FIRST TIME GENERIC APPROVAL

Brand Name	Northera®
Generic Name	droxidopa
Drug Manufacturer	Zydus Pharmaceuticals (USA) Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First time Generic Approval

FDA APPROVAL DATE

February 18, 2021

LAUNCH DATE

N/A

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 211818

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Droxidopa capsules are indicated for the treatment of orthostatic dizziness, light-headedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension (nOH) caused by primary autonomic failure (Parkinson's disease [PD], multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy.

MECHANISMS OF ACTION

The exact mechanism of action of droxidopa in the treatment of neurogenic orthostatic hypotension is unknown. Droxidopa is a synthetic amino acid analog that is directly metabolized to norepinephrine by dopa-decarboxylase, which is extensively distributed throughout the body. Droxidopa is believed to exert its pharmacological effects through norepinephrine and not through the parent molecule or other metabolites. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction. Droxidopa in humans induces small and transient rises in plasma norepinephrine.

DOSE FORM AND STRENGTH

Capsules: 100 mg, 200 mg, and 300 mg

DOSE & ADMINISTRATION

Starting dose is 100 mg three times during the day. Titrate by 100 mg three times daily, up to a maximum dose of 600 mg three times daily. Take consistently with or without food. To reduce the potential for supine hypertension,

elevate the head of the bed and give the last dose at least 3 hours prior to bedtime. Take droxidopa capsule whole.