

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### PrALDACTONE

##### Spironolactone tablets USP

Read this carefully before you start taking **ALDACTONE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ALDACTONE**.

#### Serious Warnings and Precautions

- **Avoid potassium supplements, salt substitutes and foods containing high levels of potassium** (e.g., bananas, prunes, raisins and orange juice). ALDACTONE causes the kidney to eliminate unneeded water and sodium from the body into the urine, but also reduces the loss of potassium.

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

#### What is ALDACTONE used for?

ALDACTONE is used in adults to:

- treat high levels of aldosterone, a hormone made by the adrenal gland.
- manage swelling in the body caused by a build-up of fluid in the tissues (edema) due to a medical condition. This may include conditions involving your heart, liver or kidney.
- treat high blood pressure. ALDACTONE is usually used in combination with other medicines.
- treat and prevent low levels of potassium in the blood (hypokalemia).

#### How does ALDACTONE work?

ALDACTONE works by blocking the hormone aldosterone from binding to receptors in the kidney. It causes the kidneys to remove excess water and sodium from the body. It also reduces the loss of potassium. It is a diuretic or "water pill" that increases urination.

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 healthcare professional.

#### What are the ingredients in ALDACTONE?

Medicinal ingredients: Spironolactone

Non-medicinal ingredients: Calcium sulfate, carnauba wax, corn starch, hypromellose, magnesium stearate, peppermint flavouring, povidone, , polyethylene glycol 400, , opaspray M-1-2042 (25 mg only), opaspray M-1-2668 (100 mg only), and stearic acid.

**ALDACTONE comes in the following dosage forms:**

Tablets; 25 mg and 100 mg

**Do not use ALDACTONE if:**

- you are allergic to spironolactone or to any non-medicinal ingredient in ALDACTONE.
- you have difficulty urinating or produce no urine.
- you have severe kidney problems or Addison’s disease, a condition involving your adrenal glands.
- you have high levels of potassium (hyperkalemia) in your blood.
- you are pregnant.
- you are breastfeeding. ALDACTONE passes into breast milk.
- you are taking eplerenone, used to treat heart failure and high blood pressure.
- you are taking heparin or low molecular weight heparin used to prevent blood clotting.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALDACTONE. Talk about any health conditions or problems you may have, including if you:**

- have diabetes.
- have liver or kidney problems.
- have or have ever had gout.
- are taking a Non-steroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling, such as acetylsalicylic acid, ibuprofen, naproxen, and celecoxib.
- 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).
- plan to become pregnant or think you might be pregnant. If you become pregnant while taking ALDACTONE, call your healthcare professional immediately.
- are having surgery, including dental surgery, and will be given an anesthetic. Tell the healthcare professional or dentist that you are taking ALDACTONE.
- are taking other diuretics or “water pills” used to lower blood pressure.
- have moderate to severe heart problems.
- are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- are taking any potassium supplements

**Other warnings you should know about:**

**Driving and using machines:** ALDACTONE can cause dizziness, light-headedness or fainting,

especially when you first start taking it. This can sometimes lead to falls and broken bones. Do not drive a car or do other tasks that require attention such as operating machinery until you know how ALDACTONE affects you.

**Breast development in males:** ALDACTONE contains spironolactone. Spironolactone can cause breast development in males. If you are male and develop tender or enlarged breast tissue while you are taking ALDACTONE, talk to your healthcare professional.

**Blood tests:** ALDACTONE can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with ALDACTONE:**

- alcohol, barbiturates (sleeping pills), or narcotics (strong pain medications). corticosteroids used to treat joint pain and swelling.
- digoxin, a heart medication.
- medicines that cause high levels of potassium in blood.
- lithium used to treat bipolar disorder (manic-depressive illness).
- non-steroidal anti-inflammatory drugs (NSAIDs) used to reduce pain and swelling, such as acetylsalicylic acid, ibuprofen, naproxen, and celecoxib.
- abiraterone, a medication used in prostate cancer treatment.
- other blood pressure lowering medications, including diuretics.
- antipyrine, used to relieve ear pain and swelling caused by middle ear infections.
- cholestyramine, used to lower cholesterol levels in the blood.
- adrenocorticotrophic hormone (ACTH), used to treat West Syndrome.
- heparin, used to prevent blood clots.
- norepinephrine, used to treat low blood pressure.
- eplerenone, used to treat heart failure and high blood pressure.

