthritis medicines
- other blood pressure medicines, or lithium (a medicine used to treat a certain kind of depression).

Should your doctor prescribe an antibiotic medicine for an infection, tell them that you are taking COZAAR.

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of COZAAR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

COZAAR with food and drink

Grapefruit juice should be avoided while taking COZAAR.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

The use of COZAAR while you are pregnant, or breastfeeding is contraindicated. COZAAR can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if you plan to become pregnant. If you are pregnant or become pregnant while taking COZAAR, tell your doctor right away.

You should not take COZAAR if you are pregnant or breastfeeding or planning to become pregnant, as it may harm your baby.

Driving and using machines

You should not perform tasks which may require special attention (e.g., driving an automobile or operating dangerous machinery) until you know how you tolerate COZAAR.

It is not always possible to predict to what extent COZAAR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which COZAAR affects them.

COZAAR contains lactose

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

3. How to take COZAAR

Do not share medicines prescribed for you with any other person.

Always take COZAAR 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 COZAAR, depending on your condition and whether you are taking other medicines.

High blood pressure

The usual dose of COZAAR for most patients with high blood pressure is 50 mg taken per day to control blood pressure over the 24-hour period.

Type 2 diabetes with protein in the urine

The usual dose of COZAAR for most patients is 50 mg taken once a day. The dose may be increased to 100 mg taken once daily.

COZAAR can be taken with or without food. For convenience and to help you remember, try to take COZAAR at the same time each day.

Your doctor will tell you how long your treatment with COZAAR will last. Do not stop treatment early. If you have the impression that the effect of COZAAR is too strong or too weak, tell your doctor or pharmacist.

If you take more COZAAR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take COZAAR

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

COZAAR can have side effects.

Not all side effects reported for COZAAR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COZAAR, please consult your healthcare provider for advice.

If any of the following happens, stop taking COZAAR and tell your doctor immediately or go to the casualty department at your nearest hospital:

If you develop an allergic reaction such as swelling of the face, lips and/or tongue which may cause difficulty in breathing or swallowing (angioedema).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to COZAAR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Intestinal angioedema (a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea), dizziness, fatigue, light-headedness, rash or hives, taste alteration, vomiting or increased sensitivity of the skin to sun.

Some patients, especially those with type 2 diabetes with protein in the urine, may also develop increased levels of potassium in their blood. If you have kidney disease and type 2 diabetes with protein in the urine, and/or are taking potassium supplements, potassium-sparing agents or salt substitutes containing potassium, talk to your doctor.

Your doctor or pharmacist has a more complete list. Tell your doctor or pharmacist promptly about these or any other unusual symptoms.

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 to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of COZAAR.

5. How to store COZAAR

Store COZAAR in a dry place at or below 30 °C. If the temperature rises above 30 °C for an extended period of time, you may store COZAAR in the refrigerator.

Keep the container tightly closed. Do not open the blister pack until you are ready to take the medicine.

Store all medicines out of reach of children.

Do not use this medicine after the month and year following EXP.: on the carton. Store in the

original package in order to protect from oxygen.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What COZAAR contains

The active substance is losartan potassium.

COZAAR 50 tablets contains 50 mg of losartan potassium.

COZAAR 100 tablets contains 100 mg of losartan potassium.

The other ingredients are: microcrystalline cellulose, lactose hydrous, pregelatinised starch, magnesium stearate, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, titanium dioxide and carnauba wax.

Although COZAAR contains a very small amount of potassium, it cannot replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow his advice.

What COZAAR looks like and contents of the pack

COZAAR 50 is a white, oval shaped film-coated tablet, scored one side, engraved '952' on the other side.

COZAAR 100 is a white, teardrop-shaped, film-coated tablet with '960' debossed on one side and plain on the other.

COZAAR is supplied in the following pack sizes:

COZAAR 50 Tablets are available in blister packs of 30.

COZAAR 100 Tablets are available in opaque white blister packs of 30.

Holder of Certificate of Registration

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This leaflet was last revised on

30 November 2025

Registration number(s)

COZAAR 50: 29/7.1.3/0268

COZAAR 100: 36/7.1.3/0490

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S-WPPI-OG0954-T-102024, RCN 100004247