

PART III: CONSUMER INFORMATION

ALDACTAZIDE

(spironolactone and hydrochlorothiazide)

This leaflet is part III of a three-part Product Monograph published when ALDACTAZIDE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALDACTAZIDE. Contact your doctor or pharmacist if you have any questions about the drug.

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 is a combination product. It contains spironolactone which belongs to the class of medicines known as aldosterone receptor antagonists.

ALDACTAZIDE also contains hydrochlorothiazide which belongs to the group of medicines known as diuretics, sometimes known as 'water pills'.

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:

You should not use this medicine if you have had an allergic reaction to spironolactone, thiazides or other sulfonamide drugs, or if you have kidney disease, liver disease, high levels of potassium (hyperkalemia) or calcium (hypercalcemia) in your blood, or if you are pregnant or unable to urinate.

What the medicinal ingredient is:

Spironolactone and hydrochlorothiazide tablets.

What the nonmedicinal ingredients are:

Each ALDACTAZIDE 25 mg and 50 mg tablet contains calcium sulfate, corn starch, magnesium stearate, peppermint flavouring, povidone, hypromellose, polyethylene glycol 400, carnauba wax, stearic acid, opaspray K-1-7076.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

Avoid potassium supplements and foods (e.g., bananas, prunes, raisins, and orange juice) containing high levels of potassium including salt substitutes.

Follow your doctor's directions for a low-salt or low-sodium diet and daily exercise program

Before you receive ALDACTAZIDE,

- tell your doctor and pharmacist if you are allergic to spironolactone, hydrochlorothiazide, any of the non-medicinal ingredients listed in the "What the nonmedicinal ingredients are" section earlier in this document, sulfa drugs, or any other drugs.
- tell your doctor and pharmacist what prescription, nonprescription medications and natural health products you are taking, especially low molecular weight heparins and/or heparin which is used to prevent blood clotting (coagulation); aspirin, lithium, medications for arthritis, diabetes, or high blood pressure, potassium supplements and vitamins.
- tell your doctor and pharmacist if you are taking eplerenone (INSPRA)
- tell your doctor if you have or have ever had diabetes, gout, or kidney or liver disease or skin problems (e.g. lupus).
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking ALDACTAZIDE, call your doctor.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking ALDACTAZIDE.

Also,

- you should know that this drug may make you drowsy and dizzy (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.
- Orthostatic hypotension (low blood pressure while you are standing) may occur and may be enhanced by alcohol, barbiturates or narcotics.
- Your doctor may need to monitor the electrolyte balance of your blood by a blood test.

INTERACTIONS WITH THIS MEDICATION

You should always tell your physician about all drugs you are taking including prescription, non-prescription and natural health products.

Drugs that may interact with ALDACTAZIDE include: aspirin, lithium, digoxin, antipyrine, cholestyramine, eplerenone, heparin, low molecular weight heparins, corticosteroids, norepinephrine, skeletal muscle relaxants, non-depolarizing (e.g.: tubocurarine), eplerenone (Inspra) atorvastatin along with furosemide and with aspirin as well as and medications for arthritis, diabetes, or high blood pressure.

PROPER USE OF THIS MEDICATION

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, pregnant or nursing women 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. Take ALDACTAZIDE exactly as directed by your health care professional. Do not take more or less of it or take it more often than prescribed by your doctor.

This medication controls high blood pressure but does not cure it. Continue to take ALDACTAZIDE even if you feel well. Do not stop taking ALDACTAZIDE without talking to your doctor.

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:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose: Take the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Although side effects from ALDACTAZIDE are not common, they can occur. Tell your doctor if any of these symptoms do not go away:

Gastrointestinal: Decreased appetite, gastric irritation, upset stomach, dryness of mouth, abdominal pain, nausea, vomiting, cramps, diarrhea, and constipation.

Central nervous system: Dizziness, a feeling that you or your surroundings are moving, sensation of tingling or numbness, headache, drowsiness.

Cardiovascular: postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics).

Hypersensitivity: spontaneous bleeding under the skin, sensitivity to light, rash, red patches on the skin, fever, respiratory distress including pneumonitis, anaphylactic reactions.

Other: Muscle spasm, weakness, restlessness, transient blurred vision, thirst, frequent urination, fatigue.

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 call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	Confusion		✓	
Uncommon	Allergic reactions (difficulty breathing or swallowing, rash or hives, redness, intense itching and burning swelling) anaphylactic reactions.			✓

Uncommon	Low blood pressure aggravated by change of position (may be exacerbated by alcohol, barbiturates, or narcotics).		✓		Uncommon	Chest pain			✓
					<p><i>This is not a complete list of side effects. If you have any unexpected effects after receiving ALDACTAZIDE, contact your doctor or pharmacist.</i></p>				
Uncommon	Unusual bruising or bleeding		✓		HOW TO STORE IT				
Uncommon	Enlarged or painful breasts		✓		Store the medicine at room temperature 15 to 25°C;				
Uncommon	Fever	✓			Keep all medicines out of the reach and sight of children.				
Uncommon	Irregular menstrual period		✓		REPORTING SUSPECTED SIDE EFFECTS				
Uncommon	Muscle weakness, cramps or spasms		✓		<p>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:</p> <p>-----</p> <p>\$ Report online at www.healthcanada.gc.ca/medeffect</p> <p>\$ Call toll-free at 1-866-234-2345</p> <p>\$ Complete a Canada Vigilance Reporting Form and:</p> <p style="padding-left: 20px;">- Fax toll-free to 1-866-678-6789, or - Mail to: Canada Vigilance Program Health Canada Postal Locator 0701D Ottawa, Ontario K1A 0K9</p> <p style="padding-left: 20px;">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.</p>				
Uncommon	Rapid, slow or irregular heartbeat		✓		<p><i>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.</i></p>				
Uncommon	Vomiting blood		✓		MORE INFORMATION				
Uncommon	Rapid, excessive weight loss		✓		<p>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 Inc., at: 1-800-463-6001</p> <p>This leaflet was prepared by Pfizer Canada Last revised: October 05, 2010 © Pfizer Canada Inc., 2010</p>				
Uncommon	Shortness of breath		✓						
Uncommon	Respiratory distress including pneumonitis.			✓					
Uncommon	Skin rash		✓						
Uncommon	Yellowing of the skin or eyes inflammation of the pancreas, inflammation or enlargement of salivary glands.		✓						
Uncommon	Stomach ulcer (burning pain in the gut, vomiting...)		✓						
Uncommon	Imbalance of minerals in the blood High sugar levels in the blood (hyperglycemia)		✓						
Uncommon	Blood problems (loss of energy, low blood platelet count, abnormally low white blood cell count, severe reduction in granulocytes, severe anemia due to destruction or depressed functioning of the bone marrow...).		✓						
Uncommon	Impaired sense of sight.		✓						