

PART III: CONSUMER INFORMATION

COZAAR®

losartan potassium tablets

This leaflet is part III of a three-part "Product Monograph" published when COZAAR® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about COZAAR®. Contact your physician or pharmacist if you have any questions about the drug.

Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information in the previous leaflet may have changed.

ABOUT THIS MEDICATION

What the medication is used for:

Adults

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

Children (6–16 years)

- lowering high blood pressure

What it does:

COZAAR® belongs to a class of drugs known as angiotensin II receptor antagonists. Its action is to lower blood pressure by relaxing the blood vessels.

When it should not be used:

Do not take COZAAR® if you are allergic to losartan potassium or any of the non-medicinal ingredients (see the section What the important non-medicinal ingredients are).

What the medicinal ingredient is:

Each tablet of COZAAR® contains losartan potassium.

What the important non-medicinal ingredients are:

COZAAR® contains the following non-medicinal ingredients: corn starch, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose, titanium dioxide, and carnauba wax.

COZAAR® 25 mg, 50 mg and 100 mg tablets contain the following amounts of potassium: 2.12 mg (<1 mmol), 4.24 mg (<1 mmol), and 8.48 mg (<1 mmol) respectively.

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

What dosage forms it comes in:

COZAAR® tablets of 25 mg, 50 mg and 100 mg.

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions

COZAAR® should not be used during pregnancy. If you discover that you are pregnant while taking COZAAR®, stop the medication and please contact your physician.

BEFORE you use COZAAR® talk to your physician or pharmacist if:

- you perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery). Almost all patients can, but you should not perform these tasks until you know how you respond to your medicine.
- you have or have had any medical problems, and about any allergies.
- you are taking potassium supplements, potassium-sparing agents or salts substitutes containing potassium.
- you are taking any medication including non-prescription and herbal products.
- you have recently suffered from excess vomiting or diarrhea.
- you have liver, kidney, heart or heart valve disease.
- you are allergic to this drug or to any ingredient in the formulation.

You are pregnant, breast-feeding or thinking of becoming pregnant?

Taking COZAAR® during pregnancy can cause injury and even death to your baby. This medicine should not be used during pregnancy. If you are planning to become pregnant while taking COZAAR®, contact immediately your physician.

It is possible that COZAAR® passes into breast milk. You should discuss with your physician about taking COZAAR® while breastfeeding.

Remember that your physician has prescribed this medicine only for you. Never give it to anyone else.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interaction with other drugs is possible. Therefore, do not take any other medicines unless you have discussed the matter with your physician or your pharmacist.

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

- Lithium salts
- Digitalis
- Warfarin
- Rifampin
- Erythromycin
- Fluconazole
- Phenobarbital
- Cimetidine
- Non-steroidal anti-inflammatory drugs (such as indomethacin)
- Diuretics (water pills) – patients on diuretics may occasionally experience an excessive reduction of blood pressure after initiation of therapy with COZAAR®
- Potassium supplements or salt substitutes containing potassium
- Other blood pressure medicines

Certain medicines tend to increase your blood pressure, for example, some, but not all, non-prescription preparations for appetite control, asthma, colds, coughs, hay fever and sinus problems.

PROPER USE OF THIS MEDICATION

Usual dose:

- **Take COZAAR® every day exactly as your physician has instructed.** It is important to continue taking COZAAR® for as long as your physician prescribes it in order to maintain smooth control of your blood pressure.
- **COZAAR® may be taken with or without food, but it should be taken consistently with respect to food intake, at about the same time every day.**

Hypertension

- For adult patients, the usual starting dose is 50 mg once daily. The usual dose range is 50 to 100 mg once daily.
- Most older patients require the same dose as younger patients, since COZAAR® works equally well and is equally well tolerated by most older and younger adult patients.
- For pediatric patients (6-16 years of age) who can swallow tablets, the recommended dose is 25 mg once daily in patients between 20 and 49 kg. The dose can be increased to a maximum of 50 mg once daily. In patients greater or equal to 50 kg, the starting dose is 50 mg once daily. The dose can be increased to a maximum of 100 mg once daily.

Type 2 diabetes patients with proteinuria and hypertension

- For adults, the usual starting dose is 50 mg once daily. The dose may be increased to 100 mg once daily.

Overdose:

In case of an overdose, contact a physician, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any medicine may have unintended or undesirable effects, so-called side effects. Some patients may experience fatigue, hives, taste alteration or vomiting. Tell your physician or pharmacist promptly about these or any other unusual symptoms.

Some patients, especially those with type 2 diabetes with protein in the urine, may also develop increased levels of potassium in their blood.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
	Only if severe	In all cases	
Uncommon			√
Allergic reactions involving swelling of the face, lips, throat, and/or tongue which may cause difficulty in breathing or swallowing			
Rash		√	
Lightheadedness/ Dizziness	√		
Low blood pressure	√		
Muscle pain		√	
Muscle tenderness or weakness or dark/brown urine (sign of rhabdomyolysis*)		√	

* **Rhabdomyolysis is a muscle-wasting disease which in rare cases can lead to kidney failure.**

This is not a complete list of side effects. For any unexpected effects while taking COZAAR®, contact your physician or pharmacist.

HOW TO STORE IT

Store COZAAR® at room temperature (15°C-30°C). Keep container tightly closed. Protect from light.

Keep all medicines out of the reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect

or at Merck Canada Inc. by one of the following 2 ways:

- Call toll-free at 1-800-567-2594
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-496-9092, or
 - Mail to: Merck Canada Inc.
Pharmacovigilance
P.O. Box 1005
Pointe-Claire-Dorval, QC H9R 4P8

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program or Merck do not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at:

<http://www.merck.ca>

or by contacting the sponsor, Merck Canada Inc.,
at: 1-800-567-2594

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