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

Abridged prescribing information

Ramipril & Metoprolol Succinate Extended Release Tablets
CARDACE® METO

THERAPEUTIC CATEGORY: Antihypertensive

COMPOSITION: Cardace® Meto 2.5: Each uncoated bilayer tablet contains Ramipril I.P 2.5mg + Metoprolol Succinate IP 23.75mg equivalent to (Metoprolol tartrate 25mg) (as extended release).
Cardace® Meto 5: Each uncoated bilayer tablet contains Ramipril I.P. 5mg + Metoprolol Succinate IP 47.5mg equivalent to (Metoprolol tartrate 50mg) (as extended release).
THERAPEUTIC INDICATIONS: For the treatment of essential hypertension in adults.
DOSAGE AND ADMNISTRATION: One tablet daily. The dosage should be individualized and titration may be needed in some patients. Lowest effective dose is recommended for patients with hepatic dysfunction or renal impairment and for elderly patients.
SAFETY-RELATED INFORMATION
Contraindications : Hypersensitivity to ramipril, metoprolol, beta blocker, ACE inhibitor, or any of the excipients, history of angioedema, not to be used concomitantly with sacubitril/valsartan therapy;, Do not initiate Cardace® Meto until sacubitril/valsartan is eliminated from the body. In case of switch from Cardace®Meto to sacubitril/valsartan, do not start sacubitril/valsartan until Cardace®Meto 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, severe bradycardia, second or third degree heart block cardiogenic shock, decompensated cardiac failure, sick sinus syndrome (unless a permanent pacemaker is in place), concomitant use of ACE inhibitors and extracorporeal treatments must be avoided,
WARNINGS: Discontinue treatment in case of angioedema. An increased risk of angioedema is possible with concomitant use of other drugs which may cause angioedema. Abrupt cessation of therapy may result in exacerbations of angina pectoris and myocardial infarction. Heart Failure:Worsening cardiac failure may occure during up titration of Cardace® Meto. Lowest possible dose should be used in patients with bronchospastic disease. Pheochromocytoma:If Cardace® Meto is used in the setting of pheochromocytoma, it should be given in combination with an alpha blocker and only after the alpha blocker has been initiated. Administration of beta-blockers alone in the setting of pheochromocytoma has been associated with a paradoxical increase in blood pressure due to the attentuation of beta mediated vasodilation in skeletal muscleTherapy should be withdrawn prior to major surgery. Should be used in caution in diabetic patients. Hepatic Impairment:Consider initiating Cardace® Meto therapy at doses lower than those recommended for a given indication; gradually increase dosage to optimize therapy, while monitoring closely for adverse events.Thyrotoxicosis: Abrupt withdrawal of beta blockade may precipitate a thyroid strom. Anaphylactic Reaction:While taking beta blockers,patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactve to repeated challenge and may be unresponsive to the usual doses of epinephrine used to treat an allergic reaction. Caution in patients with peripheral vascular disease and in patients treated with calcium channel blockers. Anaphylactoid and related reactions have been reported. Can cause symptomatic hypotension. Discontinue therapy in case of jaundice or marked elevations of hepatic enzymes. Not suitable for acute therapy in rapidly reducing blood pressure. Should not be used in patients aortic or mitral valve stenosis or outflow obstruction
Precautions: The use of Cardace®Meto in combination with an AIIRA is contraindicated in patients with diabetic nephropathy. Dual blockade of the renin-angiotensin-aldosterone system by combining Cardace®Meto with an angiotensin-II receptor antagonist (AIIRA) or aliskiren is not recommended .Regular medical supervision especially in patients at risk from pronounced reduction in blood pressure. Caution in patients with a hyper-stimulated rennin-angiotensin system and impaired liver function. Evaluation of renal function must be done in elderly. Monitoring of renal function, electrolyte monitoring and haematological monitoring is recommended.
Pregnancy & Lactation: Contraindicated in pregnancy, not recommended in lactation. Safety and efficacy in paediatric population has not been established.
Adverse reactions : ***Ramipril*****:** Common : headache, dizziness, non-productive tickling cough, bronchitis, sinusitis, dyspnoea, gastrointestinal inflammation, digestive disturbances, abdominal discomfort, dyspepsia, diarrhea, 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.

***Metoprolol*:** Adverse reactions reported include CNS, cardiovascular, respiratory, gastrointestinal, hematologic, musculoskeletal, reproductive adverse reactions. Hypersensitive reactions, photosensitivity, taste disturbance, blurred vision, dry eyes and tinnitus, has been reported.

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

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Source: Ramipril CCDS Version 18 dated 09th November 2017 & TOPROL-XL (Astra Zeneca) pack insert dated May 2014(accessed on 02nd February 2018)