

PART III: CONSUMER INFORMATION**ALDACTONE**
spironolactone tablets

This leaflet is part III of a three-part "Product Monograph" and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ALDACTONE. Contact your doctor or pharmacist if you have any questions about the drug.

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

ALDACTONE 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. It is also used to treat hyperaldosteronism (the body produces too much aldosterone, a naturally occurring hormone); and low potassium levels in the blood (hypokalemia).

What it does:

Spironolactone belongs to a class of medications called aldosterone receptor antagonists. It causes the kidney to eliminate unneeded water and sodium from the body into the urine, but reduces the loss of potassium from the body. This medicine does not cure high blood pressure. It helps to control it. Therefore, it is important to continue taking ALDACTONE regularly even if you feel fine. Do not stop taking ALDACTONE without talking to your doctor.

When it should not be used:

Do not take ALDACTONE if you:

- Are allergic to spironolactone or hydrochlorothiazide or to any non-medicinal ingredient in the formulation.
- Have difficulty urinating or produce no urine.
- Have kidney disease or Addison's disease
- Have high levels of potassium (hyperkalemia) in your blood
- Are pregnant
- Are breastfeeding. ALDACTONE 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.

What the nonmedicinal ingredients are:

Each ALDACTONE 25 mg and 100 mg tablet contains: Calcium sulfate, corn starch, magnesium stearate, peppermint flavouring, povidone, hypromellose, polyethylene glycol 400,

carnauba wax, stearic acid, opaspray M-1-2042 (25 mg only) and opaspray M-1-2668 (100 mg only).

What dosage forms it comes in:

ALDACTONE 25 mg: Each light yellow, round, biconvex, film-coated tablet, debossed "ALDACTONE" and "25" on one face and "SEARLE" and "1001" on the other face and with peppermint odour contains Spironolactone 25 mg.

ALDACTONE 100 mg: Each peach, round, biconvex, scored, film-coated tablet, debossed "ALDACTONE" and "100" on one face and "SEARLE" and "1031" on the other (scored) face and with peppermint odour contains Spironolactone 100 mg.

ALDACTONE tablets are available in strengths of 25 mg and 100 mg in bottles of 100.

WARNINGS AND PRECAUTIONS

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

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

- Have diabetes, kidney disease or liver disease;
- Have or have ever had gout
- 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 disorder (manic-depressive illness)
- Are pregnant, plan to become pregnant, or are breast feeding. If you become pregnant while taking ALDACTONE, call your doctor immediately;
- 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 ALDACTONE.

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

DIETARY RESTRICTIONS

Follow your doctor's directions for a low-salt or low-sodium diet and daily exercise program. Avoid potassium-containing salt substitutes. Limit your intake of potassium-rich foods (eg, bananas, prunes, raisins, and orange juice). Ask your doctor for advice on how much of these foods you may have.

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, nonprescription drugs, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with ALDACTONE

- 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.
- Corticosteroids used to treat joint pain and swelling.
- Digoxin, a heart medication
- Drugs that cause hyperkalemia (high levels of potassium in blood)
- Lithium used to treat bipolar disorder (manic-depressive illness)
- Nonsteroidal anti-inflammatory drugs (NSAIDs), use to reduce pain and swelling. Examples include Aspirin, ibuprofen, naproxen, and celecoxib.
- Other blood pressure lowering drugs, including diuretics. When taken in combination with ALDACTONE, they may cause excessively low blood pressure.

PROPER USE OF THIS MEDICATION

ALDACTONE comes as a tablet to take by mouth. Take it exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor. It usually is taken once a day in the morning with breakfast or twice a day with

breakfast and lunch. Carefully follow your doctor's instructions about any special diet.

Missed Dose: Take the missed dose as soon as you remember it. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for a missed one.

Overdose:

If you think you have taken too much ALDACTONE, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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: 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.

Other: Thirst, frequent urination, and fatigue.

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

ALDACTONE 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 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 sitting to standing up (may be exacerbated by alcohol, barbiturates, or narcotics).	Y		
	Decreased levels of potassium in the blood: Irregular heartbeats, muscle weakness and generally feeling unwell.		Y	
Uncommon	Allergic Reaction: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing, redness, intense itching and burning, anaphylactic reactions.			Y
	Kidney Disorder: Change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		Y	
	Liver Disorder: Yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		Y	
	Increased Blood Sugar: Frequent urination, thirst and hunger	Y		

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	
	Electrolyte Imbalance: Weakness, drowsiness, muscle pain or cramps, rapid, slow or irregular heartbeat		Y	
	Confusion		Y	
	Enlarged or painful breasts in men		Y	
	Fever	Y		
	Vomiting blood		Y	
	Rapid, excessive weight loss		Y	
	Shortness of breath		Y	
	Skin rash		Y	
	Yellowing of the skin or eyes.		Y	
	Stomach ulcer (burning pain in the gut, vomiting)		Y	
	Blood problems (loss of energy, severe anemia)		Y	
	Chest pain, difficulty breathing			Y
	Rare	Decreased Platelets: Bruising, bleeding, fatigue and weakness		Y
Decreased White Blood Cells: Infections, fatigue, fever, aches, pains, and flu-like symptoms			Y	
Very Rare	Toxic Epidermal Necrolysis: Severe skin peeling, especially in mouth and eyes			Y
Unknown	Anemia: Fatigue, loss of		Y	

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	
	energy, weakness, shortness of breath			
	Inflammation of the Pancreas: Abdominal pain that lasts and gets worse when you lie down, nausea, vomiting		Y	

This is not a complete list of side effects. If you have any unexpected effects after receiving ALDACTONE, contact your doctor, nurse or pharmacist.

HOW TO STORE IT

Store the medicine at room temperature 15 to 25°C, away from heat and moisture.

Keep ALDACTONE 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 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 0701D
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 found at: <http://www.pfizer.ca> or by contacting Pfizer Canada Inc., at: 1-800-463-6001

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