

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 $\leq 35\%$ 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 $\leq 40\%$ 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 $\leq 35\%$ who have a history of prior cardiovascular hospitalization or elevated plasma natriuretic peptide levels and postmyocardial infarction patients with LVEF $\leq 40\%$ 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