

PART III: CONSUMER INFORMATION**Pr
HYDROCHLOROTHIAZIDE**
Hydrochlorothiazide Tablets USP

This leaflet is part III of a three-part “Product Monograph” published when HYDROCHLOROTHIAZIDE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HYDROCHLOROTHIAZIDE. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about HYDROCHLOROTHIAZIDE.

ABOUT THIS MEDICATION**What the medication is used for:****Adults:**

- Decreases swelling caused by fluid retention (edema) due to heart failure, liver disease, kidney disease, premenstrual tension, or corticosteroid and estrogen therapy.
- Lowers high blood pressure.
- Lowers pregnancy-induced high blood pressure.

What it does:

HYDROCHLOROTHIAZIDE is a diuretic often called “water pill”. It increases urination. This lowers blood pressure and decreases swelling.

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

When it should not be used:

Do not take HYDROCHLOROTHIAZIDE if you:

- Are allergic to 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 difficulty urinating or produce no urine.
- Are breastfeeding. Hydrochlorothiazide passes into breast milk.
- Have one of the following rare hereditary diseases:
 - o Galactose intolerance
 - o Lapp lactase deficiency
 - o Glucose-galactose malabsorption
 Because lactose is a non-medicinal ingredient in HYDROCHLOROTHIAZIDE.

What the medicinal ingredient is:

Hydrochlorothiazide.

What the nonmedicinal ingredients are:

colloidal silicon dioxide, FD&C Yellow #6, lactose, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What dosage forms it comes in:

Tablets: 25 mg and 50 mg

WARNINGS AND PRECAUTIONS

Before you use HYDROCHLOROTHIAZIDE talk to your doctor, nurse or pharmacists if you:

- Are allergic to penicillin.
- Have diabetes, liver or kidney disease.
- Have lupus or gout.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are less than 18 years old
- 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.

Risk of skin cancer:

- HYDROCHLOROTHIAZIDE contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking HYDROCHLOROTHIAZIDE for many years (more than 3) or at a high dose.
- While taking HYDROCHLOROTHIAZIDE:
 - o 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.
 - o Limit your exposure to the sun and to indoor tanning. Always use sunscreen (SPF-30 or higher) and wear protective clothing when going outside.
 - o 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 HYDROCHLOROTHIAZIDE 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 HYDROCHLOROTHIAZIDE.

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

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to HYDROCHLOROTHIAZIDE. Dizziness, lightheadedness, 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 HYDROCHLOROTHIAZIDE:

- 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.
- Amphotericin 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 your bowels, including atropine, metoclopramide, and domperidone.
- Drugs used to treat epilepsy, including carbamazepine and topiramate.
- Gout medications, including allopurinol and probenecid.
- 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. When taken in combination with hydrochlorothiazide, they may cause excessively low blood pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurane.

PROPER USE OF THIS MEDICATION

Take HYDROCHLOROTHIAZIDE exactly as

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

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

In your diet, be sure to include foods that contain potassium such as tomatoes, bananas, and beans.

Usual Adult dose:

- For the treatment of high blood pressure: 50 mg or 100 mg, once a day or as a divided dose as directed by your doctor. Your doctor may increase or decrease your dose.
- For the treatment of pregnancy-induced high blood pressure: The usual dose is 100 mg. The doctor may briefly increase dosage to 200 mg. Doses may be prescribed:
 - once a day or
 - every 4 days.
- For the treatment of swelling caused by fluid retention (edema): 25 mg to 50 mg once or twice a day.

Usual Infant and Child dose:

- Infants up to 24 months: 12.5 mg to 37.5 mg twice a day.
- Children 2 to 12 years old: 37.5 mg to 100 mg twice a day.

Overdose:

If you think you, or a person you are caring for, have taken too much HYDROCHLOROTHIAZIDE, contact a healthcare 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:

- muscle cramps, spasms, and pain, weakness, restlessness

- dizziness, pins and needles in your fingers, headache
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth
- reduced libido
- bleeding under the skin, rash, red patches on the skin

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

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

Serious side effects 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. May occur when you go from lying or sitting to standing up.	✓		
	Decreased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		✓	
	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.			
Uncommon	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	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		✓	
	Increased blood sugar: frequent urination, thirst, and hunger	✓		
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓	
Ra	Decreased Platelets:		✓	

	bruising, bleeding, fatigue and weakness			
	Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
Very rare	Toxic Epidermal Necrolysis: severe skin peeling, especially in mouth and eyes			✓
Unknown	Eye Disorders: - Myopia: sudden near sightedness or blurred vision - Glaucoma: increased pressure in your eyes, eye pain			✓
	Anemia: fatigue, loss of energy, weakness, shortness of breath.		✓	
	Inflammation of the Pancreas: abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	

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

HOW TO STORE IT

- Store at controlled room temperature, 15°C - 30°C.
- Keep out of the reach and sight of children.

- Do not use after the expiry date indicated on the package.
- Protect from heat and light.

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 HYDROCHLOROTHIAZIDE:

- 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: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer’s website [www.tevacanada.com], or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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