For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Cardace® Protect

Ramipril & Atorvastatin Tablets

COMPOSITION

Each tablet contains Ramipril IP 2.5 mg + Atorvastatin Calcium IP equivalent to Atorvastatin 10 mg.

Each tablet contains Ramipril IP 5.0mg + Atorvastatin Calcium IP equivalent to Atorvastatin 10mg.

THERAPEUTIC INDICATIONS: For treatment of patients with both essential hypertension and hypercholesterolemia. Ramipril has been found to reduce risk of MI, stroke or cardiovascular death in patients with increased risk. Atorvastatin has been found to reduce the risk of MI, stroke, revascularization procedures and angina in patients with CHD.

DOSAGE AND ADMNISTRATION: One tablet daily. If control is inadequate, dose may be increased.

SAFETY RELATED INFORMATION

Contraindications : Hypersensitivity to ramipril, other ACE inhibitors, atorvastatin or any of the excipients, history of angioedema not to be used concomitantly with sacubitril/valsartan therapy, Do not initiate Cardace® Protect until sacubitril/valsartan is eliminated from the body. In case of switch from Cardace® Protect to sacubitril/valsartan, do not start sacubitril/valsartan until Cardace® Protect is eliminated from the body, hemodynamically relevant renal artery stenosis, bilateral or unilateral in the single kidney, hypotensive or hemodynamically unstable states, with aliskiren-containing medicines in patients with diabetes or with moderate to severe renal impairment (creatinine clearance <60 mL/min), with angiotensin II receptor antagonists (AIIRAs) in patients with diabetic nephropathy pregnancy, active liver disease, nursing mothers. Extracorporeal treatments such as dialysis must be avoided. Acute liver failure or decompensated cirrhosis.

Warnings and precautions:

Ramipril**:** Discontinue treatment in case of angioedema of head, neck or extremities**,** face, lips, tongue, glottis or larynx, intestinal angioedema. An increased risk of angioedema is possible with concomitant use of other drugs which may cause

angioedema, Dual blockade of the renin-angiotensin-aldosterone system. The use of Cardace® Protect in combination with an AIIRA is contraindicated in patients with diabetic nephropathy. Caution in patients with a hyper-stimulated renin-angiotensin system, liver diseases, patients at particular risk from a pronounced reduction in blood pressure, elderly. Insufficient experience for use of ramipril in children, in patients with severe impairment of renal, and in dialysis patients. Monitoring of renal function, electrolyte and hematological monitoring is recommended.

Atorvastatin**:** Rare cases of rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported. Occasionally causes myopathy. Atorvastatin may cause myopathy (muscle pain, tenderness, or weakness with creatine kinase (CK) and rhabdomyolysis. (with or without acute renal failure secondary to myoglobinuria).Rare fatalities have occurred as a result of rhabdomyolysis with statin use, including Atorvastatin. Risk increases with concomitant use of higher doses of atorvastatin with cyclosporine, fibrates and strong CYP3A4 inhibitors (clarithromycin, itraconazole, HIV protease inhibitors). Risk factors for myopathy include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher Atorvastatin dosage. Atorvastatin therapy should be temporarily withheld or discontinued in any patient with an acute, serious condition suggestive of a myopathy or having a risk factor predisposing to the development of renal failure secondary to rhabdomyolysis. Statins have been associated with biochemical abnormalities of liver function. Increases in serum transaminases have been reported with use of Atorvastatin. Liver function tests be performed prior to and at 12 weeks following both the initiation of therapy and any elevation of dose, and periodically (e.g., semiannually) thereafter. Should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of liver disease. Statins interfere with cholesterol synthesis and theoretically might blunt adrenal and/or gonadal steroid production. CNS vascular lesions, characterized by perivascular hemorrhages, edema, and mononuclear cell infiltration of perivascular spaces, have been observed in dogs treated with other members of this class. In a post-hoc analysis of a clinical trial, some baseline characteristics, including hemorrhagic and lacunar stroke on study entry, were associated with a higher incidence of hemorrhagic stroke in the atorvastatin group. It is not known if atorvastatin calcium tablets are safe and effective in children younger than 10 years of age with HeFH or HoFH or in children with other types of hyperlipidemia (other than HeFH or HoFH).

Pregnancy & Lactation: Contraindicated.

ADVERSE REACTIONS: Common adverse events reported with ramipril are headache, dizziness, non-productive tickling cough, bronchitis, sinusitis, dyspnoea, gastrointestinal inflammation, digestive disturbances, abdominal discomfort, dyspepsia, diarrhoea, nausea, vomiting, rash in particular maculo-papular, muscle

spasms, myalgia, increase in blood potassium levels, hypotension, decrease in orthostatic blood pressure, syncope, chest pain, fatigue. Most commonly reported adverse reactions in placebo controlled trials regardless of causality were: nasopharyngitis, arthralgia, diarrhoea, pain in extremity and urinary tract infection.

Common adverse events reported with Atorvastatin are Myopathy, Rhabdomyolysis, Immune-Mediated Necrotizing Myopathy, Hepatic Dysfunction and Increases in HbA1c and Fasting Serum Glucose Levels.

For full prescribing information, refer to the company website www.sanofi.in

Updated: April 2026

Reference: CCDS version 19 dated 15th January 2026 + Atorvastatin: Package Insert / Prescribing Information updated on 31st March, 2026 (Accessed on 6th April 2026).