NEBICARD

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

Abbreviated Prescribing information for NEBICARD

(Nebivolol Hydrochloride Tablets I.P) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: Nebivolol is a racemate of two enantiomers, SRRR-nebivolol (or d-nebivolol) and RSSS nebivolol (or l-nebivolol). It combines two pharmacological activities: 1) It is a competitive and selective beta-receptor antagonist: this effect is attributed to the SRRRenatiomer (d-enantiomer). 2) It has mild vasodilating properties due to an interaction with the L-arginine/nitric oxide pathway. 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 centers, (4) suppression of renin activity and (5) vasodilation and decreased peripheral vascular resistance.

INDICATIONS: It is indicated for the treatment of Hypertension.

DOSAGE AND ADMINISTRATION: Nebivolol 2.5 mg ,5 mg and 10 mg. The dose of nebivolol tablets must be individualized to the needs of the patient. For most patients, the recommended starting dose is 5 mg once daily, 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 up to 40 mg.

CONTRAINDICATION: ***Nebivolol*** is contraindicated in patients with hypersensitivity, • Liver insufficiency or liver function impairment., Acute heart failure**,** Sick sinus syndrome**,** History of bronchospasm and bronchial asthma, Untreated phaeochromocytoma, metabolic acidosis, Bradycardia, Hypotention, severe peripheral circulatory disturbances, Anuria. Second and third degree heart block (without a pacemaker).

WARNINGS & PRECAUTIONS: ***Nebivolol:*** *Anaesthesia*: Continuation of beta-blockade reduces the risk of arrhythmias during induction and intubation. If beta-blockade is interrupted in preparation for surgery, the beta-adrenergic antagonist should be discontinued at least 24 hours beforehand. *Cardiovascular*: Beta-adrenergic antagonists may induce bradycardia: if the pulse rate drops below 50-55 bpm at rest and/or the patient experiences symptoms that are suggestive of bradycardia, the dosage should be reduced. *Metabolic/Endocrinological:* Nebivolol Hydrochloride does not affect glucose levels in diabetic patients. Care should be taken in diabetic patients however, as Nebivolol may mask certain symptoms of hypoglycaemia (tachycardia, palpitations) also may mask tachycardia symptoms in hyperthyroidism. Abrupt withdrawal may intensify symptoms. *Respiratory:* In patients with chronic obstructive pulmonary disorders, beta-adrenergic antagonists should be used with caution as airway constriction may be aggravated. *Other:* Patients with a history of psoriasis should take beta-adrenergic antagonists only after careful consideration.

DRUG INTERACTIONS: ***Nebivolol:*** *Pharmacodynamic interactions* Combinations not recommended *:* Class I antiarrhythmics, Calcium channel antagonists of verapamil/diltiazem type: negative influence on contractility and atrio-ventricular conduction, Centrally-acting antihypertensive(clonidine, guanfacin, moxonidine, methyldopa, rilmenidine). Combinations to be used with caution: Class III antiarrhythmic drugs (Amiodarone): effect on atrio-ventricular conduction time may be potentiated. Combinations to be used only after careful consideration : Digitalis glycosides, Calcium antagonists of the dihydropyridine type Antipsychotics, antidepressants (tricyclics, barbiturates and phenothiazines): concomitant use may enhance the hypotensive effect of the beta-blockers (additive effect). Non-steroidal anti-inflammatory drugs (NSAID): no effect on the blood pressure lowering effect

of nebivolol. *Pharmacokinetic interactions* : Nebivolol metabolism involves the CYP2D6 isoenzyme, co-administration with substances inhibiting this enzyme, especially paroxetine, fluoxetine, thioridazine and quinidine may lead to increased plasma levels of nebivolol associated with an increased risk of excessive bradycardia and adverse events. Co-administration of cimetidine increased the plasma levels of nebivolol, without changing the clinical effect. Combining nebivolol with nicardipine slightly increased the plasma levels of both drugs, without changing the clinical effect.

ADVERSE REACTIONS: ***Nebivolol-*** tiredness, oedema, impotence, pruritus, rash erythematous, psoriasis aggravated, urticarial, constipation, nausea, diarrhoea, dyspepsia, flatulence, vomiting, bronchospasm, dyspnea, hypotension, (increase of) intermittent claudication, bradycardia, heart failure, slowed AV conduction/AV-block, impaired vision, headache, dizziness, paraesthesia, syncope, nightmares, depression, angioneurotic oedema, hypersensitivity.

MARKETED BY:

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IN/ NEBICARD 2.5, 5, 10 mg /JAN 2022/02/ABPI

(Additional information is available on request)