

Nebita™

Nebivolol

PRESENTATION

Nebita™ 2.5 Tablet: Each film coated tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 2.5 mg.

Nebita™ 5 Tablet: Each film coated tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 5 mg.

PHARMACOLOGY

Pharmacodynamics: Nebivolol is a β -adrenergic receptor blocking agent. Nebivolol is a racemate of two enantiomers, d-Nebivolol and l-Nebivolol. Nebivolol has unique pharmacologic properties, including very high selectivity for β -1 receptor and nitric oxide-mediated vasodilatory effect.

Pharmacokinetics: Nebivolol is metabolized by a number of routes, including glucuronidation and hydroxylation by CYP2D6. The active isomer (d-Nebivolol) has an effective half-life of about 12 hours in extensive metabolizers (most people), and 19 hours in poor metabolizers. Mean peak plasma Nebivolol concentrations occur approximately 1.5 to 4 hours. Plasma protein binding of Nebivolol is approximately 98%, mostly to albumin.

INDICATION

Nebivolol is indicated in the treatment of essential hypertension and adjunct in stable mild to moderate heart failure in patients over 70 years.

DOSAGE AND ADMINISTRATION

Hypertension: 5 mg daily; elderly initially 2.5 mg daily, increased if necessary to 5 mg daily. *Adjunct in heart failure:* Initially 1.25 mg once daily, then if tolerated increased at intervals of 1–2 weeks to 2.5 mg once daily, then to 5 mg once daily, then to max. 10 mg once daily.

CONTRAINDICATIONS

Nebivolol is contraindicated in the following conditions: severe bradycardia, heart block greater than first degree, patients with cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, patients with severe hepatic impairment, patients who are hypersensitive to any component of this product.

SIDE EFFECTS

The most common side effects are headache, nausea and bradycardia.

DRUG INTERACTIONS

Use caution when Nebivolol is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.). Do not use Nebivolol with other β -blockers, both digitalis glycosides and β -blockers slow atrioventricular conduction and decrease heart rate. Concomitant use can increase the risk of bradycardia, Nebivolol can exacerbate the effects of myocardial depressants or inhibitors of AV conduction, such as certain calcium antagonists (verapamil and diltiazem), or antiarrhythmic agents, such as disopyramide.

USE IN PREGNANCY AND LACTATION

β -blockers may cause intra-uterine growth restriction, neonatal hypoglycaemia, and bradycardia; the risk is greater in severe hypertension. If beta-blockers are used close to delivery, infants should be monitored for signs of β -blockade. Nebivolol is advised to avoid during breast-feeding due to possible risk of toxicity due to β -blockade.

PEDIATRIC USE

Safety and effectiveness of Nebivolol in pediatric patients have not been established.

OVERDOSE

If overdose occurs, provide general supportive and specific symptomatic treatment. Bradycardia: Administer IV atropine. Hypotension: Administer IV fluids and vasopressors. Intravenous glucagon may be useful. Heart Block (second or third degree): Monitor and treat with isoproterenol infusion. Congestive Heart Failure: Initiate therapy with digitalis glycoside and diuretics. Bronchospasm: Administer bronchodilator therapy such as a short acting inhaled β_2 -agonist and/or aminophylline. Hypoglycemia: Administer IV glucose.

STORAGE CONDITION

Store in a cool and dry place (20°C -25°C). Protect from light and moisture. Keep medicine out of the reach of children.

HOW SUPPLIED

Nebita™ 2.5 Tablet: Each box contains 30 tablets in blister pack.

Nebita™ 5 Tablet: Each box contains 30 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.

Pabna, Bangladesh

TM - Trade Mark

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