

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **COZAAR®**

losartan potassium tablets

This Patient Medication Information is written for the person who will be taking **COZAAR**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **COZAAR**, talk to a healthcare professional.

Serious warnings and precautions box

- **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 **COZAAR** is 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 **COZAAR** works:

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.

The ingredients in **COZAAR** are:

Medicinal ingredient: 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 healthcare professional has prescribed potassium supplements, continue to follow their advice.

COZAAR comes in the following dosage form:

Tablets: 25 mg, 50 mg and 100 mg.

Do not use COZAAR if:

- you are allergic to losartan potassium or any of the other ingredients in COZAAR.
- you are already taking a blood pressure-lowering medicine that contains aliskiren 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 medicine 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 medicines 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:

Serious drug interactions with COZAAR include:

- Aliskiren-containing medicines 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 medicines 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:

To treat 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.

To delay the worsening of kidney disease in 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, regional poison control centre or Health Canada’s toll-

free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or 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.

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 with COZAAR 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 healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Hyperkalemia (increased levels of potassium in the blood): generally feeling unwell, irregular heartbeats and muscle weakness		√	
Hypotension (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,		√	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
nausea, swelling of extremities, vomiting			
Liver disorder: abdominal pain, dark urine, loss of appetite, nausea, vomiting, yellowing of the skin or eyes		√	
Rare			
Rhabdomyolysis (breakdown of damaged muscle): dark brown urine, muscle pain that you cannot explain, muscle tenderness or weakness		√	
Very rare			
Thrombocytopenia (low blood platelets): bleeding, bruising, fatigue, small purple or red dots under the skin and weakness		√	
Unknown			
Intestinal angioedema (swelling of the intestine): colicky abdominal pain, diarrhea, nausea or vomiting.		√	

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.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

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 the Patient Medication Information by visiting the Health Canada Drug Product Database 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.

This leaflet was prepared by Organon Canada Inc.

Date of Authorization: 2025-06-19

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