



Federal Employee Program.

NORTHERA (droxidopa)

Preferred product: generic droxidopa

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Northera (droxidopa) is indicated for the treatment of neurogenic orthostatic hypotension (NOH). NOH is a rare, chronic and often debilitating drop in blood pressure upon standing that is associated with Parkinson's disease, multiple-system atrophy, and pure autonomic failure. Symptoms of NOH include dizziness, lightheadedness, blurred vision, fatigue and fainting when a person stands (1).

Regulatory Status

FDA-approved indication: Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated. The continued effectiveness of Northera should be assessed periodically (1).

Northera has a boxed warning to alert health care professionals and patients about the risk of increased blood pressure while lying down (supine hypertension), a common problem that affects people with primary autonomic failure and can cause stroke. It is essential that patients be reminded that they must sleep with their head and upper body elevated. Supine blood pressure should be monitored prior to and during treatment and more frequently when increasing doses (1).

Northera may exacerbate existing ischemic heart disease, arrhythmias, and congestive heart failure. Careful consideration should be given to this potential risk prior to initiating therapy in patients with these conditions (1).

Safety and effectiveness of Northera in pediatric patients have not been established (1).

Summary

Northera is indicated for the treatment of orthostatic dizziness, lightheadedness, or the "feeling that you are about to black out" in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and nondiabetic autonomic neuropathy.



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Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Northera while maintaining optimal therapeutic outcomes.

References

1. Northera [package Insert]. Deerfield, IL: Lundbeck NA Ltd; July 2019.