

PART III: CONSUMER INFORMATION

**Pr SANDOZ LOSARTAN
Losartan Potassium Tablets**

Read this carefully before you start taking Sandoz Losartan and each time you get a refill. This leaflet is a summary and will not tell you everything about Sandoz Losartan. Talk to your doctor, nurse or pharmacist about your medical condition and treatment and ask if there is any new information about Sandoz Losartan.

ABOUT THIS MEDICATION

What the medication is used for:

Adults

- Sandoz Losartan lowers high blood pressure;
- Sandoz Losartan provides 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)

- Sandoz Losartan lowers high blood pressure.

What it does:

Sandoz Losartan is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It lowers blood pressure.

This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking Sandoz Losartan regularly even if you feel fine.

When it should not be used:

Do not take Sandoz Losartan if you:

- are allergic to losartan potassium or any of the nonmedicinal ingredients in the formulation.
- have difficulty urinating or produce no urine.
- 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 nonmedicinal ingredients are:

colloidal anhydrous silica, hydroxypropyl cellulose, hypromellose, lactose monohydrate, macrogol 400, magnesium stearate, microcrystalline cellulose, pregelatinized starch, talc and colouring agents (titanium dioxide).

Sandoz 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 Sandoz Losartan tablets contain potassium, this amount is too small to replace potassium supplements. If your physician has prescribed potassium supplements, continue to follow their advice.

What dosage forms it comes in:

Tablets of 25 mg, 50 mg and 100 mg.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy
Sandoz Losartan should not be used during pregnancy. If you discover that you are pregnant while taking Sandoz Losartan, stop the medication and contact your doctor, nurse or pharmacist as soon as possible.

BEFORE you use Sandoz Losartan talk to your doctor, nurse or pharmacist if you:

- are allergic to any drug.
- have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing to any drug that blocks the renin-angiotensin renin system (ACEi, ARB, renin inhibitors). Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- 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, or a potassium-sparing diuretic (a specific kind of “water pill” that makes your body keep potassium).
- are on a low salt diet.
- are less than 18 years old.
- are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with Sandoz Losartan is not recommended.
- are taking an angiotensin-converting-enzyme inhibitor (ACE). You can recognize ACE inhibitors because their medicinal ingredient ends in “-PRIL”.
- are on dialysis.
- are taking any medication including non-prescription and herbal products.
- are dehydrated or suffer from excessive vomiting, diarrhea or sweating.
- have heart failure.
- have diabetes, liver or kidney disease.
- have to undergo any kind of surgery and general anesthesia (even at the dentist’s office). Tell the physician or dentist that you are taking Sandoz Losartan, as there may be a sudden fall in blood pressure associated with general anasthesia.

- are allergic to this drug or to any ingredient in the formulation .
- are taking other drugs that may increase serum potassium (e.g. trimethoprim-containing products).

You may become sensitive to the sun while taking Sandoz Losartan. Exposure to sunlight should be minimized until you know how you respond.

Driving and using machines: Before doing tasks which require special attention, wait until you know how you respond to Sandoz Losartan. Being dizzy, lightheaded, or fainting can occur. Take care especially after the first dose and when the dose is increased.

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

Taking Sandoz 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 Sandoz Losartan, contact your doctor, nurse or pharmacist immediately.

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

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with Sandoz Losartan:

- 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.
- Other blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), or angiotensin converting enzyme (ACE) inhibitors. When taken in combination with Sandoz Losartan, they may cause excessively low blood pressure.
- 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).

PROPER USE OF THIS MEDICATION

Take Sandoz Losartan exactly as prescribed. It is recommended to take your dose at about the same time every day.

Usual dose:

- **Take Sandoz Losartan every day exactly as your doctor has instructed.** It is important to continue taking Sandoz Losartan for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.
- **Sandoz 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.**

High blood pressure:

Adults:

- 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 Sandoz Losartan works equally well and is equally well tolerated by most older and younger adult patients.

Children (6 - 16 years):

- 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 protein in the urine and high blood pressure:

Adults

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

Overdose:

If you think you have taken too much Sandoz Losartan, contact your doctor, nurse, pharmacist, 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 dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Any medicine may have unintended or undesirable effects, so-called side effects. Tell your physician or pharmacist promptly about these or any other unusual symptoms.

Side effects may include:

- Dizziness

- Fatigue
- Rash
- Diarrhea, vomiting
- Change in taste
- Headache
- Back or leg pain, muscle cramps

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

If any of these affects you severely, tell your doctor, nurse or pharmacist.

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

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom/effect	Talk with your doctor, nurse or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
Common			
Low Blood Pressure: dizziness, fainting, lightheadedness	✓		
Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
Uncommon			
Allergic reaction: rash, hives, swelling of the face, lips, throat or tongue, difficulty breathing or swallowing			✓
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		✓	
Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
Rare			
Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine		✓	
Very rare			
Decreased Platelets: bruising, bleeding, fatigue and weakness		✓	

This is not a complete list of side effects. For any unexpected effects while taking Sandoz Losartan, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

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

Blisters: Store Sandoz Losartan between 15 and 30°C.

Keep all medicines out of the reach and sight of children.

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 (<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.

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.

MORE INFORMATION

If you want more information about Sandoz Losartan:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada Website www.canada.ca/en/health-canada or Sandoz Canada Inc. web site www.sandoz.ca or by calling Sandoz Canada Inc. at 1-800-361-3062

or by written request at:

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