

PART III: CONSUMER INFORMATION

Pr LOSARTAN/HCTZ

losartan potassium and hydrochlorothiazide tablets

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

ABOUT THIS MEDICATION

What the medication is used for:
LOSARTAN/HCTZ lower high blood pressure.

- What it does:**
LOSARTAN/HCTZ contain a combination of 2 drugs, losartan component and hydrochlorothiazide:
- Losartan component is an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It lowers blood pressure.
 - Hydrochlorothiazide is a diuretic or “water pill” that increases urination. This lowers blood pressure.

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

- When it should not be used:**
Do not take LOSARTAN/HCTZ if you:
- are allergic to losartan potassium and hydrochlorothiazide or any of the non-medicinal ingredients in the formulation;
 - are allergic to any sulfonamide-derived drugs (sulfa drugs), most of them have a medicinal ingredient that ends in “-MIDE” ;
 - 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 ARB. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you;
 - have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures;
 - 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;
 - are pregnant or intend to become pregnant. Taking LOSARTAN/HCTZ during pregnancy can cause injury and even death to your baby;
 - are breastfeeding. LOSARTAN/HCTZ passes into breast milk.

What the medicinal ingredients are:
Losartan potassium and hydrochlorothiazide

What the important nonmedicinal ingredients are:
LOSARTAN/HCTZ contain the following non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropylcellulose, hypromellose, magnesium stearate, silicified microcrystalline cellulose, silicon dioxide, talc and titanium dioxide. LOSARTAN/HCTZ 50 mg/12.5 mg and LOSARTAN/HCTZ 100 mg/25 mg also contain lake quinoline yellow and polyethylene glycol. LOSARTAN/HCTZ 50 mg/12.5 mg contains 4.24 mg (<1 mmol) of potassium and, LOSARTAN/HCTZ 100 mg/12.5 mg and LOSARTAN/HCTZ 100 mg/25 mg contain 8.48 mg (<1 mmol) of potassium, as losartan potassium.

Although LOSARTAN/HCTZ tablets contain a very small amount of potassium, they cannot replace potassium supplements. If your physician has prescribed potassium supplements, continue to follow his advice.

What dosage forms it comes in:
Tablets: LOSARTAN/HCTZ 50 mg/12.5 mg, 100 mg/12.5 mg, and 100 mg/25 mg.

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions - Pregnancy

LOSARTAN/HCTZ should not be used during pregnancy. If you discover that you are pregnant while taking LOSARTAN/HCTZ, stop the medication and contact your doctor, nurse, or pharmacist as soon as possible.

- BEFORE you use LOSARTAN/HCTZ talk to your doctor, nurse or pharmacist if you:**
- are allergic to any drug used to lower blood pressure, including angiotensin converting enzyme (ACE) inhibitors, or penicillin.
 - have narrowing of an artery or a heart valve.
 - have had a heart attack or stroke.
 - have recently received or are planning to get allergy shots for bee or wasp stings.
 - have heart failure.
 - have diabetes, liver or kidney disease.
 - you are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with LOSARTAN/HCTZ is not recommended.
 - you are taking an angiotensin-converting-enzyme inhibitor (ACEI).
 - have lupus or gout.
 - are on dialysis.
 - are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
 - are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).

- are on a low-salt diet.
- are less than 18 years old.
- are receiving gold (sodium aurothiomalate) injections.
- 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 LOSARTAN/HCTZ, as there may be a sudden fall in blood pressure associated with general anesthesia.
- are hypersensitive to this drug or to any ingredient in the formulation.
- are taking other drugs that may increase serum potassium (e.g. trimethoprim-containing products)
- have had skin cancer or have a family history of skin cancer.
- Have a greater chance of developing skin cancer because you have light-coloured skin, get sunburned easily, or are taking drugs to suppress your immune system.

Hydrochlorothiazide in LOSARTAN/HCTZ can cause Sudden Eye Disorders:

- Myopia: sudden nearsightedness or blurred vision.
- Glaucoma: an increased pressure in your eyes, eye pain.
- Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting LOSARTAN/HCTZ.

Risk of skin cancer:

LOSARTAN/HCTZ contain hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking LOSARTAN/HCTZ for many years (more than 3) or at a high dose.

While taking LOSARTAN/HCTZ

- Make sure to regularly check your skin for any new lesions. Check areas that are most exposed to the sun, such as the face, ears, hands, shoulders, upper chest and back.
- Limit your exposure of skin to sun and avoid indoor tanning. Always use sunscreen (SPF 30 or higher) and wear protective clothing when going outside.
- Talk to your doctor immediately if you get more sensitive to the sun or UV light or if you develop an unexpected skin lesion (such as a lump, bump, sore, or patch) during the treatment.

You may become sensitive to the sun while taking LOSARTAN/HCTZ. Exposure to sunlight should be minimized.

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

Taking LOSARTAN/HCTZ, 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/HCTZ, contact

immediately your physician.