**How to take ALDACTONE:**

- Take ALDACTONE exactly as your healthcare professional tells you. Talk to your healthcare professional if you are uncertain.
- ALDACTONE is usually taken once a day in the morning or twice a day with breakfast and lunch. It is recommended that you take your dose at about the same time every day.

**Usual dose:**

Your healthcare professional will decide on the dose that is right for you. Your dose will depend on what ALDACTONE is being used to treat, your age, and other conditions or illnesses

you have, and if you are taking other medications. Based on how you respond to ALDACTONE, your healthcare professional may change your dose.

**Overdose:**

Symptoms of an overdose may include:

- nausea and vomiting,
- drowsiness,
- dizziness,
- confusion,
- diarrhea,
- rash.

If you think you, or a person you are caring for, have taken too much ALDACTONE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, do not take the missed dose or take a double dose to make up for the missed tablet. Instead, go back to your regular dosing schedule. If you are unsure, talk to your healthcare professional.

**What are possible side effects from using ALDACTONE?**

These are not all the possible side effects you may have when taking ALDACTONE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- constipation, diarrhea,
- nausea, vomiting,
- loss of appetite,
- upset stomach, indigestion,
- enlargement of the glands in your mouth,
- dry mouth, thirst,
- abdominal pain and cramps,
- dizziness, spinning sensation (vertigo),
- pins and needles sensation,
- headache,
- drowsiness,
- fever,
- restlessness,
- reduced libido,
- muscle cramps, spasms, pain and/or weakness,

- in men: breast swelling, difficulty in getting or maintaining erections,
- in women: breast discomfort, irregular or missed menstrual periods, postmenopausal bleeding,
- frequent urination.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Hypotension</b> (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)	√		
<b>Hypokalemia</b> (low level of potassium in the blood): muscle weakness, muscle spasms, cramping, constipation, feeling of skipped heart beats or palpitations, fatigue, tingling or numbness		√	
<b>UNCOMMON</b>			
<b>Allergic Reaction:</b> difficulty swallowing or breathing, wheezing, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat.			√
<b>Kidney Problems:</b> nausea, vomiting, fever, swelling of extremities, fatigue, thirst, dry skin, irritability, dark urine, increased or decreased urine output, blood in the urine, rash, weight gain (from retaining fluid), loss of appetite, abnormal blood test results, mental status changes (drowsiness, confusion, coma)		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Liver Problems:</b> yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite		√	
<b>Hyperglycemia</b> (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue	√		
<b>Electrolyte Imbalance:</b> weakness, drowsiness, muscle pain or cramps, rapid, slow or irregular heartbeat		√	
<b>Confusion</b>		√	
<b>Gynecomastia:</b> breast enlargement in men		√	
<b>Vomiting blood</b>		√	
<b>Rapid, excessive weight loss</b>		√	
<b>Dyspnea</b> (shortness of breath)		√	
<b>Urticarial reaction:</b> skin with red spots which burn, itch or sting		√	
<b>Stomach Ulcer</b> (burning pain in the gut): heartburn, long lasting stomach pain, loss of appetite and weight loss		√	
<b>Lung Problems:</b> chest pain, difficulty breathing			√
<b>RARE</b>			
<b>Thrombocytopenia</b> (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue and weakness		√	
<b>Leukopenia</b> (decreased white blood cells): infections, fatigue, fever, aches, pains and flu-like symptoms		√	
<b>VERY RARE</b>			

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Serious Skin Reactions (Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS)):</b> severe skin peeling, scaling or blistering which may also affect your mouth, eyes, nose or genitals, itching, severe rash, skin pain, skin color changes (redness, yellowing, purplish), swelling and redness of eyes or face, flu-like feeling, fever, chills, body aches, swollen glands, cough			√
<b>UNKNOWN FREQUENCY</b>			
<b>Anemia</b> (decreased number of red blood cells): fatigue, loss of energy, looking pale, shortness of breath, weakness		√	
<b>Pancreatitis</b> (inflammation of the pancreas): upper abdominal pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### **Reporting Side Effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

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

Keep out of reach and sight of children.

### **If you want more information about ALDACTONE:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.pfizer.ca>, or by calling 1-800-463-6001.

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