NEBICARD T 2.5 mg

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

Abbreviated Prescribing information for NEBICARD T 2.5 mg [Nebivolol Hydrochloride and Telmisartan Tablets (2.5 mg + 40 mg)]
[Please refer the complete prescribing information available at www.torrentpharma.com]

WARNING: FETAL TOXICITY

- When pregnancy is detected, discontinue Telmisartan as soon as possible.
- Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Nebivolol:*** The mechanism of action of the antihypertensive response of Nebivolol has not been definitively established. Possible factors that may be involved include: (1) decreased heart rate, (2) decreased myocardial contractility, (3) diminution of tonic sympathetic outflow to the periphery from cerebral vasomotor centres, (4) suppression of renin activity and (5) vasodilation and decreased peripheral vascular resistance. ***Telmisartan*****:** Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland.

INDICATIONS: It is indicated for the management of essential Hypertension.

DOSAGE AND ADMINISTRATION: ***Nebivolol:*** For most patients, the recommended starting dose is 5 mg once daily. In patients with severe renal impairment (ClCr less than 30 mL/min) the recommended initial dose is 2.5 mg once daily. ***Telmisartan*****:** The usual starting dose of Telmisartan tablets is 40 mg orally once a day.

CONTRAINDICATION: ***Nebivolol:*** Severe bradycardia. •Heart block greater than first degree. •Patients with cardiogenic shock. •Decompensated cardiac failure. •Sick sinus syndrome (unless a permanent pacemaker is in place) • Patients with severe hepatic impairment (Child-Pugh >B) .•Patients who are hypersensitive to any component of this product. ***Telmisartan***: Telmisartan is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product. Do not co-administer aliskiren with Telmisartan in patients with diabetes.

WARNINGS & PRECAUTIONS: ***Nebivolol:*** When discontinuation of Nebivolol is planned, carefully observe and advise patients to minimize physical activity. Taper Nebivolol over 1 to 2 weeks when possible. In general, patients with bronchospastic diseases should not receive β-blockers. If β-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures. Beta-blockers may prevent early warning signs of hypoglycemia, such as tachycardia, and increase the risk for severe or prolonged hypoglycemia. Abrupt withdrawal of β-blockers may be followed by an exacerbation of the symptoms of hyperthyroidism or may precipitate a thyroid storm. β-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease. Renal clearance of nebivolol is decreased in patients with severe renal impairment. Metabolism of nebivolol is decreased in patients with moderate hepatic impairment. In patients with known or suspected pheochromocytoma, initiate an α-blocker prior to the use of any β-blocker. ***Telmisartan:*** When pregnancy is detected, discontinue Telmisartan as soon as possible. In patients with an activated renin-angiotensin system, such as volume- or salt-depleted patients (e.g., those being treated with high doses of diuretics), symptomatic hypotension may occur after initiation of therapy with Telmisartan. Hyperkalemia may occur in patients on ARBs, consider periodic determinations of serum electrolytes to detect possible electrolyte imbalances, particularly in patients at risk. patients with biliary obstructive disorders or hepatic insufficiency can be expected to have reduced clearance. In patients whose renal function may depend on the activity of the renin-angiotensin-aldosterone system, treatment with angiotensin receptor antagonists has been associated with oliguria and/or progressive azotemia and (rarely) with acute renal failure. Do not co-administer aliskiren with Telmisartan in patients with diabetes. Avoid concomitant use of aliskiren with Telmisartan in patients with renal impairment (GFR < 60 mL/min/1.73 m^2).

DRUG INTERACTIONS: ***Nebivolol:*** Use caution when Nebivolol is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc). Do not use Nebivolol with other β-blockers. Concomitant use with digitalis glycosides can increase the risk of bradycardia. Nebivolol can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (particularly of the phenylalkylamine and benzothiazepine classes), or antiarrhythmic agents. ***Telmisartan:*** Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium. In patients who are elderly, volume-depleted (including those on diuretic therapy), or with compromised renal function, co-administration of NSAIDs, including selective COX-2 inhibitors, with telmisartan, may result in deterioration of renal function, including possible acute renal failure. The antihypertensive effect of telmisartan may be attenuated by NSAIDs.

ADVERSE REACTIONS: Hyperkalaemia, bradycardia, diarrhea, nausea, fatigue, chest pain, headache, dizziness, insomnia, dyspnea, asthenia, abdominal pain, paraesthesia, increase in BUN, uric acid, triglycerides, decrease in HDL cholesterol, increased AST, ALT and bilirubin, acute pulmonary edema, acute renal failure, atrioventricular block (both second and third degree), bronchospasm, erectile dysfunction, hypersensitivity (including urticaria, allergic vasculitis and rare reports of angioedema), myocardial infarction, psoriasis, raynaud's phenomenon, peripheral ischemia/claudication, syncope, thrombocytopenia, vertigo, vomiting, lichenoid keratosis, upper respiratory tract infection, back pain, sinusitis, pharyngitis, coughing, hypertension, peripheral edema, impotence, increased sweating, flushing, fever, leg pain, malaise, palpitation, angina pectoris, tachycardia, leg edema, abnormal ECG, somnolence, migraine, paresthesia, involuntary muscle contractions, hypoesthesia, flatulence, constipation, gastritis, dry mouth, hemorrhoids, gastroenteritis, enteritis, gastroesophageal reflux, toothache, non-specific gastrointestinal disorders, gout, hypercholesterolemia, diabetes mellitus, arthritis, arthralgia, leg cramps, anxiety, depression, nervousness, infection, fungal infection, abscess, otitis media, asthma, bronchitis, rhinitis, epistaxis, dermatitis, rash, eczema, pruritus, micturition frequency, cystitis, cerebrovascular disorder, abnormal vision, conjunctivitis, tinnitus, earache, anemia, eosinophilia, thrombocytopenia, face edema, increased CPK, uric acid increased, angioedema (with fatal outcome), angioneurotic edema, drug eruption (toxic skin eruption mostly reported as toxicoderma, rash, and urticaria), erythema, hypotension (including postural hypotension), and rhabdomyolysis.

MARKETED BY:

TORRENT PHARMA

Torrent Pharmaceuticals Limited.

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(Additional information is available on request)