Nebifast
Tablet

DRUG INTERNATIONAL LTD.

Composition : **Nebifast-2.5 mg Tablet :** Each film coated tablet contains Nebivolol 2.5 mg as Nebivolol Hydrochloride INN.
Nebifast-5 mg Tablet : Each film coated tablet contains Nebivolol 5 mg as Nebivolol Hydrochloride INN.
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 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.
Indications : Nebivolol tablets are indicated for the management of hypertension one of several preferred initial therapies in hypertensive patients with heart failure, post myocardial infarction, high CHD risk and diabetes mellitus.
Dosage and administration : **Hypertension :** The dose must be individualized to the needs of the patient. For most patients, the 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. **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. **Hepatic Impairment :** In patients with moderate hepatic impairment, the initial dose is 2.5 mg once daily; titrate up slowly if needed. Or, as directed by the registered physicians.
Contraindication : Nebivolol tablets are contraindicated in the following conditions: severe bradycardia, heart block greater than first degree, cardiogenic shock, decompensated cardiac failure, sick sinus syndrome, severe hepatic impairment, patients who are hypersensitive to any component of this product.
Precautions : Abrupt discontinuation of ?-blockers may cause severe exacerbation of angina, myocardial infarction and ventricular arrhythmias in patients with coronary artery disease following. Patients with coronary artery disease treated with Nebivolol should be advised against abrupt discontinuation of therapy.
Side effects : Adverse reactions leading to withdrawal from Nebivolol tablets included: headache, fatigue, dizziness, siarrhoea, nausea.
Use in pregnancy and lactation : Pregnancy category C. β-blockers may cause intra-uterine growth restriction, neonatal hypoglycaemia, and bradycardia, the risk is greater in servere hypertension. If β-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.
Use in Child : Safety and effectiveness in children has not been established.
Drug interactions : Use caution when Nebivolol is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.) Nebivolol should not use 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.
Overdose : Symptoms of overdose may include bradycardia and hypotension. Other important adverse reactions reported with Nebivolol overdose include cardiac failure, dizziness, hypoglycemia, fatigue, vomiting, bronchospasm and heart block.
Storage : Store below 30°C in a dry place.
Packing : **Nebifast-2.5 mg Tablet :** Each box contains 2 x 14's tablets in blister pack.
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