

Composition : Spironolactone 25mg Tablet.

Indications : Spironolactone is indicated in the management of oedema and ascites in hepatic cirrhosis, malignant ascites, nephrotic syndrome, congestive cardiac failure and primary aldosteronism.

Dosage and administration : Administration of Spironolactone once daily with a meal is recommended.

Adults: Congestive cardiac failure: Usual dose 100mg/day. In difficult or severe cases the dosage may gradually increased up to 400mg/day. When oedema is controlled, the usual maintenance level is 75mg-200mg/day.

Hepatic cirrhosis with ascites and oedema: If urinary Na⁺/K⁺ ratio is greater than 1.0, 100mg/day. If the ratio is less than 1.0, 200-400mg/day. Maintenance dosage should be individually determined.

Malignant ascites: Initial dose usually 100-200mg/day. In severe cases the dosage may be gradually increased up to 400mg/day. When oedema is controlled, maintenance dosage should be individually determined.

Nephrotic syndrome: Usual dose 100-200mg/day. Spironolactone has not been shown to be anti-inflammatory, nor to affect the basic pathological process. Its use only advised if glucocorticoids by themselves are insufficiently effective.

Diagnosis and treatment of primary aldosteronism: Spironolactone may employed as an initial diagnostic measure to provide presumptive evidence of primary hyperaldosteronism while patients are on normal diets.

Long test : Spironolactone is administered at a daily dosage of 400mg for three to four weeks. Correction of hypokalaemia and of hypertension provides presumptive evidence for the diagnosis of primary hyperaldosteronism.

Short test : Spironolactone is administered at a daily dosage of 400mg for four days. If serum potassium increases during Spironolactone

Spiretic

Film Coated Tablet

administration but drops when Spironolactone is discontinued, a presumptive diagnosis of primary hyperaldosteronism should be considered.

Children : Initial daily dosage should provide 3mg of spironolactone per kilogram body weight given in divided doses. Dosage should be adjusted on the basis of response and tolerance. If necessary a suspension may be prepared by crushing Spironolactone tablets.

Contraindications : Spironolactone is contraindicated in patients with anuria, acute renal insufficiency, rapidly deteriorating or severe impairment of renal function, hyperkalaemia, Addison's disease and in patients who are hypersensitive to spironolactone.

Pregnancy and lactation : This medication should be used only when clearly needed during pregnancy. This drug breaks down into other products that pass into breast milk. Therefore, breast-feeding while using this medication is not recommended. Pregnancy Category **C** by FDA.

Side effects : Gynecomastia may develop in association with the use of spironolactone. Other adverse reactions include gastrointestinal intolerance, drowsiness, lethargy, headache, mental confusion, ataxia, drug fever, skin rashes, menstrual irregularities, breast soreness, impotence and mild androgenic effects.

Precautions : This drug may make you drowsy; use caution engaging in activities requiring alertness such as driving or using machinery.

Drug interactions : ACE inhibitors, alcohol, barbiturates, or narcotics, lithium, corticosteroids. Acute overdose may be manifested by drowsiness, mental confusion, nausea, vomiting or diarrhea.

Packing : **Spiretic** : 3 x 10's □ tablets in blister pack.