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Droxidopa Capsules (Northera)

??? ??????: 30 ??????/?????? 2017

section of the label: **WARNINGS AND PRECAUTIONS** The following adverse reactions with NORTHERA are included in more detail in the

-]**WARNINGS AND PRECAUTIONS** Supine Hypertension [see
-]**WARNINGS AND PRECAUTIONS** Hyperpyrexia and Confusion [see
-]**WARNINGS AND PRECAUTIONS** May exacerbate existing ischemic heart disease, arrhythmias, and congestive heart failure [see

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

The safety evaluation of NORTHERA is based on two placebo-controlled studies 1-2 weeks in duration (studies 301 and 302), one 8-week placebo-controlled study (study 306) and two long-term open label extension studies (studies 303 and 304). In the placebo-controlled studies, a total of 485 patients with Parkinson's disease, multiple system atrophy, pure autonomic failure, dopamine beta-hydroxylase deficiency, or non-diabetic autonomic neuropathy were randomized and treated, 245].**Clinical Trials**with NORTHERA and 240 with placebo [see

Placebo-Controlled Experience

The most commonly observed adverse reactions (those occurring at an incidence of greater than 5% in the NORTHERA group and with at least a 3% greater incidence in the NORTHERA group than in the placebo group) in NORTHERA-treated patients during the three placebo-controlled trials were headache, dizziness, nausea, hypertension. The most common adverse reactions leading to discontinuation from NORTHERA were hypertension or increased blood pressure and nausea.

Table 1: Most Common Adverse Reactions Occurring More Frequently in the NORTHERA Group

	Study 306 (8-10 Week Randomized Treatment)		Study 301 and Study 302 (1-2 Weeks Randomized Treatment)	
	NORTHERA (N=114) n (%)	Placebo (N=108) n (%)	NORTHERA (N=131) n (%)	Placebo (N=132) n (%)
Headache	15 (13.2)	8 (7.4)	8 (6.1)	4 (3.0)
Dizziness	11 (9.6)	5 (4.6)	5 (3.8)	2 (1.5)
Nausea	10 (8.8)	5 (4.6)	2 (1.5)	2 (1.5)
Hypertension	8 (7.0)	1 (0.9)	2 (1.5)	0

Note: n=number of patients. Table displays adverse reactions that were reported in greater than 5% of patients in the NORTHERA group and with at least a 3% greater incidence in the NORTHERA group than in the placebo group.

Long-Term, Open-Label Tr ials with NORTHERA

In the long-term open label extension studies, a total of 422 patients, mean age 65 years, were treated with NORTHERA for a mean total exposure of approximately one year. The commonly reported adverse events were falls (24%), urinary tract infections (15%), headache (13%), syncope (13%), and dizziness (10%).