Nebita[™] Plus 5/12.5

Nebivolol 5 mg + Hydrochlorothiazide 12.5 mg

Composition

Nebita[™] **Plus** 5/12.5: Each film coated tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 5 mg and Hydrochlorothiazide BP 12.5 mg.

Clinical Pharmacology

The Combination of these ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone. Nebivolol has mild vasodilating properties which reduces heart rate and blood pressure in hypertensive patients. Hydrochlorothiazide affects the renal tubular mechanisms of electrolyte reabsorption which directly increase the excretion of sodium and chloride in approximately equivalent amounts. The diuretic action of Hydrochlorothiazide reduces plasma volume, increases plasma renin activity and increases aldosterone secretion.

Indications

Essential hypertension.

Dosage & Administration

Once daily, preferably at the same time every day.

Contraindication

- Hypersensitivity to the active substances, Liver function impairment
- Severe renal insufficiency (Creatinine clearance < 30 ml/min.), Bradycardia, Hypotension

Warnings & Precautions

Nebivolol: Beta-blockers should not be used in patients with untreated Congestive Heart Failure (CHF) & bradycardia. In patients with Chronic Obstructive Pulmonary Diseases (COPD), beta-blockers should be used with caution as airway constriction may be aggravated.

Hydrochlorothiazide: In patients with renal disease, thiazides may increase azotaemia. If progressive renal impairment becomes evident, careful reappraisal of therapy is necessary. Thiazides can cause fluid or electrolyte imbalance. Thiazides may decrease urinary calcium excretion and may cause slight elevation of serum calcium in the absence of known disorders of calcium metabolism.

Adverse Effects

Nebivolol: Headache, Dizziness, Tiredness, Diarrhoea, Constipation, Nausea etc. Hydrochlorothiazide: Vertigo, Itchiness, Rash, Increased sensitivity of skin to sunlight etc.

Use in Pregnancy & Lactation

This combination is not recommended during pregnancy. It is also not recommended for mothers who are breast-feeding.

Pediatric Population

Use in children is not recommended.

Drug Interaction

Nebivolol

- Class I & III Antiarrhythmics, Calcium channel blocker (Verapamil/Diltiazem)
- Centrally-acting antihypertensives, Anaesthetics
- Antipsychotics, Antidepressants, NSAIDs

Hydrochlorothiazide

- Drugs affecting Potassium & Calcium level
- Non-steroidal anti-inflammatory drugs (NSAIDs)
- Concomitant administration of this combination with Antipsychotics, Tricyclic Antidepressants & Barbiturates may enhance the hypotensive effect and lead to postural hypotension.

Overdose

No data are available on Overdosage with Nebivolol. Overdosage with Hydrochlorothiazide is associated with electrolyte depletion and dehydration resulting from excessive diuresis.

Storage Condition

Protect from light & moisture. Store below 30° C. Keep out of reach of children.

How Supplied

Each box contain 30's tablet in Alu-PVDC blister packs.

Manufactured by

