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

**Abridged Prescribing Information**

**CARDACE® am**
**Ramipril and Amlodipine Tablets**

**COMPOSITION: Cardace® am 10:** Each uncoated tablet contains: Ramipril IP 10.0 mg and Amlodipine Besylate IP equivalent to Amlodipine 5.0 mg. **Cardace® am 5:** Each uncoated tablet contains: Ramipril IP 5.0 mg and Amlodipine Besylate IP equivalent to Amlodipine 5.0 mg. **Cardace® am 2.5:** Each uncoated tablet contains: Ramipril IP 2.5 mg and Amlodipine Besylate IP equivalent to Amlodipine 5.0 mg.
**THERAPEUTIC INDICATIONS:** For the treatment of hypertension.
**DOSAGE & ADMINISTRATION:** Recommended initial dose: Cardace® am 2.5mg once daily which may be increased based on patient response. Cardace® am 5mg/5mg or Cardace® am 10mg/5mg may be used for higher dosing. Maximum daily dose of ramipril and amlodipine is 10mg each.
SAFETY RELATED INFORMATION
**Contraindications:** Related to both ramipril and amlodipine: in patients with hypersensitivity to ramipril, amlodipine, other ACE inhibitors, dihydropyridine derivatives or to any of the excipients Ramipril: history of angioedema; not to be used concomitantly with sacubitril/valsartan therapy; Do not initiate Cardace®am until sacubitril/valsartan is eliminated from the body. In case of switch from Cardace®am to sacubitril/valsartan, do not start sacubitril/valsartan until Cardace®am is eliminated from the body; haemodynamically relevant renal artery stenosis, bilateral or unilateral in the single kidney; hypotensive or haemodynamically 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;Concomitant use of ACE inhibitors and extracorporeal treatments leading to contact of blood with negatively charged surfaces must be avoided. **Amlodipine:** in patients with severe hypotension, in patients with shock (including cardiogenic shock), in patients with obstruction of the outflow tract of the left ventricle (e.g. high grade aortic stenosis), in patients with haemodynamically unstable heart failure after acute myocardial infarction
**Warnings:** ***Ramipril:*** Angioedema of head, neck region and extremities necessitates immediate discontinuation of the drug. Intestinal angioedema reported with abdominal pain (with or without nausea or vomiting); some cases of, angioedema of the face extremities, lips, tongue, glottis or larynx. Symptoms resolved after stopping the ACE inhibitor. An increased risk of angioedema is possible with concomitant use of other drugs which may cause angioedema. The likelihood and severity of anaphylactic and anaphylactoid reactions to insect venoma is increased ***Amlodipine:*** Elderly patients should start therapy at a lower dose. Mild renal impairment does not have an effect on the plasma concentrations. Severe renal impairment and hepatic impairment may require a dosage reduction. Slow dose titration and careful monitoring may be required in patients with severe hepatic impairment. Patients with heart failure should be treated with caution. Increased incidence of pulmonary oedema reported in heart failure.
**Precautions:** Caution is recommended in patients who are being treated concurrently with diuretics since these patients may be volume and/or salt depleted. Renal function and serum potassium should be monitored Dual blockade of the renin-angiotensin-aldosterone system (RAAS). The use of Cardace® am in combination with aliskiren is contraindicated in patients with diabetes mellitus or with renal impairment. Significant activation of the renin angiotensin system is to be anticipated. Regular medical supervision. The use of Cardace® am in combination with an AIIRA is contraindicated in patients with diabetic nephropathy. **Patients with hyper-stimulated rennin angiotensin system:** Particular caution must be exercised. Risk of an acute pronounced fall in blood pressure and deterioration of renal function especially when an ACE inhibitor or a concomitant diuretic is given for the first time or for the first time at an increased dose. **Patients with liver diseases:** Response to treatment may be either increased or reduced. In patients with severe liver cirrhosis with oedema and/or ascites, the renin angiotensin system may be significantly activated. **Patients at particular risk from a pronounced reduction in blood pressure:** The initial phase of treatment requires special medical supervision. **Elderly:** Some elderly patients may be particularly responsive to ACE inhibitors. Evaluation of renal function at the beginning of treatment is recommended. Increase of the dosage should take place with care. **Monitoring of renal function:** Recommended that renal function be monitored, particularly in the initial weeks of treatment. Particularly careful monitoring is required in patients with heart failure, renovascular disease, impairment of renal function**,** kidney transplant **Electrolyte monitoring:** Serum potassium is recommended to be monitored regularly. **Hematological monitoring:** The white blood cell count should be monitored to permit detection of a possible leucopenia.**Surgery:** It is recommended that treatment should be discontinued where possible one day before surgery
**Pregnancy & lactation:** Not be taken during pregnancy. Not recommended in lactation, alternative treatment preferable.
Amlodipine is excreted in human milk. The proportion of the maternal dose received by the infant has been estimated with an interquartile range of 3 – 7%, with a maximum of 15%. The effect of amlodipine on infants is unknown.

**Adverse reactions: Ramipril:** Common (> 1 % and < 10 %): Blood potassium increased, Headache, dizziness (lightheadedness), Hypotension, orthostatic blood pressure decreased (disturbed orthostatic regulation), syncope, Non-productive tickling cough, bronchitis, sinusitis, dyspnea, Gastrointestinal inflammation (inflammatory reactions of the gastrointestinal tract), digestive disturbances, abdominal discomfort, dyspepsia, diarrhoea, nausea, vomiting, Rash in particular maculo-papular, Muscle spasms (muscle cramps), myalgia, Chest pain, fatigue. **Amlodipine:** *Very common ≥ 10%:* Oedema Common (> 1 % and < 10 %):

Somnolence, dizziness, headache (especially at the beginning of the treatment) , Visual disturbance (including diplopia), Palpitations , Flushing , Dyspnoea , Abdominal pain, nausea, dyspepsia, altered bowel habits (including diarrhoea and constipation), Ankle swelling, muscle cramps , Impotence, gynaecomastia ,Fatigue, asthenia

For full prescribing information, please contact: Sanofi India Limited, Registered Office: Sanofi House, C.T.S No-117- B, L& T Business park, Saki Vihar Road, Powai, Mumbai 400072- India
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