

## NEBICARD LN

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

Abbreviated Prescribing information for NEBICARD LN (Nebivolol Hydrochloride & Cilnidipine Tablets)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** Nebivolol combines two pharmacological activities: It is a competitive and selective beta-receptor antagonist: this effect is attributed to the SRRR-enantiomer (d-enantiomer). It has mild vasodilating properties due to an interaction with the L-arginine/nitric oxide pathway. Cilnidipine acts on the L-type calcium channels of blood vessels by blocking the incoming calcium and suppressing the contraction of blood vessels, thereby reducing blood pressure. It also works on the N-type calcium channel located at the end of the sympathetic nerve, inhibiting the emission of norepinephrine and suppressing the increase in stress blood pressure.

**DOSAGE AND ADMINISTRATION:** One tablet once daily or as directed by physician.

**CONTRAINDICATION:** Contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to the active substance or to any of the excipients. Liver insufficiency or liver function impairment. Acute heart failure, cardiogenic shock or episodes of heart failure decompensation requiring i.v. inotropic therapy. Nebivolol is also contraindicated in: sick sinus syndrome, including sino-atrial block, second and third degree heart block (without a pacemaker), history of bronchospasm and bronchial asthma, untreated phaeochromocytoma, metabolic acidosis, bradycardia (heart rate < 60 bpm prior to start therapy), hypotension (systolic blood pressure < 90 mmHg), severe peripheral circulatory disturbances.

**WARNINGS & PRECAUTIONS:** **Nebivolol Hydrochloride** *Anaesthesia:* Caution should be observed with certain anaesthetics that cause myocardial depression. The patient can be protected against vagal reactions by intravenous administration of atropine. *Cardiovascular:* It should be used with caution: in patients with peripheral circulatory disorders (Raynaud's disease or syndrome, intermittent claudication), as aggravation may occur; with first degree heart block, because of the negative effect of beta-blockers on conduction time; with Prinzmetal's angina due to unopposed alpha receptor mediated coronary artery vasoconstriction: beta-adrenergic antagonists may increase the number and duration of anginal attacks. *Metabolic/Endocrinological:* Care should be taken in diabetic patients, as nebivolol may mask certain symptoms of hypoglycaemia (tachycardia, palpitations). *Respiratory:* It should be used with caution as airway constriction may be aggravated. Psoriasis should take beta-adrenergic antagonists only after careful consideration. *Other:* It may increase the sensitivity to allergens and the severity of anaphylactic reactions. It contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Cilnidipine:** Cilnidipine should be used with caution in patients with Hypotension, poor cardiac reserve and heart failure. Discontinue in patients who experience ischemic pain following administration.

**DRUG INTERACTION:** **Nebivolol Hydrochloride:** *Pharmacodynamic interactions:* Combinations not recommended: Class I antiarrhythmics: effect on atrio-ventricular conduction time may be potentiated and negative inotropic effect increased. Calcium channel antagonists of verapamil/diltiazem type: negative influence on contractility and atrio-ventricular conduction. Centrally-acting antihypertensives: worsen heart failure by a decrease

in the central sympathetic tonus. Combinations to be used with caution: Class III antiarrhythmic drugs (Amiodarone): effect on atrio-ventricular conduction time potentiated. Anaesthetics - volatile halogenated: concomitant use of beta-adrenergic antagonists and anaesthetics may attenuate reflex tachycardia and increase the risk of hypotension. Insulin and oral antidiabetic drugs: although nebivolol does not affect glucose level, concomitant use may mask certain symptoms of hypoglycaemia (palpitations, tachycardia). Mefloquine (antimalarian drug): Co-administration with  $\beta$ -adrenergic blocking agents might contribute to a prolongation of the QTc interval. *Pharmacokinetic interactions* Co-administration with substances inhibiting CYP2D6 enzyme, especially paroxetine, fluoxetine and quinidine increase plasma levels of nebivolol associated with an increased risk of excessive bradycardia and adverse events. Cilnidipine: Cilnidipine can interact with aldesleukin, quinidine, phenytoin, rifampicin, erythromycin, other anti-hypertensive drugs and anti-psychotic drugs.

**ADVERSE REACTIONS:** Angioneurotic oedema and hypersensitivity, nightmares, depression, headache, dizziness, paraesthesia, syncope, impaired vision, bradycardia, heart failure, slowed AV conduction/ AV-block, hypotension, Intermittent claudication, dyspnoea, bronchospasm, constipation, nausea, diarrhoea, dyspepsia, flatulence, vomiting, pruritus, rash erythematous, Psoriasis aggravated, urticarial, tiredness, oedema.

**Marketed BY:**

Manufactured in India by:  
Windlas Biotech Private Limited (Plant-2)  
Khasra No.: 141 to 143 & 145,  
Mohabewala Industrial Area,  
Dehradun-248110, Uttarakhand.

**IN/NEBICARD LN 2.5, 5, 10 mg/NOV-20/01/ABPI**  
(Additional information is available on request)