The highly effective solution

CODAL-SYNTO

Spiro®

Spironolactone

Spiro® 25mg tablets • **Spiro**®100mg tablets

Summary of SPC for Spiro®

Trade Name of the Medicinal Product:	Spiro®
Qualitative and Quantitative Composition:	Each tablet contains 25/100 mg of spironolactone.
Pharmaceutical Form:	Tablet.
Therapeutic indications & Posology and Method of Administration:	Adults: **Congestive cardiac failure with oedema:** 100 mg either single or divided doses is recommended, but may range from 25 mg to 200 mg daily; **Severe heart failure:** Treatment in conjunction with standard therapy should be initiated at a dose of 25 mg once daily. Patients who tolerate 25 mg once daily may have their dose increased to 50 mg once daily as clinically indicated. Patients who do not tolerate 25 mg once daily may have their dose reduced to 25 mg every other day; **Hepatic cirrhosis with ascites and oedema:** If urinary Na+/K+ ratio is greater than 1.0, 100 mg/day. If the ratio is less than 1.0, 200-400 mg/day; **Malignant ascites:** Initial dose 100-200 mg/day. In severe cases dosage may be gradually increased up to 400 mg/day; **Nephrotic syndrome:** Usual dose 100-200mg/day. Its use is only advised if glucocorticoids by themselves are insufficiently effective; **Diagnosis and treatment of primary aldosteronism:** Spiro® may be employed as an initial diagnostic measure to provide presumptive evidence of primary hyperaldosteronism while patients are on normal diets. Long test: Daily dosage of 400 mg for 3 to 4 weeks. Short test: Daily dosage of 400 mg for 4 days. After the diagnosis of hyperaldosteronism has been established by more definitive testing procedures, Spiro® may be administered at doses of 100-400 mg daily in preparation for surgery. For patients who are considered unsuitable for surgery, Spiro® may be employed for long-term maintenance therapy at the lowest effective dosage determined for the individual patient. Elderly: Start with the lowest dose and titrated upwards as required to achieve maximum benefit. Paediatric population: Initial daily dosage 1-3 mg per kg body weight given in divided doses. Dosage should be adjusted on the basis of response and tolerance. Children should only be treated under guidance of a paediatric specialist.
Contra-indications:	Hypersensitivity; Acute renal insufficiency, significant renal compromise, anuria; Addison's disease; Hyperkalaemia; Concomitant use of eplerenone or other potassium sparing diuretics and potassium supplements; Paediatric patients with moderate to severe renal impairment.
Special Warnings and Precautions for Use:	Elderly; Renal and hepatic impairment; Hyperkalaemia; Reversible increases in blood urea; Hypertensive paediatric patients with mild renal insuffiency; Spiro® contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.
Interactions with other Medicaments and other forms of Interaction:	Concomitant use of drugs known to cause hyperkalaemia, trimethoprim/sulfamethoxazole; Digoxin; Antihypertensive drugs, ACE inhibitors; Carbenoxolone; NSAIDs; Spironolactone reduces vascular responsiveness to noradrenaline in management of patients subjected to regional or general anaesthesia; Compounds with similar fluorescence characteristics; Antipyrine.
Pregnancy and Lactation:	The use of spironolactone in pregnant women requires that the anticipated benefit be weighed against the possible hazards to the mother and foetus. If the use of spironolactone is considered essential, breast feeding must be discontinued.
Undesirable Effects:	Gynaecomastia, breast enlargement, benign breast neoplasm; Leukopenia, thrombocytopenia; Electrolyte disturbances, hyperkalaemia; Changes in libido, confusion; Dizziness; Gastrointestinal disturbances, nausea; Hepatic function abnormal; Stevens-Johnson syndrome, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms, alopecia, hypertrichosis, pruritus, rash, urticaria, pemphigoid; Leg cramps; Acute renal failure; Menstrual disorders, breast pain; Malaise.
Date of Revision of the Text:	05/2016.
	MAH: Codal Synto Ltd.