SPIRONOLACTONE

Class: Diuretic, Potassium Sparing; Selective Aldosterone Blocker

Indications: Management of edema associated with excessive aldosterone excretion or with congestive heart failure (HF) unresponsive to other therapies; hypertension; primary hyperaldosteronism (establishing diagnosis, short-term preoperative treatment, and long-term maintenance therapy in selected patients); hypokalemia; cirrhosis of liver accompanied by edema or ascites; nephrotic syndrome; severe HF (NYHA class III-IV) to increase survival and reduce hospitalization when added to standard therapy.

Unlabeled: Female acne (adjunctive therapy); hirsutism; hypertension (pediatric); diuretic (pediatric); HF (NYHA class II) with LVEF ≤35% in patients who have a history of prior cardiovascular hospitalization or elevated plasma natriuretic peptide levels to reduce morbidity and mortality; to reduce morbidity and mortality following acute MI with LVEF ≤40% in patients who develop HF symptoms or have a history of diabetes mellitus.

Available dosage form in the hospital: 25MG TAB, 50MG TAB, 100MG TAB

Dosage:

- **Edema:** Oral: 25-200 mg daily in 1-2 divided doses
- **Hypokalemia:** Oral: 25-100 mg once daily
- **Hypertension:** Oral: 25-50 mg daily in 1-2 divided doses
- **Diagnosis of primary aldosteronism:** Oral: Long test: 400 mg once daily for 3-4 weeks; short test: 400 mg once daily for 4 days; maintenance until surgical correction: 100-400 mg once daily
- **Heart failure, severe (NYHA class III-IV; with ACE inhibitor and a loop diuretic with or without digoxin):** 12.5-25 mg once daily; maximum daily dose: 50 mg. If 25 mg once daily not tolerated, may reduce to 25 mg every other day. The ACCF/AHA 2013 HF guidelines also recommend the use of aldosterone receptor antagonists (eg, spironolactone) in patients with NYHA class II HF and LVEF ≤35% who have a history of prior cardiovascular hospitalization or elevated plasma natriuretic peptide levels and postmyocardial infarction patients with LVEF ≤40% who develop HF symptoms or have a history of diabetes mellitus (Yancy, 2013).
  
  Note: If potassium >5 mEq/L or serum creatinine >4 mg/dL (or worsening renal function [Yancy, 2013]), discontinue or interrupt therapy.
- **Acne in women (unlabeled use):** Oral: 50-200 mg once daily.
- **Hirsutism in women (unlabeled use):** Oral: 50-200 mg daily in 1-2 divided doses.

Geriatric

Oral: Indication specific: Initial: 25-50 mg daily in 1-2 divided doses; increase by 25-50 mg every 5 days as needed. Adjust for renal impairment.

Renal Impairment

- **Heart failure:**
  - eGFR ≥50 mL/minute/1.73 m²: Initial dose: 12.5-25 mg once daily; Maintenance dose (after 4 weeks of treatment with potassium ≤5 mEq/L): 25 mg once or twice daily
  - eGFR 30-49 mL/minute/1.73 m²: Initial dose: 12.5 mg once daily or every other day; Maintenance dose (after 4 weeks of treatment with potassium ≤5 mEq/L): 12.5-25 mg once daily
  - eGFR <30 mL/minute/1.73 m²: Not recommended.
**Note:** Contraindicated in patients with anuria, acute renal insufficiency, or significant impairment of renal excretory function.

**Hepatic Impairment:**
No dosage adjustment provided in manufacturer’s labeling.

**Common side effect:** Cardiovascular: Vasculitis
Central nervous system: Ataxia, confusion, drowsiness, headache, lethargy
Dermatologic: Erythematous maculopapular rash, Stevens-Johnson syndrome, toxic epidermal necrolysis, urticaria
Endocrine & metabolic: Amenorrhea, gynecomastia, hyperkalemia
Gastrointestinal: Abdominal cramps, diarrhea, gastritis, gastrointestinal hemorrhage, gastrointestinal ulcer, nausea, vomiting
Genitourinary: Impotence, irregular menses, postmenopausal bleeding
Hematologic & oncologic: Agranulocytosis, malignant neoplasm of breast
Hepatic: Hepatotoxicity

**Pregnancy Risk Factor:** C