Nebipres

Nebivolol Tablet

Presentation:
Nebipres 2.5 Tablet: Each film coated tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 2.5 mg.
Nebipres 5 Tablet: Each film coated tablet contains Nebivolol Hydrochloride INN equivalent to Nebivolol 5 mg.

Indication:
Nebivolol is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Dosage & Administration:
Hypertension: 5 mg once daily with or without food, as monotherapy or in combination with other agents.

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.

Patients with Hepatic Disease: In patients with moderate hepatic impairment, the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed.

Side effects:
The most common side effects are headache (0.4%), nausea (0.2%) and bradycardia (0.2%).

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 (Child-Pugh >B), Patients who are hypersensitive to any component of this product.

Drug interactions:
Use caution when Nebivolol is co-administered with CYP2D6 inhibitors (quinidine, propafenone, fluoxetine, paroxetine, etc.). Do not use Nebivolol 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.

Precautions:
Abrupt Cessation of Therapy: Do not abruptly discontinue Nebivolol therapy in patients with coronary artery disease. Severe exacerbation of angina, myocardial infarction and ventricular arrhythmias have been reported in patients with coronary artery disease following the abrupt discontinuation of therapy with β-blockers.

Bronchospastic Diseases: In general, patients with bronchospastic diseases should not receive β-blockers.

Anesthesia and Major Surgery: Because beta-blocker withdrawal has been associated with an increased risk of MI and chest pain, patients already on beta-blockers should generally continue treatment throughout the perioperative period. If Nebivolol is to be continued perioperatively, monitor patients closely when anesthetic agents which depress myocardial function, such as ether, cyclopropane, and trichloroethylene, are used. If β-blocking therapy is withdrawn prior to major surgery, the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

Non-dihydropyridine Calcium Channel Blockers: Because of significant negative inotropic and chronotropic effects in patients treated with β-blockers and calcium channel blockers of the verapamil and diltiazem type, monitor the ECG and blood pressure in patients treated concomitantly with these agents.

Impaired Renal Function: Renal clearance of nebivolol is decreased in patients with severe renal impairment. Nebivolol has not been studied in patients receiving dialysis.
Impaired Hepatic Function: Metabolism of nebivolol is decreased in patients with moderate hepatic impairment. Nebivolol has not been studied in patients with severe hepatic impairment.

Risk of Anaphylactic Reactions: While taking β-blockers, patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive to repeated accidental, diagnostic, or therapeutic challenge. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reactions.

Use in Pregnancy and Lactation:
Pregnancy Category C and Nebivolol is not recommended during Lactation.

Storage Condition:
Store in a cool (below 30^{o}C) and dry place, away from light. Keep out of the reach of children.

Commercial pack:
Nebipres 2.5 Tablet: Each box contains 3 blister strips of 10 tablets.
Nebipres 5 Tablet: Each box contains 3 blister strips of 10 tablets.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

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