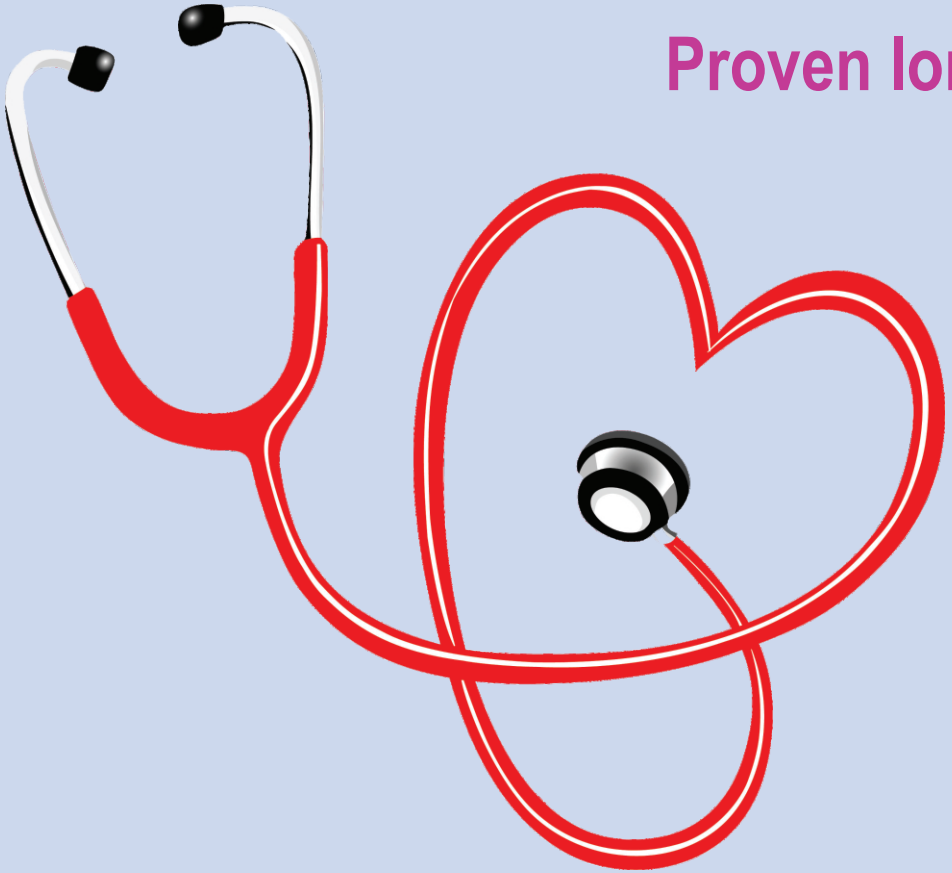

Proven long term efficacy

CODAL-SYNTO

Aceprotin®

Captopril

ACEPROTIN® 25mg tablets • **ACEPROTIN®** 50mg tablets

Summary of SPC for Aceprotin®

Trade Name of the Medicinal Product:	Aceprotin®
Qualitative and Quantitative Composition:	Each tablet contains 25 mg or 50 mg captopril.
Therapeutic Indications:	Hypertension; Heart Failure; Myocardial Infarction; Type 1 Diabetic Nephropathy.
Posology and Method of Administration:	Hypertension: The recommended starting dose is 25-50 mg daily in two divided doses. The dose may be increased incrementally, with intervals of at least 2 weeks, to 100-150 mg/day in two divided doses as needed to reach target blood pressure. Heart failure: The usual starting dose is 6.25 mg-12.5 mg BID or TID. Titration to the maintenance dose (75-150 mg per day) should be carried out based on patient's response, clinical status and tolerability, up to a maximum of 150 mg per day in divided doses. Myocardial infarction: Short-term treatment: Aceprotin treatment should begin in hospital as soon as possible. A 6.25 mg test dose should be administered, with a 12.5 mg dose being administered 2 hours afterwards and a 25 mg dose 12 hours later. From the following day, Aceprotin should be administered in a 100 mg/day dose, in two daily administrations, for 4 weeks, if warranted by the absence of adverse haemodynamic reactions. Chronic treatment: If Aceprotin treatment has not begun during the first 24 hours of the acute myocardial infarction stage, it is suggested that treatment be instigated between the 3rd and 16th day post-infarction once the necessary treatment conditions have been attained. Treatment should be started in hospital under strict surveillance until the 75 mg dose is reached. Treatment should be initiated with a dose of 6.25 mg followed by 12.5 mg 3 times daily for 2 days and then 25 mg 3 times daily if warranted by the absence of adverse haemodynamic reactions. The recommended dose for effective cardioprotection during long-term treatment is 75 to 150 mg daily in two or three doses. Type I Diabetic nephropathy: The recommended daily dose of captopril is 75-100 mg in divided doses. Renal impairment: Dosage should be reduced or the dosage interval should be increased. Elderly patients: Consideration should be given to initiating therapy with a lower starting dose (6.25 mg BID) in elderly patients. Paediatric population: The use of captopril in children and adolescents should be initiated under close medical supervision. The initial dose of captopril is about 0.3 mg/kg body weight. Generally, captopril is administered to children 3 times a day, but dose and interval of dose should be adapted individually according to patient's response.
Contra-indications:	Hypersensitivity to the active substance or to any of the excipients; History of angioedema associated with previous ACE inhibitor therapy; Hereditary/idiopathic angioneurotic oedema; Second and third trimester of pregnancy.
Special Warnings and Precautions for Use:	Hypotension; Renovascular hypertension; Renal impairment; Angioedema; Cough; Hepatic failure; Hyperkalaemia; Lithium; Aortic and mitral valve stenosis/Obstructive hypertropic cardiomyopathy; Neutropenia/Agranulocytosis; Proteinuria; Anaphylactoid reactions during desensitization and high-flux dialysis/lipoprotein apheresis membrane exposure; Surgery/Anaesthesia; Diabetic patients; Ethnic differences; Aceprotin contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption should not take this medicine.
Interactions with Other Medicinal Products and Other Forms of Interaction:	Potassium sparing diuretics or potassium supplements; Thiazide or loop diuretics; Other antihypertensive agents; Lithium; Tricyclic antidepressants/antipsychotics; Allopurinol, procainamide, cytostatic or immunosuppressive agents; NSAIDs; Sympathomimetics; Antidiabetics.
Pregnancy and Lactation:	The use of ACE inhibitors is not recommended during the first trimester of pregnancy and is contraindicated during the second and third trimesters of pregnancy. **Lactation:** Not recommended for preterm infants and for the first weeks after delivery, In the case of an older infant, the use of Aceprotin in a breast-feeding mother may be considered if this treatment is necessary for the mother and the child is observed for any adverse effect.
	MAH: Codal Synto Ltd.