

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

COZAAR®

losartan potassium tablets

Read this carefully before you start taking **COZAAR®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **COZAAR®**.

Serious Warnings and Precautions

- COZAAR® should not be used during pregnancy. Taking COZAAR® during pregnancy can cause injury or even death to your baby. If you discover that you are pregnant while taking COZAAR®, stop the medication and contact your healthcare professional as soon as possible.

What is COZAAR® used for?

COZAAR® is used in adults to:

- lower high blood pressure.
- provide kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein in the urine (proteinuria) and high blood pressure.

COZAAR® is used in children (6 to 16 years of age) to:

- lower high blood pressure.

How does COZAAR® work?

COZAAR® is an angiotensin receptor blocker (ARB). It lowers blood pressure. This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking COZAAR® regularly even if you feel fine.

What are the ingredients in COZAAR®?

Medicinal ingredients: losartan potassium.

Non-medicinal ingredients: carnauba wax, corn starch, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose and titanium dioxide.

Although COZAAR® tablets contain potassium, this amount is too small to replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow their advice.

COZAAR® comes in the following dosage forms:

Tablets: 25 mg, 50 mg and 100 mg.

Do not use COZAAR® if:

- you are allergic to losartan potassium or any of the non-medicinal ingredients in COZAAR®.
- you are already taking a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take COZAAR®. Talk about any health conditions or problems you may have, including if you:

- have had an allergic reaction to any drug used to lower blood pressure, including angiotensin converting enzymes (ACE) inhibitors.
- are taking an ACE inhibitor.
- have narrowing of an artery or a heart valve.
- have had a heart attack or stroke.
- are taking a salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of “water pill” that makes your body keep potassium), or other drugs that may increase potassium levels (such as trimethoprim-containing products).
- are on a low salt diet.
- are on dialysis.
- are dehydrated or suffer from excessive vomiting, diarrhea or sweating.
- have difficulty urinating or produce no urine.
- have heart failure.
- have diabetes, liver or kidney disease.
- are pregnant, planning to become pregnant or think you are pregnant
- are breastfeeding or plan to breastfeed

Other warnings you should know about:

Sun exposure: You may become sensitive to the sun while taking COZAAR®. Exposure to sunlight should be minimized until you know how you respond.

Use of anesthesia: If you are about to have a surgery or dental procedure with anesthesia, be sure to tell your healthcare professional that you are taking COZAAR®, as there may be a sudden fall in blood pressure.

Testing and check-ups: During treatment with COZAAR®, your healthcare professional may monitor:

- Your kidney function
- Your blood pressure
- The amount of potassium in your blood
- Your liver function

Driving and using machines: Before doing tasks which require special attention, wait until you know how you respond to COZAAR®. Dizziness, lightheadedness, or fainting can occur especially after the first dose and when the dose is increased.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

- Aliskiren-containing drugs if you have diabetes or kidney disease.

The following may also interact with COZAAR®:

- Other medications used to lower blood pressure such as diuretics.
- Digoxin, a heart medication.

- Lithium used to treat bipolar disease.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Warfarin used to thin the blood and prevent blood clots.
- Antibiotics used to treat bacterial infections, such as rifampin and erythromycin.
- Fluconazole, used to treat fungal infections.
- Phenobarbital, used to treat epilepsy.
- Cimetidine, used to treat heartburn and stomach ulcers.
- Agents increasing serum potassium, such as potassium supplements, salt substitutes containing potassium, a potassium-sparing diuretic (a specific kind of “water pill”) or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
- Grapefruit juice (which should be avoided while taking COZAAR®).

How to take COZAAR®:

- Take COZAAR® exactly as prescribed.
- It is recommended to take your dose at about the same time every day.
- COZAAR® may be taken with or without food, but it should be taken the same way each day.

Usual dose:

High blood pressure:

Adults:

- The usual starting dose is 50 mg once daily. The usual dose range is 50 to 100 mg once daily.

Children (6 to 16 years of age) who can swallow tablets:

- For patients who weigh between 20 kg and less than 50 kg, the recommended dose is 25 mg once daily. The dose can be increased by your healthcare professional to a maximum of 50 mg once daily.
- For patients who weigh 50 kg or more, the starting dose is 50 mg once daily. The dose can be increased by your healthcare professional to a maximum of 100 mg once daily.

Type 2 diabetes patients with protein in the urine and high blood pressure:

Adults:

- The usual starting dose is 50 mg once daily. Your healthcare professional may increase the dose to 100 mg once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much COZAAR®, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double the dose.

What are possible side effects from using COZAAR®?

These are not all the possible side effects you may have when taking COZAAR®. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- diarrhea
- vomiting
- fatigue
- back or leg pain
- muscle cramps
- change in taste
- dizziness
- headache
- rash

COZAAR® can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Increased levels of potassium in the blood: generally feeling unwell, irregular heartbeats and muscle weakness		√	
Low Blood Pressure: dizziness, fainting, light-headedness (may occur when you go from lying or sitting to standing up)	√		
UNCOMMON			
Allergic reaction: difficulty breathing or swallowing, hives, skin rash and swelling of the face, lips, throat or tongue			√
Kidney Disorder: change in frequency of urination, fatigue, nausea, swelling of extremities, vomiting		√	
Liver Disorder: abdominal pain, dark urine, loss of appetite, nausea, vomiting, yellowing of the skin or eyes		√	
RARE			
Rhabdomyolysis: dark brown urine, muscle pain that you cannot		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
explain, muscle tenderness or weakness			
VERY RARE			
Decreased Platelets: bleeding, bruising, fatigue, small purple or red dots under the skin and weakness		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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Storage:

Store COZAAR® at room temperature (15°C-30°C). Keep container tightly closed. Protect from light. Keep out of reach and sight of children.

If you want more information about COZAAR®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer’s website www.organon.ca, or by calling 1-844-820-5468.

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