It is possible that LOSARTAN/HCTZ passes into breast milk. You should discuss with your physician about taking LOSARTAN/HCTZ 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 LOSARTAN/HCTZ:

- Adrenocorticotrophic hormone (ACTH) used to treat West Syndrome.
- Alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). They may cause low blood pressure and dizziness when you go from lying or sitting to standing up.
- Amphoterecin B, an antifungal drug.
- Anticancer drugs, including cyclophosphamide and methotrexate.
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Antidiabetic drugs, including insulin and oral medicines.
- Bile acid resins used to lower cholesterol.
- Calcium or vitamin D supplements.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication.
- Drugs that slow down or speed up bowel function, including atropine, metoclopramide, and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gout medications, including allopurinol and probenecid.
- Glycyrrhizin (found in liquorice).
- Lithium used to treat bipolar disease.
- Medicines may cause high blood pressure (adrenaline).
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs. When taken in combination with LOSARTAN/HCTZ, they may cause excessively low blood pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurane.
- Sympathomimetics which may be found in some decongestants, cough/cold, hay fever, sinus medicines.
- Potassium supplements, salt substitutes containing potassium or other drugs that may increase serum potassium (e.g., trimethoprim-containing products)

PROPER USE OF THIS MEDICATION

Take LOSARTAN/HCTZ exactly as prescribed. It is recommended to take your dose at about the same time

everyday.

LOSARTAN/HCTZ can be taken with or without food. If LOSARTAN/HCTZ causes upset stomach, take it with food or milk.

Usual Adult dose:

- **Take LOSARTAN/HCTZ every day exactly as your doctor has instructed.** It is important to continue taking LOSARTAN/HCTZ for as long as your physician prescribes it in order to maintain smooth control of your blood pressure.
- The usual dose of LOSARTAN/HCTZ for most patients with high blood pressure is 1 tablet of LOSARTAN/HCTZ 50 mg/12.5 mg per day to control blood pressure over the 24-hour period.

Overdose:

If you think you have taken too much LOSARTAN/HCTZ, contact your health care 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 dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Back or leg pain, muscle cramps, spasms and pain, weakness, restlessness, joint pain
- Dizziness, pins and needles in your fingers, headache
- Constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- Bleeding under the skin, rash, red patches on the skin
- Drowsiness, insomnia
- Erectile dysfunction/impotence
- Reduced libido
- Increased sensitivity to the sun
- A feeling of dizziness or lightheadedness due to a sudden drop in blood pressure when standing up quickly
- Cramping
- Fatigue
- Hives, itch and bruising
- Taste alteration,
- Seeing more of the colour yellow in your vision, or temporary blurred vision
- Dry cough, nasal congestion and upper respiratory infections
- Fever

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

LOSARTAN/HCTZ 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 physician or pharmacist | | Stop taking drug and seek immediate medical help |
| | | Only if severe | In all cases | |
| Uncommon /rare | Low Blood Pressure: dizziness, fainting, lightheadedness may occur when you go from lying or sitting to standing up | | | ✓ |
| | Allergic Reaction: skin rash, skin eruption or other effect on the skin or eyes, swelling of the face, lips, tongue or throat, accompanied by difficulty in swallowing, breathing, or speaking (signs of angioedema) | | | ✓ |
| | Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite | | | ✓ |
| | Increased blood sugar: frequent urination, thirst, and hunger, sugar in the urine | | ✓ | |
| Common | Non-melanoma skin cancer: lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly. | | ✓ | |
| | Electrolyte imbalance including decreased or increased levels of potassium in the blood or decreased levels of sodium in the blood: irregular | | ✓ | |

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 seek immediate medical help |
|---|--|----------------------|--|
| | Only if severe | In all cases | |
| heartbeats, muscle weakness, generally feeling unwell, drowsiness, muscle pain or cramps, lack of energy, confusion, muscle twitching | | | |
| Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue | ✓ | ✓ (renal failure) | |
| Chest pain | | ✓ | |
| Swelling of the hands or ankles | ✓ | | |
| Red, tender, hot, swollen joint (gout), high uric acid levels in the blood (hyperuricemia) | ✓ (hyperuricemia) | ✓ (gout) | |
| Rare | | | |
| Rhabdomyolysis: muscle pain that you cannot explain, muscle tenderness or weakness, dark brown urine | | ✓ | |
| Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms | | ✓ | |
| Unknown | | | |
| Decreased Platelets: bruising, bleeding, fatigue and weakness | | ✓ | |
| Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes | | | ✓ |
| Eye disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain | | | ✓ |
| Uncommon | | | |
| Anemia: fatigue, loss of energy, weakness, shortness of breath | | ✓ | |

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 seek immediate medical help |
|---|--|--------------|--|
| | Only if severe | In all cases | |
| Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting | | | ✓ |
| Racing or irregular heart rate | ✓ | | |

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

HOW TO STORE IT

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

Keep all medicines out of the reach 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](#) 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

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: February 10, 2020