

IvololTM

Nebivolol tablet

Presentation

IvololTM 2.5 : Each tablet contains Nebivolol hydrochloride INN equivalent to Nebivolol 2.5 mg.

IvololTM 5 : Each tablet contains Nebivolol hydrochloride INN equivalent to Nebivolol 5 mg.

Description

Nebivolol is a novel beta blocker. 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 reduces heart rate & lowers blood pressure at rest as well as during exercise.

Indications

Nebivolol is indicated in treatment of essential hypertension and treatment of stable mild and moderate chronic heart failure.

Dosage and administration

Hypertension

Adults: 5mg daily, preferably at the same time of the day.

Elderly (In patients over 65 years): The recommended starting dose is 2.5 mg daily. The dose may be increased to 5mg daily if needed.

Patient with renal insufficiency: The recommended starting dose is 2.5 mg daily. The daily dose may be increased to 5mg if needed.

Patients with hepatic insufficiency: Data in patients with hepatic insufficiency or impaired liver function are limited. Therefore the use of Nebivolol in these patients is contra-indicated.

Chronic Heart Failure

The initial uptitration 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.

1.25mg daily, to be increased to 2.5mg once daily, then to 5mg once daily and then to 10mg once daily. The maximum recommended dose is 10mg daily.

Use in children

In children safety and efficacy of Nebivolol has not been demonstrated.

Use in pregnancy and lactation

Nebivolol is contra-indicated in pregnancy and lactation.

Precautions

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.

Contraindications

Nebivolol is contraindicated in patients with severe bradycardia, heart block greater than first degree, cardiogenic shock, sick sinus syndrome, or severe hepatic impairment, and in patients who are hypersensitive to any component of this product.

Drug Interactions

As 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.

Overdosage

The symptoms of overdose are bradycardia, hypotension, bronchospasm and acute cardiac insufficiency.

Commercial Pack

IvololTM 2.5: Each box contains 3 blister strips of 10 tablets

IvololTM 5: Each box contains 3 blister strips of 10 tablets