Achieving Control

CODAL-SYNTO

Albigone®

Lisinopril

ALBIGONE® 5mg tablets • ALBIGONE® 10mg tablets • ALBIGONE® 20mg tablets

Summary of the SPC for Albigone®

Trade Name of the Medicinal Product:	Albigone®
Qualitative and Quantitative Composition:	Each tablet contains lisinopril dihydrate equivalent to 5/10/20 mg anhydrous lisinopril.
Pharmaceutical Form:	Tablet.
Therapeutic Indications & Posology and Method of Administration:	**Hypertension:** Usual starting dose is 10 mg. Patients with a strongly activated /rennin – angiotensin – aldosterone system (RAAS): Starting dose of 2.5 – 5 mg. A lower starting dose is required in the presence of renal impairment. The maintenance dosage is 20 mg daily. Paediatric patients aged 6 –16 years: Initial dose is 2.5 mg once daily in patients 20 to < 50 kg, and 5 mg once daily in patients ⩾ 50 kg. The dosage should be individually adjusted to a maximum of 20 mg daily in patients weighing 20 to < 50 kg, and 40 mg in patients ⩾ 50 kg. In children with decreased renal function, a lower starting dose or increased dosing interval should be considered. **Heart Failure:** Starting dose of 2.5 mg once a day. The highest dose tolerated by the patient is up to a maximum of 35 mg once daily. **Acute Myocardial Infarction:** Treatment may be started within 24 hours of the onset of symptoms. Treatment should not be started if systolic blood pressure is lower than 100 mm Hg. The first dose of Dapril is 5 mg given orally, followed by 5 mg after 24 hours, 10 mg after 48 hours and then 10 mg once daily. Patients with a low systolic blood pressure (120 mm Hg or less) should be given a lower dose 2.5 mg. The maintenance dose is 10 mg once daily. **Renal Complications of Diabetes Mellitus:** Usual dose is 10 mg once daily which can be increased to 20 mg once daily.
Contra-indications:	Hypersensitivity; History of angioedema associated with previous ACE inhibitor therapy; Hereditary or idiopathic angioedema; Second and third trimesters of pregnancy; Concomitant use with aliskiren-containing products in patients with diabetes mellitus or renal impairment.
Special Warnings and Precautions for Use:	Dual blockade of the RAAS; Symptomatic hypotension, patients with heart failure, with or without associated renal insufficiency, ischemic heart or cerebrovascular disease; Hypotension in Acute Myocardial Infarction; Aortic and Mitral Valve Stenosis/Hypertrophic Cardiomyopathy; Renal Impairment; Hypersensitivity/Angioedema; Anaphylactoid reactions in haemodialysis patients and during LDL apheresis; Desensitisation; Hepatic Failure; Neutropenia/Agranulocytosis; Race, black patients; Non-productive cough; Surgery/Anaesthesia; Hyperkalaemia; Diabetic patients.
Interaction with Other Medicinal Products and Other Forms of Interaction:	Dual blockade of the RAAS through the combined use of ACE-inhibitors, angiotensin II receptor blockers or aliskiren; Diuretics; Potassium Supplements, potassium – sparing diuretics or potassium – containing salt substitutes; Lithium; NSAIDs; Other antihypertensive agents; TCAs/Antipsychotics/Anaesthetics; Sympathomimetics; Antidiabetics.
Pregnancy and Lactation:	The use of ACE inhibitors is not recommended during the first trimester of pregnancy. The use of ACE inhibitors is contraindicated during the second and third trimesters of pregnancy. The use of Albigone® during breastfeeding is not recommended.
Undesirable Effects:	Decreases in haemoglobin & haematocrit, bone marrow depression, anaemia, thrombocytopenia, leucopoenia, neutropenia, agranulocytosis, haemolytic anaemia, lymphadenopathy, autoimmune disease; Hypoglycaemia; Mood alterations, sleep disturbances, mental confusion; Dizziness, headache, paresthesia, vertigo, taste disturbance; Orthostatic effects, myocardial infarction or cerebrovascular accident, palpitations, tachycardia, Raynaud's phenomenon; Cough, rhinitis, bronchospasm, sinusitis, allergic alveolitis/eosinophilic pneumonia; Diarrhoea, vomiting, nausea, abdominal pain & indigestion, dry mouth, pancreatitis, intestinal angioedema; Hepatitis, jaundice and hepatic failure; Rash, pruritus, hypersensitivity/angioneurotic oedema, urticaria, alopecia, psoriasis, diaphoresis, pemphigus, toxic epidermal necrolysis, Stevens Johnson Syndrome, erythema multiforme, fever, vasculitis, myalgia, arthralgia/arthritis, a positive antinuclear antibodies, elevated red blood cell sedimentation rate, eosinophilia and leucocytosis, rash, photosensitivity or other dermatological manifestations; Renal dysfunction, uraemia, acute renal failure, oliguria/anuria, impotence, gynecomastia; Fatigue, asthenia; Increases in blood urea, serum creatinine, serum bilirubin and in liver enzymes, hyperkalaemia, hyponatraemia.
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MAH: Codal Synto Ltd.