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

Abridged Prescribing Information

Ramipril & Hydrochlorothiazide Tablets IP

CARDACE®H

THERPAEUTIC CATEGORY

Antihypertensive

COMPOSITION

Each tablet contains 2.5 / 5 / 10 mg of Ramipril IP and Hydrochlorothiazide IP 12.5 mg

THERAPEUTIC INDICATIONS

For the treatment of mild to moderate hypertension in patients (in whom combination therapy is appropriate) who have been stabilized on the individual components given in the same proportion. Not suitable for treatment of hypertension due to primary hyperaldosteronism.

DOSAGE AND ADMINISTRATION

Usual initial dose: 2.5 mg ramipril/12.5mg hydrochlorothiazide daily. Dose may be increased at intervals of 2 to 3 weeks. For 10mg / 12.5mg : One tablet once daily in patients whose blood pressure is controlled with ramipril and hydrochlorothiazide given individually at the same doses or in patients whose blood pressure is not adequately controlled with ramipril 10mg alone. Maximum permitted daily dose: 10 mg ramipril/50 mg hydrochlorothiazide. Not recommended in children and adolescents below 18 years of age. Initial dose should be lower and subsequent dose titration should be more gradual in elderly. Contraindicated in patients with severe renal impairment and in dialysis patients and in severe hepatic impairment.

SAFETY-RELATED INFORMATION

Contraindications : Hypersensitivity to ramipril, any other ACE inhibitor, hydrochlorothiazide, other thiazide diuretics, sulphonamides or any excipients; history of angioedema;not to be used concomitantly with sacubitril/valsartan therapy. Do not initiate Cardace® H until sacubitril/valsartan is eliminated from the body. In case of switch from Cardace® H to sacubitril/valsartan, do not start sacubitril/valsartan until Cardace® H is eliminated from the body.; severe renal impairment of renal function with a creatinine clearance below 30 ml/min per 1.73 m2 body surface area and dialysis ; haemodynamically relevant renal artery stenosis, bilateral or unilateral in the single kidney; clinically relevant electrolyte disturbances which may worsen following treatment with Cardace H (e.g., hypokalaemia, hyponatrameia, or hypercalcaemia); severe impairment of liver function; 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 and lactation. Concomitant use of ACE inhibitors and extracorporeal treatments leading to contact of blood with negatively charged surfaces must be avoided, may lead to severe anaphylactoid reactions.

Warnings:Choroidal effusion, Secondary Acute Angle – Closure Glaucma and/or Acute Myopia, Angioedema - Head, Neck or Extremities; Intestinal Angioedema, An increased risk of angioedema is possible with concomitant use of other drugs which may cause angioedema. Severe cases of acute respiratory toxicity, including acute respiratory distress syndrome (ARDS) have been reported after taking hydrochlorothiazide. Pulmonary oedema typically develops within minutes to hours after hydrochlorothiazide intake.Non-melanoma skin cancer : patients should be informed of the risk on non-melanoma skin and lip cancer and advised regular check. Special attention is advised in patients with known risk factors of skin cancer. Photosensitivity : Photosensitivity reactions have been reported with the use of thiazide diuretics. If photosensitivity reactions occur, treatment should be stopped.

Precautions: Dual blockade of the renin-angiotensin-aldosterone system (RAAS) by combining Cardace® H 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.. Treatment requires regular medical supervision. The use of Cardace® H in combination with an AIIRA is contraindicated in patients with diabetic nephropathy. Caution in patients with hyper-stimulated renin angiotensin system, patients at particular risk from a pronounced reduction in blood pressure, elderly patients. Monitoring of renal function particularly in initial weeks of treatment. Electrolyte and haematological monitoring is recommended.

Adverse reactions : Common adverse reactions include headache, dizziness (light headedness), non-productive tickling cough, bronchitis, diabetes mellitus inadequate control, glucose tolerance decreased, blood glucose increased, blood uric acid increased, gout aggravated, choroidal effusion blood cholesterol and / or triglycerides increased due to hydrochlorothiazide, fatigue, asthenia.

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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