

**PART III: CONSUMER INFORMATION**

**Pr LISINOPRIL/HCTZ (TYPE Z)**

Lisinopril and hydrochlorothiazide tablets

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

LISINOPRIL/HCTZ (TYPE Z) lowers high blood pressure.

**What it does:**

LISINOPRIL/HCTZ (TYPE Z) contains a combination of 2 drugs, lisinopril and hydrochlorothiazide:

- Lisinopril is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in ‘-PRIL’. 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 LISINOPRIL/HCTZ (TYPE Z) regularly even if you feel fine.

**When it should not be used:**

Do not take LISINOPRIL/HCTZ (TYPE Z) if you:

- Are allergic to lisinopril, hydrochlorothiazide, or to any non-medicinal ingredient 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 itching, hives,

feeling dizzy, swelling of the hands, feet, or ankles, face, lips, tongue, throat or sudden difficulty breathing or swallowing, to any ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.

- Are already taking a blood pressure-lowering medicine that contains aliskiren and you have one of the following conditions:
  - o diabetes
  - o kidney disease
  - o high potassium levels
  - o heart failure combined with low blood pressure
- Are taking an angiotensin receptor blocker (ARB), another medicine to treat your high blood pressure, or another ACE inhibitor **and** have one of the following conditions:
  - o diabetes with end organ damage
  - o kidney disease
  - o high potassium levels
  - o heart failure combined with low blood pressure

You can recognize ARBs because their medicinal ingredient ends in “-**SARTAN**”.

- 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.
- Are taking Sacubitril/Valsartan, due to the increased risk of serious allergic reaction which causes swelling of the face or throat (angioedema) when taken with LISINOPRIL/HCTZ (TYPE Z).
- Have certain kidney diseases or have difficulty urinating or produce no urine.
- Are pregnant or intend to become pregnant. Taking LISINOPRIL/HCTZ (TYPE Z) during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. LISINOPRIL/HCTZ (TYPE Z) passes into breast milk.

**What the medicinal ingredients are:**

Lisinopril and hydrochlorothiazide

**What the non-medicinal ingredients are:**

Corn starch, dibasic calcium phosphate, magnesium stearate, mannitol,

pregelatinized corn starch, red iron oxide and yellow iron oxide (10/12.5 mg tablet and 20/25 mg tablet).

**What dosage forms it comes in:**

Lisinopril and hydrochlorothiazide tablets: 10/12.5 mg, 20/12.5 mg and 20/25 mg.

**WARNINGS AND PRECAUTIONS**

**Serious Warnings and Precautions – Pregnancy**

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

Before you use LISINOPRIL/HCTZ (TYPE Z) talk to your doctor, nurse, or pharmacist if you:

- Have experienced an allergic reaction to any drug used to lower blood pressure or penicillin.
- Have recently received or are planning to get allergy shots for bee or wasp stings or have an allergy.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Have lupus, gout, or asthma.
- 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 taking a medicine that contains aliskiren, used to lower high blood pressure. The combination with LISINOPRIL/HCTZ (TYPE Z) is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in ‘-SARTAN’.
- Are on a low-salt diet.
- Are on dialysis.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Are on LDL Apheresis (a treatment to lower the LDL cholesterol in the blood).

- 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.
- Are taking drugs such as:
  - o Temsirolimus and everolimus (used to treat cancer),
  - o Sirolimus (used to prevent organ rejection after a transplant),
  - o A neutral endopeptidase inhibitor.

Taking ACE inhibitors, such as LISINOPRIL/HCTZ (TYPE Z) with these types of drugs may increase your chances of having an allergic reaction (angioedema).

**Risk of skin cancer:**

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

While taking LISINOPRIL/HCTZ (TYPE Z):

- 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 to the sun and to 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.

**Hydrochlorothiazide in LISINOPRIL/HCTZ (TYPE Z) can cause Sudden Eye Disorders:**

- **Myopia:** sudden near-sightedness 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 LISINOPRIL/HCTZ (TYPE Z).

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking LISINOPRIL/HCTZ (TYPE Z).

**Driving and using machines:** Before you perform tasks which may require special attention, wait until you know how you respond to LISINOPRIL/HCTZ (TYPE Z). Dizziness, light-headedness, or fainting can especially occur after the first dose and when the dose is increased.

### 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 LISINOPRIL/HCTZ (TYPE Z):

- Adrenocorticotrophic hormone (ACTH) may be used to treat nephrotic syndrome and in diagnostic tests.
- 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.
- Amantadine used to treat the flu and reduce symptoms of Parkinson's disease.
- Amphotericin B, an antifungal drug.
- Antacids.
- Drugs used to treat cancer (such as cyclophosphamide, methotrexate, temsirolimus and everolimus).
- Antidepressants, in particular selective serotonin reuptake inhibitors (SSRIs), including citalopram, escitalopram, and sertraline.
- Drugs to treat diabetes such as:
  - o Insulin,
  - o Oral medications (such as sulphonylureas).
- Your dose of these types of drugs may need to be changed when taking them in combination with LISINOPRIL/HCTZ (TYPE Z). Bile acid resins used to lower cholesterol.
- Blood pressure-lowering drugs, including diuretics ('water pills'), aliskiren-containing products, diazoxide, methyldopa and beta blockers such as atenolol, metoprolol, propranolol, calcium channel blockers such as felodipine, amlodipine, nifedipine, and angiotensin II receptor blockers such as candesartan, valsartan, losartan. When taken in combination with LISINOPRIL/HCTZ (TYPE Z) may cause excessively low blood pressure.
- Calcium or vitamin D supplements.
- Capsaicin, an ingredient in some creams used to relieve arthritis pain.
- Corticosteroids used to treat joint pain and swelling.
- Cyclosporine used to treat autoimmune diseases.
- Digoxin, a drug used to treat heart conditions, or other medicines to control the rhythm of your heart.
- Drugs that slow down or speed up bowel function, including atropine, biperiden, domperidone and metoclopramide.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gold (sodium aurothiomalate), used to treat autoimmune conditions such as rheumatoid arthritis and psoriatic arthritis.
- Gout medications, including allopurinol and probenecid.
- Lithium, a medicine to treat bipolar disease.
- Drugs that can cause low blood potassium levels (hypokalemia) such as:
  - o Laxatives,
  - o Corticosteroids (such as prednisone),
  - o Salicylic acid derivatives.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Drugs that can increase blood potassium levels (hyperkalemia) such as:
  - o Potassium supplements,
  - o Salt substitutes.

