

Bipinor[®]

Nebivolol

Description

Bipinor[®] is a preparation of Nebivolol, which 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 beta₁ – receptor and nitric oxide-mediated vasodilatory effect. Bipinor[®] reduces heart rate & blood pressure at rest & during exercise significantly.

Indications

Bipinor[®] is indicated in

- Treatment of essential hypertension
- 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 2.5mg daily. The dose may be increased to 5mg daily if needed.

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

Note: An additional antihypertensive effect is observed when Bipinor[®] 5mg is combined with hydrochlorothiazide 12.5-25mg.

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.

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

Clinical trial of Nebivolol demonstrates that discontinuation of therapy due to side effects is similar to placebo. 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, decompensated cardiac failure, sick sinus syndrome, or severe hepatic impairment, and in patients who are hypersensitive to any component of this product.

Drug Interactions

Nebivolol interacts with Verapamil / Diltiazem type calcium antagonists, Class I antiarrhythmic drugs and Amiodarone.

Overdosage

The symptoms of overdose are bradycardia, hypotension, bronchospasm and acute cardiac insufficiency. Symptomatic and supportive therapy should be given in overdose.

Pharmaceutical precautions

Store in a cool dry place. Protect from light.

Presentation

Bipinor[®] 2.5 mg Tablets: Each tablet contains Nebivolol 2.5 mg as hydrochloride INN.

Bipinor[®] 5 mg Tablets: Each tablet contains Nebivolol 5 mg as hydrochloride INN.

Package quantities

Bipinor[®] 2.5 mg Tablets: Cartons of 30 tablets in Alu-PVC blister.

Bipinor[®] 5 mg Tablets: Cartons of 30 tablets in Alu-PVC blister.

® Registered Trade Mark



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