

# Inospiron®

Spirolactone

## Presentation

Inospiron® 25 : Each tablet contains Spirolactone BP 25 mg.

Inospiron® 100 : Each tablet contains Spirolactone BP 100 mg.

## Description

Spirolactone is a long-acting aldosterone antagonist and potassium-sparing diuretic. It acts primarily through competitive binding of receptors at the aldosterone dependent sodium-potassium exchange site in the distal convoluted renal tubule. Spirolactone causes increased amount of sodium and water to be excreted, while potassium and magnesium are retained.

## Indications and Uses

- Essential hypertension
- Congestive heart failure
- Hepatic cirrhosis with ascites and edema
- Nephrotic syndrome
- Primary hyperaldosteronism
- For the treatment of patients with hypokalemia

## Dosage and administration

*Essential hypertension:* For adults, an initial daily dose is 50 mg to 100 mg administered in either single or divided doses.

*Edema in adults (congestive heart failure, hepatic cirrhosis, or nephrotic syndrome):* An initial daily dose is 100 mg administered in either single or divided doses, but may range from 25 to 200 mg daily. Combined therapy with other diuretics is indicated when more rapid diuresis is desired.

*Primary hyperaldosteronism:* After the diagnosis of hyperaldosteronism, Spirolactone may be administered in dosage of 100 to 400 mg daily in preparation for surgery. For patients who are considered unsuitable for surgery, Spirolactone may be employed for long-term maintenance therapy at the lowest effective dosage determined for the individual patient.

*Hypokalemia:* Spirolactone in a dosage ranging from 25 mg to 100 mg daily is useful in treating diuretic-induced hypokalemia.

## Side effects

Gynaecomastia may develop in association with the use of Spirolactone. Other adverse reactions are- GI symptoms including cramping and diarrhoea, drowsiness, lethargy, headache, urticaria, mental confusion, impotence, irregular menses or amenorrhoea and post-menopausal bleeding.

## Contraindications

Spirolactone is contraindicated in patients with acute renal insufficiency, significant impairment of renal function, anuria, hyperkalemia or sensitivity to Spirolactone.

## Precautions

All patients receiving diuretic therapy should be observed for evidence of fluid or electrolyte imbalance. Hyperkalemia may occur in patients with impaired renal function or excessive potassium intake and can cause cardiac irregularities, which may be fatal.

## Use in pregnancy & lactation

*Pregnancy:* Spirolactone should not be used during pregnancy.

*Lactation:* Canrenone, an active metabolite of Spirolactone, appears in breast milk. If use of the drug is deemed essential an alternative method of infant feeding should be instituted.

## Overdosage

Symptoms of overdosage include drowsiness, mental confusion, dizziness, diarrhoea and vomiting. Patients should induce vomiting or evacuate the stomach by lavage during Spirolactone overdose.

## Drug interactions

*ACE inhibitors:* Concomitant administration of ACE inhibitors with potassium-sparing diuretics has been associated with severe hyperkalemia.

*Alcohol, barbiturates, or narcotics:* Potentiation of orthostatic hypotension may occur.

*Corticosteroids, ACTH:* Intensified electrolyte depletion, particularly hypokalemia, may occur.

*Lithium:* Lithium generally should not be given with diuretics. Diuretic agents reduce the renal clearance of lithium and add a high risk of lithium toxicity.

*Digoxin:* Spirolactone has been shown to increase the half-life of digoxin.

## Storage

Do not store above 30° C. Keep away from light and out of the reach of children.

## Commercial Pack

Inospiron® 25: Each box contains 10 blister strips of 10 tablets.

Inospiron® 100: Each box contains 3 blister strips of 10 tablets.

Manufactured by  
 **Incepta Pharmaceuticals Ltd**  
Savar, Dhaka, Bangladesh  
® Registered Trademark

V.N. 01  
INP