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

Abridged Prescribing Information

Ramipril Tablets IP

CARDACE®

THERAPEUTIC CATEGORY
Antihypertensive

COMPOSITION
Each tablet contains 1.25 / 2.5 / 5 / 10 mg of Ramipril IP.

THERAPEUTIC INDICATION
For reducing the risk of myocardial infarction, stroke, cardiovascular death or revascularization procedures in diabetic patients 55 years or more with one or more of the following risk factors: systolic blood pressure >160mmHg or diastolic blood pressure > 90mmHg (or on antihypertensive treatment); total cholesterol >5.2mmol/L; HDL cholesterol < 0.9mmol/L; current smoker; known microalbuminuria; any evidence of previous vascular disease. Prevention of myocardial infarction, stroke or cardio-vascular death and reduction of need for revascularization procedures in patients with an increased cardiovascular risk such as manifest coronary heart disease, a history of stroke or a history of peripheral vascular disease. Treatment of patients who within the first few days after an acute myocardial infarction have demonstrated clinical signs of congestive heart failure. Treatment of hypertension and cardiac failure. Treatment of non-diabetic or diabetic overt glomerular or incipient nephropathy.

DOSAGE AND ADMINISTRATION
Hypertension - Initial dose 2.5 mg od; Maintenance dose 2.5-5.0 mg daily. Maximum dose 10mg daily. Congestive heart failure - Initial dose 1.25mg od; Maximum daily dose 10mg. Treatment after myocardial infarction – Initial dose 5 mg daily; Maximum daily dose 10mg. Reduction in the risk of myocardial infarction, stroke, or cardiovascular death: Initial dose: 2.5 mg od; maintenance dose 10mg od. Diabetic or non-diabetic nephropathy – Initial dose 1.25mg od, may be increased to 5mg od. Dose to be adjusted in special populations like patients with impaired renal function; patients pre-treated with diuretic; patients with impaired liver function; elderly.

SAFETY-RELATED INFORMATION
Contraindications: Hypersensitivity to ramipril, ACE inhibitor or any excipients; history of angioedema;
not to be used concomitantly with sacubitril/valsartan therapy. Do not initiate Cardace® until sacubitril/valsartan is eliminated from the body. In case of switch from Cardace® to sacubitril/valsartan, do not start sacubitril/valsartan until Cardace® is eliminated from the body; haemodynamically relevant renal artery stenosis; hypotensive or heamodynamically unstable states; with aliskiren-containing medicines in patients with diabetes or with moderate to severe renal impairment (creatinine clearance <60 ml/min); pregnancy; extracorporeal treatments such as dialysis must be avoided. Must not be used with angiotensin II receptor antagonists (AIIRAs) in patients with diabetic nephropathy.
Warnings: Angioedema of head, neck or extremities, necessitates immediate discontinuation of the drug. Angioedema – Intestinal; symptoms resolved after stopping ACE inhibitor. An increased risk of angioedema is possible with concomitant use of other drugs which may cause angioedema. Insufficient experience concerning the use of ramipril in children, patients with severe impairment of renal function and in dialysis patients.
Precautions: Dual blockade of the renin-angiotensin-aldosterone system (RAAS) by combining CARDACE® with an angiotensin- II receptor antagonist (AIIRA) or with aliskiren is not recommended since there are increased risks of hypotension, hyperkalemia and changes in renal function compared to monotherapy. The use of CARDACE® in combination with an AIIRA is contraindicated in patients with diabetic nephropathy. Medical supervision in case of patients with hyper-stimulated renin-angiotensin system, liver disease, patients at particular risk from a pronounced reduction in blood pressure, elderly. Monitoring of renal function, electrolyte and hematological monitoring.
Pregnancy & lactation: Contraindicated in pregnancy, Insufficient information in lactation hence not recommended.
Adverse reactions: Common : 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, blood potassium increased, hypotension, orthostatic blood pressure decreased, chest pain and fatigue.

For full prescribing information please contact : Sanofi India Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai 400072

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