Spironolactone Shortage

For the current status of drug shortages and discontinuations, refer to Drug Shortages Canada at www.drugshortagescanada.ca.

This document was developed collaboratively by the Canadian Pharmacists Association (CPhA) and the Canadian Society of Healthcare-Systems Pharmacy (CSHP), with input from the Canadian Cardiovascular Society (CCS) and the Canadian Heart Failure Society (CHFS) for managing cardiovascular conditions.

The document is designed to support health professionals in managing patients prescribed spironolactone during the ongoing spironolactone shortage affecting Canada. The guidance presented here aims to assist health-care providers in navigating drug shortages and selecting suitable alternative therapies; it is not intended as a comprehensive review or clinical practice guideline. Clinical decisions should be based on professional knowledge and judgment, referencing CPS Full Access or other authoritative resources as needed.

TABLE 1: **Spironolactone products marketed in Canada**[1]

Product	Strength	DIN	Manufacturer
JAMP-Spironolactone	25 mg 100 mg	02518821 02518848	JAMP Pharma Corporation
Mint-Spironolactone	25 mg 100 mg	02488140 02488159	Mint Pharmaceuticals Inc.
Aldactone	25 mg 100 mg	00028606 00285455	Pfizer Canada ULC
Teva-Spironolactone	25 mg 100 mg	00613215 00613223	Teva Canada Limited
Combination products containing spironolactone			
Teva-Spironolactone/HCTZ	25 mg 50 mg	00613231 00657182	Teva Canada Limited

Health Canada–approved indications for spironolactone:[2]

- Primary hyperaldosteronism
- Edematous conditions
  - congestive heart failure (CHF)
  - cirrhosis of the liver accompanied by edema and/or ascites
  - nephrotic syndrome
- Essential hypertension
- Hypokalemia

Common off-label uses of spironolactone:

- Acne[3]
- Excessive hair growth[4]
- Gender-affirming care[5]
- Seborrheic dermatitis[6]

Management Options:

During a drug shortage, it is essential to prioritize limited supplies based on clinical need to maximize benefit and minimize harm. Ethical principles of consistency, equity and transparency ensure fair and defensible allocation. Given spironolactone's wide range of uses, clinicians should individually assess patients, balance risks and benefits, and consider clinical monitoring and drug coverage options.

- Avoid starting patients on spironolactone while the shortage persists.
- Consider a temporary pause on spironolactone and restart when the drug shortage has been resolved.
- Discontinue spironolactone if not indicated or supported by appropriate clinical guidelines, including CCS/CHFS heart failure guidelines and other appropriate guidelines.
- Prioritize using the medication where there is no alternative (e.g., primary aldosteronism).
- Offer an alternative therapy for diseases such as hypertension, where there may be several alternatives.
- Where there is an evidence or knowledge gap, enrol patients into a clinical trial testing newer generations of aldosterone synthase inhibitors or mineralocorticoid receptor antagonists. Refer to clinicaltrials.gov for studies that are currently recruiting patients.
- Do not prescribe or dispense large quantities of spironolactone during the shortage. Stockpiling can result in further exacerbations of shortages and disproportionately impact equity-deserving and low-income groups. Encourage patients to limit refill prescriptions to a 30-day supply and contact their pharmacy or health-care provider in advance of depleting their current supply.
- 100 mg tablets, when available, can be split and quartered.
- Ensure timely, clear and transparent communication with patients regarding the shortage and rationale behind any changes to their care plan.

Therapeutic Alternatives/Considerations:

Spironolactone is a high-affinity mineralocorticoid aldosterone antagonist. As such, it can be therapeutically used for idiopathic hyperaldosteronism, potassium-sparing diuresis, and its antihypertensive effect in various indications.[2]

Primary hyperaldosteronism is recognized as an important cause of resistant hypertension.[7] The CCS/CHFS does not recommend any alternatives to spironolactone for this indication. As such, prioritize using remaining spironolactone supply for these patients during the shortage.

Heart failure is a clinical syndrome recognized by a cluster of signs and symptoms including dyspnea, fluid retention, fatigue, and some form of structural or functional heart disease. Both spironolactone and eplerenone can be used combined with other drugs in the treatment of this condition.[8]

Cirrhosis is the advanced scarring of hepatic tissue caused by various diseases and conditions. Edema and/or ascites can develop as a result of the portal hypertension associated with cirrhosis.[9] Spironolactone tends to be the diuretic of choice, as sodium and fluid retention is associated with the high plasma aldosterone levels in patients. Amiloride can be substituted for spironolactone if intolerable side effects develop.[9]

Essential hypertension can be treated with diuresis.[10] Low-dose thiazide or related diuretics are often used as first-line therapy for uncomplicated hypertension.[10] Even though indicated for essential hypertension, spironolactone is generally reserved for patients with resistant hypertension[10] and those with concomitant heart failure.[8] Amiloride can be used as a potassium-sparing diuretic for this indication.[10]

Hypokalemia is an electrolyte disturbance associated with potentially fatal cardiac arrhythmias, as well as musculoskeletal, neurologic and psychiatric complications.[11] Potassium-sparing diuretics are used if increased kidney potassium losses are involved in the pathogenesis of hypokalemia (e.g., hyperaldosteronism, concomitant use of other diuretics).[11] As such, eplerenone and amiloride are suitable therapeutic alternatives for spironolactone.[11]

Spironolactone has some affinity for other receptors; namely, androgen receptors. As such, it is used off-label for its antiandrogenic effect in multiple indications. For off-label indications, refer to the relevant CPS chapters: **Acne,**[3] **Hair Care and Hair Growth,**[4] **Gender-Affirming Care for Transgender and Gender-Diverse Individuals,**[5] **Dandruff and Seborrheic Dermatitis.**[6]

TABLE 2: **Mineralocorticoid receptor antagonists for heart failure**[8]

Drug	Dosage	Adverse Effects
Eplerenone	Initial: 25 mg once daily PO or every 2 days Target: 50 mg once daily	Hyperkalemia, dehydration, dizziness, diarrhea, nausea.

TABLE 3: **Second-line diuretic for cirrhosis accompanied by edema and/or ascites**[9]

Drug	Dosage	Adverse Effects
Amiloride	Initial: 5 mg daily PO once daily or BID; maximum of 30 mg PO BID	Hyperkalemia, gynecomastia, muscle cramps, hyperchloremic metabolic acidosis.

TABLE 4: **Potassium-sparing diuretics for treatment of essential hypertension**[10]

Drug	Dosage	Adverse Effects
Amiloride	Initial: 5 mg once daily PO Usual: 10 mg once daily PO	Hyperkalemia, muscle cramps, headache, gastrointestinal symptoms.

TABLE 5: **Potassium-sparing diuretics for treatment of hypokalemia**[11]

Drug	Dosage	Adverse Effects
Amiloride	5–20 mg once daily PO	Hyperkalemia, muscle cramps, headache, gastrointestinal symptoms (rare).
Eplerenone	25–50 mg once daily PO	Hyperkalemia, dizziness, headache, rise in serum creatinine.

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