

ORNEB

NEBIVOLOL HYDROCHLORIDE INN

Compositions:

Orneb 2.5 Tablet: Each tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 2.5 mg. Orneb 5 Tablet: Each tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 5 mg.

Pharmacology:

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. 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.

Dosage And Administration:

Hypertension Adults: 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. A more frequent dosing regimen is unlikely to be beneficial. **Elderly (In patients over 65 years):** No overall differences in safety or effectiveness were observed between elderly and younger patients. **Patients with renal impairment:** In patients with severe renal impairment (ClCr less than 30 mL/min) the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. It has not been studied in patients receiving dialysis. **Patients with hepatic impairment:** In patients with moderate hepatic impairment, the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. It has not been studied in patients with severe hepatic impairment and therefore it is not recommended in that population. **Chronic Heart Failure** The initial up-titration in case of chronic heart failure patients should be done according to the following steps at 1-2 weekly intervals based on patient's tolerability. Initially 1.25 mg daily, to be increased to 2.5 mg once daily, then to 5 mg once daily and then to 10 mg once daily. The maximum recommended dose is 10 mg daily. **Missed Dose:** If a dose is missed, take the next scheduled dose only (without doubling it).

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.

Warning And Precaution:

Patients with coronary artery disease treated with Nebivolol should be advised against abrupt discontinuation of therapy. Caution should be exercised in patients with circulatory disorders, first degree heart block, anesthesia, diabetes, hyperthyroidism, chronic obstructive pulmonary disorders and allergen sensitivity.

Side Effects:

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

Use in Pregnancy and Lactation:

Pregnancy: 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. Lactation: Nebivolol is advised to avoid during breast-feeding due to possible risk of toxicity due to β -blockade.

Drug Interaction:

Valsartan, Rifampin, Mefenamic acid either increase or decrease plasma concentration of Dapagliflozin. Dapagliflozin either increase or decrease plasma concentration of Bumetanide, Pioglitazone and Valsartan.

Overdosage:

Very limited information is available on Trimetazidine overdose. Treatment should be symptomatic.

Storage:

Store in a cool (within 30°C) and dry place protected from light and moisture. Keep out of the reach of children.

Packing:

Orneb 2.5 Tablet: Each box contains 5 x 10 tablets in Alu-Alu blister pack. Orneb 5 Tablet: Each box contains 3 x 10 tablets in Alu-Alu blister pack.

Manufactured By:

The IBN SINA Pharmaceutical Industry PLC.

Shafipur, Gazipur, Bangladesh.