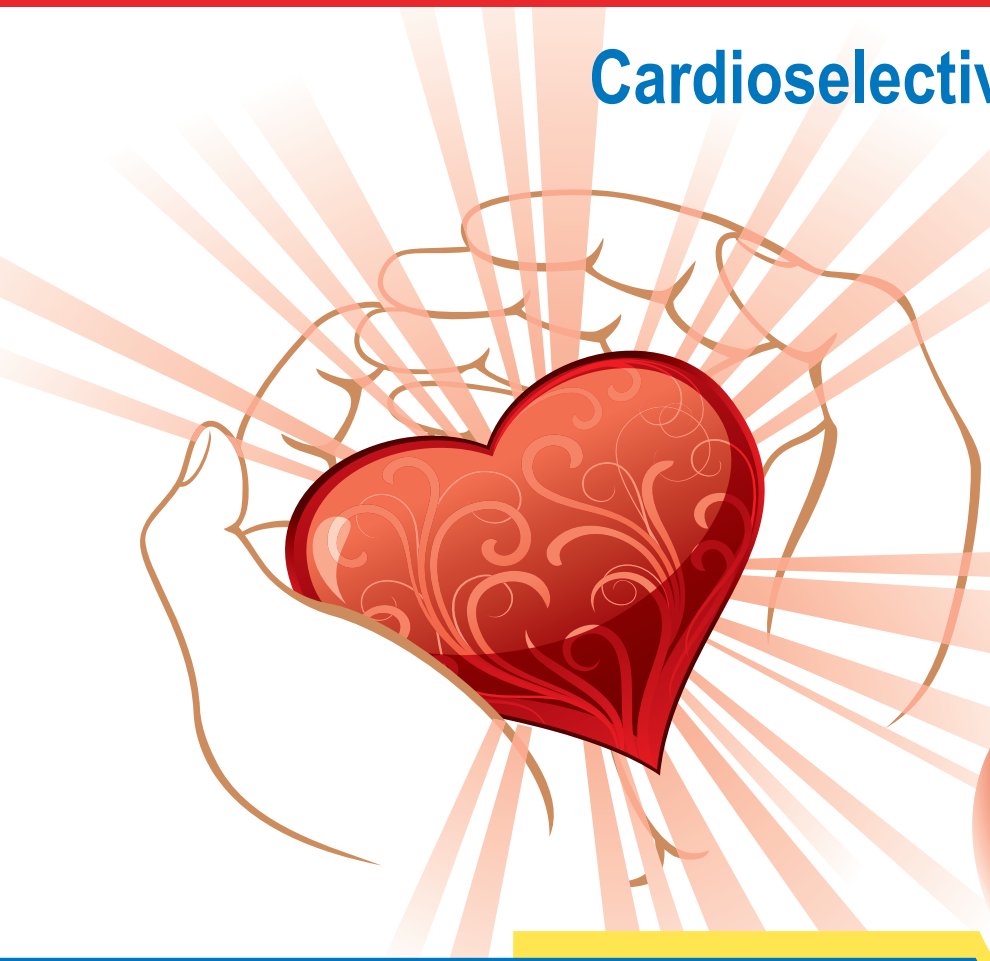
Cardioselective beta blocker



CODAL-SYNTO

Codanol®

Atenolol

CODANOL® 50mg film-coated tablets • **CODANOL®** 100mg film-coated tablets

Summary of the SPC for Codanol®

Trade Name of the Medicinal Product:	Codanol®
Qualitative and Quantitative Composition:	Each tablet contains 50mg/100mg of atenolol.
Therapeutic Indications:	Management of hypertension, angina pectoris, cardiac arrhythmias; Early intervention in the acute phase of myocardial infarction.
Posology and Method of Administration:	Hypertension: Usual dose is 100mg once a day. Some patients will respond to 50mg given as a single daily dose. It takes one to two weeks to establish the full effect. Angina pectoris: A daily dose of 100mg, given either as a single dose of 100mg or a twice daily dose of 50mg. Arrhythmias: Following initial control of the arrhythmias, maintenance can be achieved by a single daily dose of 50mg-100mg, titrated to the patients response. Myocardial infarction: Following control of the early acute phase, 100mg once a day. If bradycardia and/or hypotension needing treatment, or other adverse effects occur, treatment should be discontinued. Elderly: Dosage reduction may be necessary. Haemodialysis: A dose of 50mg after each dialysis session, this should be done under close supervision as severe falls in blood pressure can happen. Severe hepatic/renal impairment: A dosage reduction may be necessary. Paediatric population: Not recommended.
Contra-indications:	Hypersensitivity; Patients with uncontrolled heart failure, second or third degree heart block, bradycardia, cardiogenic shock, severe peripheral arterial circulation disturbances, hypotension, metabolic acidosis, untreated phaeochromocytoma or sick sinus syndrome; Concomitant administration of atenolol 100mg with a Class 1 antiarrhythmic agent.
Special Warnings and Precautions for Use:	Patients whose signs of heart failure have been controlled; Patients with Prinzmetal's angina; Peripheral arterial circulatory disturbances; Patients with first degree heart block; Atenolol can mask the symptoms of thyrotoxicosis and hypoglycemia; Reduced heart rate; Patients with ischemic heart disease; History of anaphylactic reactions to allergens; Patients with reversible obstructive airways disease, asthmatic; Concomitant administration of atenolol 50mg with a Class 1 antiarrhythmic agent.
Interactions with Other Medicinal Products and Other Forms of Interaction:	Calcium channel blockers, such as diltiazem, verapamil, nifedipine; Clonidine; Digitalis glycosides; Sympathomimetic agents; Insulin and oral antidiabetic drugs; NSAIDs; Anaesthetic agents.
Pregnancy and Lactation:	Use of atenolol in women who are, or may, become pregnant, especially in the first and second trimester, requires careful assessment of the clinical benefits versus the possible risks. Atenolol has been used for the treatment of mild to moderate hypertension in the third trimester, under close supervision, but has been associated with intrauterine growth retardation. Breast-feeding: Not recommended.
Undesirable effects:	Thrombocytopenia, purpura; Sleep disturbances, mood changes, confusion, psychoses and hallucinations; Dizziness, headache, paresthesia; Visual disturbances, dry eyes; Bradycardia, heart failure deterioration, precipitation of heart block; Cold extremities, postural hypotensions, syncope, Raynaud's phenomenon, intermittent claudication; Bronchial asthma or history of asthma, bronchospasm; GI disturbances, dry mouth; Elevations of transaminase levels, hepatic toxicity, intrahepatic cholestasis; Alopecia, psoriasiform skin reactions or worsening of psoriasis, skin rashes; Fatigue; Increase in ANA.
Date of Revision of the Text:	02/2014.
	MAH: Codal Synto Ltd.