

NEBICARD SM

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

Abbreviated Prescribing information for **NEBICARD SM** [Nebivolol hydrochloride 5mg and S-Amlodipine Besylate 2.5mg Tablets] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Nebivolol: It is a competitive and highly selective β_1 receptor antagonist. However, in poor metabolizers and at higher doses, nebivolol inhibits both β_1 and β_2 receptors. 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. **S-amlodipine** is a long-acting calcium channel blocker that inhibits the trans membrane influx of calcium ions into vascular smooth muscle and cardiac muscle.

INDICATION: Indicated in the treatment of essential hypertension

DOSAGE AND ADMINISTRATION: One tablet of NEBICARD-SM daily, preferably at the same time of the day. The tablets may be taken with meals.

CONTRAINDICATION: In patients with having hypersensitivity to nebivolol or dihydropyridine calcium antagonists, liver insufficiency or liver function impairment, pregnancy and lactation, cardiogenic shock, uncontrolled heart failure, sick sinus syndrome, including sino-atrial block, second and third degree heart block, history of bronchospasm and bronchial asthma, untreated pheochromocytoma, metabolic acidosis, bradycardia, hypotension and severe peripheral circulatory disturbances

WARNINGS & PRECAUTIONS: Use cautiously or stop the **nebivolol** patient with renal insufficiency, hepatic insufficiency, elderly, children, pregnancy and lactation. **S-amlodipine:** It is recommended that nursing be discontinued while this combination is administered. The combination may be used during lactation only when there is no safer alternative and the potential benefits outweigh the potential risks.

DRUG INTERACTIONS: Nebivolol: Drugs that inhibit CYP2D6, calcium antagonists (verapamil or diltiazem and Intravenous verapamil), anti-arrhythmic (Class I anti-arrhythmic drugs and amiodarone), clonidine, digitalis, insulin and oral anti-diabetic drugs, anaesthetics, cimetidine, nicardipine, sympathomimetic agents, tricyclic antidepressants, barbiturates and phenothiazines. **S-amlodipine:** Safely administered with thiazide diuretics, beta adrenoceptor blocking drugs, angiotensin converting enzyme inhibitors, long acting nitrates, sublingual glyceryl trinitrate, nonsteroidal anti-inflammatory drugs, antibiotics, and oral hypoglycemic agents.

ADVERSE REACTIONS: Nebivolol: Headache, dizziness, tiredness, paresthesia, diarrhoea, constipation, nausea, dyspnea, oedema, bradycardia, slowed AV-conduction/AV-block, hypotension, heart failure, (increase of) intermittent claudication, impaired vision, impotence, depression, nightmares, dyspepsia, flatulence, vomiting, bronchospasm, urticaria, rash, hallucinations, psychoses, confusion, cold/cyanotic extremities, Raynaud's phenomenon, dry eyes, and oculomucocutaneous toxicity of the practolol-type. **S- amlodipine:** Headache, edema, fatigue, flushing, dizziness, nausea, abdominal pain, somnolence, palpitations, muscle cramps, micturition, nocturia, coughing, breathlessness, epistaxis, impotence, nervousness and conjunctivitis.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

IN/NEBICARD SM 5,2.5mg/FEB-2022/02/ABPI

(Additional information is available on request)