FIRST TIME GENERIC APPROVAL

Brand Name	Nebivolol
Generic Name	nebivolol
Drug Manufacturer	Torrent Pharmaceuticals Limited.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

September 09, 2021

LAUNCH DATE

September 17, 2021

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 203966

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Nebivolol is a beta-adrenergic blocking agent 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.

MECHANISMS OF ACTION

The mechanism of action of the antihypertensive response of nebivolol has not been definitively established. Possible factors that may be involved include: (1) decreased heart rate, (2) decreased myocardial contractility, (3) diminution of tonic sympathetic outflow to the periphery from cerebral vasomotor centers, (4) suppression of renin activity and (5) vasodilation and decreased peripheral vascular resistance.

DOSE FORM AND STRENGTH

Tablets: 2.5, 5, 10, 20 mg.

DOSE & ADMINISTRATION

The dose of nebivolol tablets must be individualized to the needs of the patient. For most patients, the recommended 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. A more frequent dosing regimen is unlikely to be beneficial.

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. Nebivolol tablets have not been studied in patients receiving dialysis.

Hepatic Impairment: In patients with moderate hepatic impairment, the recommended initial dose is 2.5 mg once daily; titrate up slowly if needed. Nebivolol tablets have not been studied in patients with severe hepatic impairment and therefore it is not recommended in that population.