

PART III: CONSUMER INFORMATION

Pr AMI-HYDRO

(hydrochlorothiazide 50 mg and amiloride hydrochloride 5 mg Tablets USP)

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

ABOUT THIS MEDICATION

What the medication is used for:

AMI-HYDRO is used in adults for:

- Swelling of the hands, ankles or feet in patients with hepatic cirrhosis (a liver disease).
- Patients with swelling of the hands, ankles or feet caused by heart problems or patients with high blood pressure (hypertension) who have low levels of potassium in their blood (hypokalemia) or who need to maintain normal levels of potassium.

What it does:

AMI-HYDRO contains a combination of 2 drugs, amiloride hydrochloride and hydrochlorothiazide:

- amiloride hydrochloride helps the body lose excess salt but keep a normal amount of potassium (an electrolyte) in the blood.
- 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 AMI-HYDRO regularly even if you feel fine.

When it should not be used:

Do not take AMI-HYDRO if you:

- Are allergic to amiloride hydrochloride or 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.
- Have high potassium levels (hyperkalemia).
- Have kidney failure, severe or worsening kidney disease or problems with your kidneys because of diabetes (diabetic nephropathy).
- Are using any form of potassium supplementation.
- Are taking any other potassium-conserving medications or “water pills”.
- Are breastfeeding. AMI-HYDRO passes into breast milk.
- Have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in AMI-HYDRO.

What the medicinal ingredients are:

amiloride hydrochloride and hydrochlorothiazide.

What the non-medicinal ingredients are:

Colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium bicarbonate and sunset yellow aluminium lake 40 %

What dosage forms it comes in:

Tablet; amiloride hydrochloride 5 mg and hydrochlorothiazide 50 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use AMI-HYDRO talk to your doctor, nurse, or pharmacist if you:

- Are allergic to penicillin.
- Have diabetes, liver, heart or kidney disease.
- Have cardiopulmonary disease (disease involving both the lungs and heart).
- Had a sympathectomy (a surgery to remove part of a nerve from your spinal cord).
- Have lupus or gout.
- Have a stomach (peptic) ulcer.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are pregnant or thinking of becoming pregnant.
- Are less than 18 or over 65 years of age.

Hydrochlorothiazide in AMI-HYDRO 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 AMI-HYDRO.

You may become sensitive to the sun while taking AMI-HYDRO. 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 AMI-HYDRO. 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 AMI-HYDRO:

- 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.
- 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 bowel function, 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 AMI-HYDRO, they may cause excessively low blood pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurane.

PROPER USE OF THIS MEDICATION

Take AMI-HYDRO exactly as prescribed. It is recommended to take your dose at about the same time every day.

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

Usual Adult dose:

For Swelling of the hands, ankles or feet in Patients with Hepatic Cirrhosis: 1 tablet given once a day. The dosage should not exceed 4 tablets a day in single or divided doses.

For Swelling of the hands, ankles or feet caused by Heart Problems: 1 or 2 tablets given once a day or in divided doses. The dosage should not exceed 4 tablets a day.

For High Blood Pressure (Hypertension): 1 or 2 tablets given once a day or in divided doses. The dosage should not exceed 4 tablets a day.

Overdose:

If you think you have taken too much AMI-HYDRO 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:

- muscle cramps, spasms, and pain, weakness, restlessness
- dizziness, pins and needles in your fingers, headache, being in a daze, trouble sleeping, nervousness, sleepiness, fatigue, tiredness
- constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth, stomach pain, hiccups, thirst, gas, bad taste, dry mouth
- reduced libido
- bleeding under the skin, rash, red patches on the skin, itching, flushing
- stuffy nose

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

AMI-HYDRO 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. 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		√	
Uncommon	Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√

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	
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		√	
Gastrointestinal bleeding: black stool or blood in stool		√	
Depression: feeling sad, not interested in usual activities, weight change and sleep disruptions	√		
Mental confusion: Inability to know the date, where and who you are	√		
Angina: Chest pain			√

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	
Rare	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		√	

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	
Hepatic encephalopathy : forgetfulness, confusion, irritability, sleeping during the day and being awake at night			√
Necrotizing angitis : fever, stomach pain, numbness and tingling in the hands and feet, swelling in the hands, ankles or feet, changes in frequency of urination			√
Respiratory distress : trouble breathing, shortness of breath, skin turning blue around the mouth, lips and fingernails			√

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

HOW TO STORE IT

Store at room temperature (15-30°C).
Keep out of reach and sight 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 Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or info@prodoc.qc.ca.

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