

**PART III: CONSUMER INFORMATION**

**ALDACTAZIDE®**

(spironolactone and hydrochlorothiazide tablets USP)

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

**ABOUT THIS MEDICATION**

**What the medication is used for:**

ALDACTAZIDE is used to treat high blood pressure and fluid retention (edema) caused by various conditions, including heart disease, cirrhosis of the liver and nephrotic syndrome.

**What it does:**

ALDACTAZIDE contains a combination of 2 drugs, spironolactone and hydrochlorothiazide:

- Spironolactone belongs to a class of medicines known as aldosterone receptor antagonists.
- 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 ALDACTAZIDE regularly even if you feel fine. Do not stop taking ALDACTAZIDE without talking to your doctor.

ALDACTAZIDE causes the kidney to eliminate unneeded water and sodium from the body into the urine, but also reduces the loss of potassium.

**When it should not be used:**

Do not take ALDACTAZIDE if you:

- Are allergic to spironolactone or hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- Are allergic to sulfonamide-derived drugs (sulfa drugs); most of them have a medicinal ingredient that ends in “-MIDE”.
- Have difficulty urinating or produce no urine.
- Have severe kidney disease, severe liver disease or Addison’s disease

- Have high levels of potassium (hyperkalemia) or calcium (hypercalcemia) in your blood
- Are pregnant
- Are breastfeeding. ALDACTAZIDE passes into breast milk.
- Are taking eplerenone (INSPRA)
- Are taking heparin or low molecular weight heparin used to prevent blood clotting

**What the medicinal ingredient is:**

Spironolactone and hydrochlorothiazide tablets.

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

Calcium sulfate, carnauba wax, corn starch, magnesium stearate, opaspray K-1-7076, peppermint flavouring, povidone, hypromellose, polyethylene glycol 400, stearic acid.

**What dosage forms it comes in:**

Tablets: 25/25 mg and 50/50 mg of spironolactone and hydrochlorothiazide

**WARNINGS AND PRECAUTIONS**

**Avoid potassium supplements, salt substitutes and foods containing high levels of potassium** (e.g., bananas, prunes, raisins, and orange juice). Follow your doctor's directions for a low-salt or low-sodium diet and daily exercise program

Before you receive ALDACTAZIDE, talk to your doctor, nurse, or pharmacist if you:

- Are allergic to penicillin.
- Have diabetes, liver or kidney disease
- Have or ever had lupus or gout.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are less than 18 years old
- Are taking medications for diabetes
- Are taking a Non-steroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling. Examples include Aspirin, ibuprofen (Advil, Motrin), naproxen (Aleve), and celecoxib (Celebrex)
- Are taking an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their medicinal ingredient ends in “PRIL”. It lowers blood pressure.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. It lowers blood pressure
- Are taking lithium used to treat bipolar disease

- Are taking Lipitor (atorvastatin) or Lasix (furosemide)
- Are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking ALDACTAZIDE, call your doctor.
- Are a man and develop tender or enlarged breast tissue
- Are having surgery (including dental surgery) and will be given an anesthetic. Be sure to tell the doctor or dentist that you are taking ALDACTAZIDE.
- 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:**

- ALDACTAZIDE contains hydrochlorothiazide. Treatment with hydrochlorothiazide may increase the risk of developing non-melanoma skin cancer. The risk is higher if you have been taking ALDACTAZIDE for many years (more than 3) or at a high dose.
- While taking ALDACTAZIDE:
  - 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 ALDACTAZIDE can cause Sudden Eye Disorders:**

- **Choroidal effusion:** an abnormal buildup of liquid in your eye that may result in vision changes.
- **Myopia:** Sudden nearsightedness or blurred vision.
- **Glaucoma:** An increased pressure in your eyes, eye pain. Untreated, it may lead to permanent vision loss.

If your vision changes, stop taking ALDACTAZIDE and seek immediate medical help. These eye disorders are related and can develop within hours to weeks of starting ALDACTAZIDE.

You may become sensitive to the sun while taking ALDACTAZIDE. 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 ALDACTAZIDE. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is decreased (sometimes leading to falls and fractures or broken bones). Do not drive a car or operate machinery until you know how this drug affects you. Remember that alcohol can add to the drowsiness caused by this drug.

**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 ALDACTAZIDE:

- 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.
- Drugs that cause hyperkalemia (high levels of potassium in blood) including aminoglycoside antibiotics, cisplatin and foscarnet
- Gout medications, including allopurinol and probenecid.

- Lithium used to treat bipolar disorder (manic-depressive illness)
- Nonsteroidal anti-inflammatory drugs (NSAIDs), use to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including diuretics. When taken in combination with ALDACTAZIDE, they may cause excessively low blood pressure.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurarine

### PROPER USE OF THIS MEDICATION

Take ALDACTAZIDE exactly as prescribed by your doctor. It is recommended to take your dose at about the same time every day.

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

**Always follow your doctor's instructions carefully.**

ALDACTAZIDE comes as a tablet to take by mouth. It is usually taken once a day in the morning.