**IMPORTANT: PLEASE READ**

- Rituximab used to treat cancer, transplant rejection, and some autoimmune diseases.
- Sirolimus, a drug used to prevent organ rejection after a transplant.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- Tetracycline antibiotics.
- Tissue plasminogen activator (TPA) that is used to dissolve blood clots that have formed in blood vessels.

**PROPER USE OF THIS MEDICATION**

Take LISINOPRIL/HCTZ (TYPE Z) exactly as prescribed.

It is recommended to take your dose at about the same time every day.

LISINOPRIL/HCTZ (TYPE Z) can be taken with or without food. If LISINOPRIL/HCTZ (TYPE Z) causes upset stomach, take it with food or milk.

LISINOPRIL/HCTZ (TYPE Z) should be taken whole, with water. Do not crush, split or chew the tablet

**Usual Adult Dose:**

The dosage of LISINOPRIL/HCTZ (TYPE Z) is individualized and taken once a day. It may be prescribed as follows:

One tablet of 10/12.5 mg

Or

One or two tablets of 20/12.5 mg

One or two tablets of 20/25 mg

**Overdose:**

If you think you have taken too much LISINOPRIL/HCTZ (TYPE Z) 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**

Side effects may include:

- dizziness
- headache
- cough
- drowsiness, fatigue, weakness
- rash
- abdominal pain, upset stomach, decreased appetite, constipation
- muscle pain or cramps

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

LISINOPRIL/HCTZ (TYPE Z) 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 to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Common</b> <b>Low Blood Pressure:</b> dizziness, fainting, light-headedness. May occur when you go from lying or sitting to standing up	✓		
<b>Decreased or increased levels of potassium in the blood:</b> irregular heartbeats, muscle weakness and generally feeling unwell		✓	
<b>Non-melanoma skin cancer:</b> lump or discoloured patch on the skin that stays after a few weeks and slowly changes. Cancerous lumps are		✓	

**IMPORTANT: PLEASE READ**

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom/Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help	
	Only if severe	In all cases		
	red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.			
<b>Uncommon</b>	<b>Allergic reaction:</b> rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
	<b>Kidney disorder:</b> decreased urination, nausea, vomiting, swelling of extremities, fatigue		✓	
	<b>Liver disorder:</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
	<b>Increased blood sugar:</b> frequent urination, thirst and hunger	✓		
	<b>Electrolyte Imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
<b>Rare</b>	<b>Decreased Platelets:</b> bruising, bleeding, fatigue and weakness		✓	
	<b>Decreased white blood</b>		✓	

<b>SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM</b>				
Symptom/Effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help	
	Only if severe	In all cases		
	cells: infections, fatigue, fever, aches, pains and flu-like symptoms			
<b>Very Rare</b>	<b>Serious Skin Reactions (Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis):</b> any combination of itchy skin, rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain.			✓
	<b>Eye disorders:</b> <b>Myopia:</b> sudden near sightedness or blurred vision <b>Glaucoma:</b> increased pressure in your eyes, eye pain			✓
	<b>Anemia:</b> fatigue, loss of energy, weakness, shortness of breath		✓	
<b>Unknown</b>	<b>Inflammation of the pancreas:</b> abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	
	<b>Hallucinations:</b>		✓	

## IMPORTANT: PLEASE READ

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

Symptom/Effect		Talk to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
	sensation of seeing or hearing things			
	<b>Lupus-like reactions:</b> associated with fever, malaise, joint pains, myalgias, fatigues etc. May be activated, or lupus status may worsen		✓	

*This is not a complete list of side effects. For any unexpected effects while taking LISINOPRIL/HCTZ (TYPE Z), contact your doctor, nurse or pharmacist.*

#### HOW TO STORE IT

- Store between 15°C - 30°C. Protect from light and moisture.
- When you first open the package, if you find any damage to the plastic seal or foil which exposes the tablet, ask your pharmacist to check the package.
- Do not transfer LISINOPRIL/HCTZ (TYPE Z) to other pill containers.
- **Keep out of reach and sight of children.** Never take medicine in front of small children as they will want to copy you.
- Do not keep or use LISINOPRIL/HCTZ (TYPE Z) after the expiry date indicated on the package. Unused medicines, which you know you will no longer need, should be carefully discarded. You may wish to seek advice from your pharmacist.
- **Remember** to get a new prescription from your doctor or a refill from your pharmacy a few days before all your tablets are taken.

#### 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

This document plus the full product monograph, prepared for health professionals can be found by contacting the sponsor, Sanis Health Inc., at:

1-866-236-4076  
or [quality@sanis.com](mailto:quality@sanis.com)

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