

## 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:

- Fluid retention (edema) caused by various conditions, including heart disease, cirrhosis of the liver and nephrotic syndrome;
- High blood pressure;
- Hyperaldosteronism (the body produces too much aldosterone, a naturally occurring hormone);
- Low potassium levels in the blood (hypokalemia).

#### What it does:

Spironolactone is in 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.

#### When it should not be used:

You should not use this medicine if you have had an allergic reaction to spironolactone, or if you have certain kidney diseases, high levels of potassium in your blood (hyperkalemia), or if you are pregnant or unable to urinate.

#### What the medicinal ingredient is:

Spironolactone.

#### What the important 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 and foods containing high levels of potassium including salt substitutes.**

Before taking ALDACTONE,

- tell your doctor and pharmacist if you are allergic to spironolactone, sulfa drugs, or any other drugs;
- Tell your doctor and pharmacist if you are taking eplerenone (INSPIRA)
- tell your doctor and pharmacist what prescription and nonprescription medications 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 if you have or have ever had diabetes, gout, or kidney or liver disease;
- tell your doctor if you are pregnant, plan to become pregnant, or are breast feeding. If you become pregnant while taking spironolactone, call your doctor immediately;
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking spironolactone;
- you should know that this drug may make you drowsy or dizzy. Do not drive a car or operate machinery, or do anything else that could be dangerous if you are not alert 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

Drugs that may interact with ALDACTONE include: aspirin, lithium, digoxin, antipyrine, cholestyramine, eplerenone, heparin, low molecular weight heparins and medications for arthritis, diabetes, or high 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:**

You should not take more tablets than your doctor tells you. If you take more ALDACTONE than what has been prescribed to you, call your doctor or poison control center, or go to an emergency room.

## SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

- upset stomach
- abdominal pain
- frequent urination
- dryness of mouth, thirst

## 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	
Vomiting	✓		
Diarrhea	✓		
Dizziness	✓		
Headache	✓		

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

	Talk with your doctor or pharmacist		
Drowsiness	✓		
Fatigue	✓		
Fever	✓		
Enlarged or painful breasts		✓	
Irregular menstrual period		✓	
Confusion		✓	
Muscle weakness or cramps		✓	
Rapid, excessive weight loss		✓	
Rapid, slow or irregular heartbeat		✓	
Shortness of breath		✓	
Unusual bruising or bleeding		✓	
Yellowing of the skin or eyes		✓	
Skin rash			✓
Vomiting blood			✓

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

## HOW TO STORE IT

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

**Keep all medicines out of the reach 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:**

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- \$ Report online at  
[www.healthcanada.gc.ca/medeffect](http://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](http://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

This leaflet was prepared by Pfizer Canada Inc.

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