Food increases the effect of ALDACTAZIDE. Patients with kidney and liver problems, and the elderly are particularly at risk. If you take this medication with food, your doctor must monitor you for signs that can be associated with excessive exposure of ALDACTAZIDE. Overdose symptoms include nausea, vomiting, drowsiness, dizziness, decreased consciousness, coma, mental confusion, diarrhea, red spots/bruising/rash and irregular results on blood tests including increased serum potassium levels. These symptoms usually disappear when ALDACTAZIDE is discontinued.

#### Usual Dose

**Edema in adults:** (congestive heart failure, hepatic cirrhosis or nephrotic syndrome): Daily dosage of 2 to 4 tablets of ALDACTAZIDE 25 or 1 to 2 tablets of ALDACTAZIDE 50 in single or divided doses should be adequate for most patients, but may range from 2 to 8 tablets daily of ALDACTAZIDE 25 or 1 to 4 tablets of ALDACTAZIDE 50.

**Edema in children:** The usual daily maintenance dose of ALDACTAZIDE should be that which provides 0.75 to 1.5 mg of spironolactone per pound of body weight (1.65 to 3.3 mg/kg).

**Essential hypertension:** A daily dosage of 2 to 4 ALDACTAZIDE 25 tablets or 1 to 2 ALDACTAZIDE 50 tablets in single or divided doses, will be adequate for most patients, but may range from 2 to 8 tablets of ALDACTAZIDE 25 or 1 to 4 tablets of ALDACTAZIDE 50.

#### **Overdose:**

If you think you have taken too much ALDACTAZIDE 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:

**Gastrointestinal:** Constipation, diarrhea, nausea, vomiting, decreased appetite, upset stomach, enlargement of the glands in your mouth, indigestion, dryness of mouth, abdominal pain, and cramps.

**Central nervous system:** Dizziness, pins and needles in your fingers, headache, a feeling that you or your surroundings are moving, sensation of tingling or numbness and drowsiness.

**Cardiovascular:** low blood pressure while you are standing (postural hypotension), may be aggravated by alcohol, barbiturates, or narcotics.

**Hypersensitivity:** sensitivity to light, fever, difficulty breathing, anaphylactic reactions.

**Musculoskeletal:** Muscle cramps, spasms, and pain, weakness, restlessness

**Psychiatric:** Reduced libido

**Reproductive:** In men: breast swelling, difficulty in getting or maintaining erections. In women: breast discomfort, irregular or missed menstrual periods, postmenopausal bleeding.

**Skin:** Bleeding under the skin, rash, red patches on the skin, suspicious skin lesions

**Other:** Blurred vision, thirst, frequent urination, and fatigue.

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

ALDACTAZIDE 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**

Table 1 – Serious side effects, how often they happen and what to do about them

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
<b>Common</b>	<b>Low Blood Pressure:</b> Dizziness, fainting, lightheadedness. May occur when you go from sitting to standing up (may be exacerbated by alcohol, barbiturates, or narcotics).	✓		
	<b>Decreased 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 red/pink and firm and sometimes turn into ulcers. Cancerous patches are usually flat and scaly.		✓	

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

Table 1 – Serious side effects, how often they happen and what to do about them

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
<b>Uncommon</b>	<b>Allergic Reaction:</b> Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, redness, intense itching and burning, anaphylactic reactions.			✓
	<b>Kidney Disorder:</b> Change in frequency of 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, rapid, slow or irregular heartbeat		✓	
	Confusion		✓	
	Enlarged or painful breasts in men		✓	
	Fever	✓		
	Vomiting blood		✓	
	Rapid, excessive weight loss		✓	

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

**Table 1 – Serious side effects, how often they happen and what to do about them**

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Shortness of breath		✓	
	Skin rash		✓	
	Yellowing of the skin or eyes		✓	
	Stomach ulcer (burning pain in the gut, vomiting)		✓	
	Blood problems (loss of energy, severe anemia).		✓	
	Impaired sense of sight		✓	
	Chest pain, difficulty breathing			✓
<b>Rare</b>	<b>Decreased Platelets:</b> Bruising, bleeding, fatigue and weakness		✓	
	<b>Decreased White Blood Cells:</b> Infections, fatigue, fever, aches, pains, and flu-like symptoms		✓	
<b>Very Rare</b>	<b>Toxic Epidermal Necrolysis:</b> Severe skin peeling, especially in mouth and eyes			✓
<b>Unknown</b>	<b>Eye Disorders:</b> <b>-Choroidal effusion:</b> blind spots, eye pain, blurred vision <b>-Myopia:</b> Sudden near sightedness or blurred vision <b>-Glaucoma:</b> Increased pressure in your eye, eye pain			✓

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Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	<b>Anemia:</b> Fatigue, loss of energy, weakness, shortness of breath		✓	
	<b>Inflammation of the Pancreas:</b> Abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		✓	

**This is not a complete list of side effects. If you have any unexpected effects while taking ALDACTAZIDE, contact your doctor, nurse, or pharmacist.**

**HOW TO STORE IT**

Store ALDACTAZIDE at room temperature 15 to 25°C

**Keep ALDACTAZIDE out of the 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**  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>
- **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 1908C**  
**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**  
<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>.

*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 found at:  
<http://www.pfizer.ca>  
or by contacting the sponsor, Pfizer Canada ULC, at:  
1-800-463-6001

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