

Optimised Therapy



CODAL-SYNTO

# Cardamlo

Amlodipine

CARDAMLO 5mg tablets • CARDAMLO 10mg tablets

## Summary of the SPC for Cardamlo

<b>Trade Name of the Medicinal Product:</b>	Cardamlo.
<b>Qualitative and Quantitative Composition:</b>	Each tablet contains 5/10 mg of amlodipine as amlodipine besilate.
<b>Therapeutic Indications:</b>	Essential hypertension; Chronic stable and vasospastic angina pectoris.
<b>Posology and Method of Administration:</b>	Adults: Initial dose for the treatment of hypertension and angina pectoris is 5 mg once daily. If the desired therapeutic effect cannot be achieved within 2-4 weeks this dose may be increased to a maximum dose of 10 mg daily (as a single dose) depending on the individual patient's response. Paediatric population: Not recommended in children and adolescents below 18 years of age.
<b>Contra-indications:</b>	Hypersensitivity to dihydropyridine derivatives, amlodipine, or to any of the excipients; Severe hypotension; Shock; Obstruction of the outflowtract of the left ventricle; Haemodynamically unstable heart failure after acute myocardial infarction.
<b>Special Warnings and Precautions for Use:</b>	Patients with cardiac failure; Hepatic failure; Elderly patients; Paediatric population; Renal failure.
<b>Interactions with Other Medicinal Products and Other Forms of Interaction:</b>	Amlodipine should be used with caution together with CYP3A4 inhibitors and CYP3A4 inducers; The blood pressure lowering effects of amlodipine adds to the blood pressure-lowering effects of other antihypertensive agents.
<b>Pregnancy and Lactation:</b>	Use in pregnancy is only recommended when there is no safer alternative and when the disease itself carries greater risk for the mother and foetus. A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with amlodipine should be made taking into account the benefit of breastfeeding to the child and the benefit of amlodipine therapy to the mother.
<b>Effects on Ability to Drive and Use Machines:</b>	Amlodipine can have minor or moderate influence on the ability to drive and use machines.
<b>Undesirable Effects:</b>	Leukocytopenia, thrombocytopenia; Allergic reactions; Hyperglycaemia; Insomnia, mood changes, depression, confusion; Somnolence, dizziness, headache, tremor, dysgeusia, syncope, hypoesthesia, paresthesia, Hypertonia, peripheral neuropathy; Visual disturbance; Tinnitus; Palpitations, myocardial infarction, arrhythmia; Flushing, hypotension, vasculitis; Dyspnoea, rhinitis, cough; Abdominal pain, nausea, vomiting, dyspepsia, altered bowel habits, dry mouth, pancreatitis, gastritis, gingival hypeplasia; Hepatitis, jaundice, hepatic enzymes increased; Alopecia, purpura, skin discolouration, hyperhydrosis, pruritus, rash, exanthema, angioedema, erythema multiforme, urticaria, exfoliative dermatitis, Stevens-Johnson syndrome, Quincke oedema, photosensitivity; Ankle swelling, arthralgia, myalgia, muscle cramps, back pain; Micturition disorder, nocturia, increased urinary frequency; Impotence, gynecomastia; Oedema, fatigue, chest pain, asthenia, pain, malaise ; Weight increase, weight decrease.
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**MAH:** Codal Synto Ltd.

