Spironolactone Tablets BP

Composition:
Each uncoated tablet contains:
Spironolactone BP 50 mg
Excipients q.s.

Dosage and Method of Administration
Dosage: Spironolactone tablets should always be administered with fluids and preferably with food to aid absorption.
Adults: Congestive Heart Failure with Edema:
For the treatment of edema, an initial daily dose of 100 mg of spironolactone is recommended, administered as a single dose or in divided doses; however, this may range from 25 mg to 200 mg per day. The maintenance dose should be determined individually.

Therapeutic Indications:
- Congestive heart failure
- Nephrotic syndrome
- Hepatic cirrhosis with ascites and edema
- Malignant ascites
- Diagnosis and treatment of primary aldosteronism.

Contraindications
- Spironolactone therapy is contraindicated in the following cases:
- Hypersensitivity to the active substance.
- Anuria (patients are at increased risk of developing hyperkalemia).
- Active, rapidly progressing, or severe renal insufficiency (spironolactone may exacerbate electrolyte imbalance, and the risk of developing hyperkalemia is increased).
- Hyperkalemia (spironolactone may further increase serum potassium concentrations).
- Addison's disease.
- Concomitant use of eplerenone or other potassium-sparing diuretics.
- Spironolactone is contraindicated in pediatric patients with moderate to severe renal insufficiency.
- Spironolactone tablets should not be administered concomitantly with other potassium-sparing diuretics, and potassium supplements should not be routinely administered with spironolactone tablets, as hyperkalemia may be induced.

Warnings and Special Precautions
Fluid and Electrolyte Balance:
Patients receiving spironolactone should be carefully evaluated for possible disturbances in fluid and electrolyte balance, particularly in the elderly and in those with significant renal and hepatic impairment.
Hyperkalemia may occur in patients with renal impairment or excessive potassium intake and can cause cardiac irregularities that may be fatal. Should hyperkalemia develop, spironolactone should be discontinued, and, if necessary, active measures should be taken to reduce serum potassium to normal levels. Dilutional hyponatremia may be induced, especially when spironolactone is administered concomitantly with other diuretics.
Caution should be exercised in patients suffering from hyponatremia.
Urea:
Reversible increases in blood urea have been reported with spironolactone therapy, particularly in the presence of renal impairment.
Hyperkalemia in Patients with Severe Heart Failure:
Hyperkalemia can be fatal. It is essential to monitor and manage serum potassium in patients with severe heart failure receiving spironolactone. Avoid using other potassium-sparing diuretics. Avoid the use of oral potassium supplements in patients with serum potassium >3.5 mEq/L. The recommended monitoring schedule for potassium and creatinine is 1 week after initiation or dose increase of spironolactone, monthly during the first 3 months, then quarterly for one year, and thereafter every 6 months. Discontinue or interrupt treatment for serum potassium >5 mEq/L or for serum creatinine >4 mg/dL.
Caution is required in critically ill patients and in those with relatively low urine volumes, who are at higher risk of developing hyperkalemia.
Caution is required in patients predisposed to metabolic or respiratory acidosis. Acidosis potentiates the hyperkalemic effects of spironolactone, and spironolactone may potentiate acidosis.
Spironolactone has been shown to produce tumors in rats when administered at high doses over a prolonged period. The significance of these findings regarding clinical use is uncertain. However, the prolonged use of spironolactone in young patients requires careful consideration of the benefits versus the potential risks involved.
Caution should be exercised in patients diagnosed with porphyria, as spironolactone is considered unsafe in these patients.
Caution should be exercised in patients suffering from menstrual irregularities or breast enlargement.
Pediatric Population:
Potassium-sparing diuretics should be used with caution in hypertensive pediatric patients with mild renal impairment due to the risk of hyperkalemia. (Spironolactone is contraindicated for use in pediatric patients with moderate or severe renal impairment.)

Fertility, Pregnancy, and Lactation
Pregnancy:
Spironolactone or its metabolites may cross the placental barrier. With spironolactone, feminization has been observed in male rat fetuses. Spironolactone should be used with caution in pregnant women, weighing the potential risk to the mother and fetus against the possible benefits.
Breastfeeding:
Canrenone, a metabolite of spironolactone, appears in breast milk; therefore, an alternative method of infant feeding should be instituted.

Overdosage
The toxic effects of overdosage include drowsiness, mental confusion, nausea, vomiting, dizziness, or diarrhea. Hyponatremia or hyperkalemia may be induced, but it is unlikely that these effects would be associated with acute overdosage. Symptoms of hyperkalemia may manifest as paresthesia, lassitude, muscle weakness, flaccid paralysis, or muscle spasm, and may be clinically difficult to distinguish from hypokalemia.
No specific antidote has been identified. Improvement can be expected upon discontinuation of therapy. Electrocardiographic changes are the first specific signs of potassium disturbances. General supportive measures, including fluid and electrolyte replacement, may be indicated. For hyperkalemia, reduce potassium intake and administer potassium-excreting diuretics, intravenous glucose with regular insulin, or oral ion-exchange resins.

Storage
Store protected from light and moisture.

Keep this medication out of the reach of children.

Presentation: One package of 10 x 10 tablets.

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