

PART III: CONSUMER INFORMATION

**Pr LOSARTAN
Losartan Potassium Tablets**

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

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:

LOSARTAN 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 LOSARTAN if you are allergic to losartan potassium or any of the nonmedicinal ingredients (see What the important nonmedicinal ingredients are).

Do not take LOSARTAN if you are already taking a blood pressure lowering medicine that contains aliskiren (such as Rasilez) and you have diabetes or kidney disease.

What the medicinal ingredient is:

Losartan potassium

What the important nonmedicinal ingredients are:

LOSARTAN contains the following nonmedicinal ingredients: colloidal anhydrous silica, hydroxypropyl cellulose, hypromellose, lactose monohydrate, macrogol 400, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc and colouring agents (titanium dioxide).

LOSARTAN 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 LOSARTAN tablets contain potassium, this amount is too small to replace potassium supplements. If

your doctor has prescribed potassium supplements, continue to follow his advice.

What dosage forms it comes in:

Tablets of 25 mg, 50 mg and 100 mg.

WARNINGS AND PRECAUTIONS

**Serious Warnings and Precautions
LOSARTAN should not be used during pregnancy. If you discover that you are pregnant while taking LOSARTAN, stop the medication and please contact your physician.**

BEFORE you use LOSARTAN talk to your doctor 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 salt substitutes containing potassium.
- you are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with LOSARTAN is not recommended.
- you are taking an angiotensin-converting-enzyme inhibitor (ACEI).
- 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 LOSARTAN 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 LOSARTAN, contact immediately your physician.

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

Remember that your doctor 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 doctor or your pharmacist. It is important to tell your doctor 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 LOSARTAN.
- Potassium supplements or salt substitutes containing potassium.
- Other blood pressure lowering 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 LOSARTAN every day exactly as your doctor has instructed.** It is important to continue taking LOSARTAN for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.
- **LOSARTAN 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 LOSARTAN 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 LOSARTAN 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 doctor 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 doctor or pharmacist		Stop taking drug and call your doctor 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 LOSARTAN, contact your doctor or pharmacist.

HOW TO STORE IT

Bottles: Store LOSARTAN between 15 and 30°C. Keep container tightly closed. Protect from light.

Keep all medicines out of 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, Ontario
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.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document, plus the full Product Monograph prepared for health professionals, can be obtained by contacting the sponsor, Sanis Health Inc., at:
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Last revised: May 3, 2017