NEBICARD-T

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

Abbreviated Prescribing information for NEBICARD-T (Nebivolol Hydrochloride 5mg and Telmisartan 40mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Nebivolol: - The possible factors involved for antihypertensive activity of Nebivolol may include 1) Decreased heart rate 2) Decreased myocardial contractility 3) Diminution of tonic sympathetic outflow to the periphery from cerebral vasomotor centers 4) Suppression of rennin activity 5) Vasodilation and decreased peripheral vascular resistance. Telmisartan: - Angiotensin ll is formed from angiotensin I in a reaction catalyzed by angiotensin converting enzyme (ACE, kininase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium.

INDICATIONS: Nebicard-T is indicated in the treatment of essential hypertension.

DOSAGE AND ADMINISTRATION: For most patients, the recommended starting dose is one tablet a day, with or without food, as monotherapy or in combination with other agents. For patients requiring further reduction in blood pressure, the dose can be increased at 2-week intervals.

CONTRAINDICATIONS: Nebicard-T is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, or severe hepatic impairment, and in patients who are hypersensitive to any component of this product.

PRECAUTIONS Do not abruptly discontinue this drug therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with beta blockers, patient's with bronchospastic diseases, diabetes and hypoglycemia, thyrotoxicosis, peripheral vascular disease, impaired renal function, pheochromocytoma should receive beta-blockers with prior caution as it can precipitate or aggravate symptoms. Drugs that act directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. As the majority of telmisartan is eliminated by biliary excretion, patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance, hence telmisartan should be used with caution in these patients, with a smaller dosage. Do not co-administer aliskiren with telmisartan in patients with diabetes.

DRUG INTERACTIONS: Drugs that inhibit CYP2D6, calcium antagonists, anti-arrhythmic, clonidine, digitalis, insulin and oral anti-diabetic drugs, anaesthetics, digoxin, warfarin, acetaminophen, amlodipine, glibenclamide, simvastatin, hydrochlorothiazide or ibuprofen.

ADVERSE REACTIONS: Headache, fatigue, dizziness, diarrhea, nausea, asthenia, abdominal pain hypercholesterolemia and hyperuricemia, paraesthesia, impotence, increased sweating, flushing, palpitation, dependent edema, angina pectoris, tachycardia, leg edema, abnormal ECG, insomnia, somnolence, migraine, vertigo, paresthesia, involuntary muscle contractions, hypoaesthesia, flatulence, constipation, gastritis, vomiting, dry mouth, hemorrhoids, gastroenteritis, enteritis, gastroesophageal reflux, toothache, non-specific gastrointestinal disorders, gout, hypercholesterolemia, diabetes mellitus, arthritis, arthralgia, leg cramps, anxiety, depression, nervousness, fungal infection, abscess, otitis media, asthma, bronchitis, rhinitis, dyspnea, epistaxis, dermatitis, urticaria, rash, eczema, pruritis, micturition frequency, cystitis, abnormal vision, conjunctivitis and tinnitus.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ NEBICARD-T 5, 40 mg /FEB-2022/02/ABPI

(Additional information is available on request)