GETTING YOUR PATIENT STARTED WITH NORTHERA® (droxidopa)

Northera®
(droxidopa) capsules
100 mg • 200 mg • 300 mg

NORTHERA is only available via Specialty Pharmacy by using the enclosed NORTHERA Treatment Form.

Complete the NORTHERA Treatment Form in its entirety and fax pages 1, 2, and 3 to 844-601-0102.

Every effort is made to limit the number of calls to your office.
Please ensure that:

- ☐ All required **(red and underlined)** fields are complete
- ☐ Patient (or authorized representative) has signed the HIPAA release on page 1
- ☐ Prescription Information, including titration or fixed dose, is completed
- ☐ Prescriber's signature appears on the bottom of page 3

Upon receipt of your patient's completed forms, the NORTHERA Support Center will help confirm insurance coverage information.

The Support Center may contact your office via phone or fax to:

- Obtain any information that was left off the Treatment Form
- Clarify the prescription for the Specialty Pharmacy

The Starter Rx Program provides a one-time 30-day supply shipment of NORTHERA to eligible commercial patients who qualify.

Eligibility requirements:

- New patients age 17 and older with a valid NORTHERA prescription
- Commercially insured patients
- Diagnosis consistent with labeling

If the patient doesn't meet eligibility criteria for the Starter Rx Program, the prescription will be filled by the Specialty Pharmacy. Complete Terms and Conditions for the Starter Rx Program are available at www.NORTHERA.com.

Please advise your patient that the NORTHERA Support Center or Specialty Pharmacy will be calling to help ensure delivery of his or her NORTHERA prescription.

Please inform your patient that:

- The NORTHERA Support Center and Specialty Pharmacy require verbal confirmation of the delivery address from your patient prior to mailing his or her medication

Please see Important Safety Information, including Boxed Warning for supine hypertension, on the back of page 3. For more information, please see the accompanying NORTHERA full Prescribing Information, or go to www.NORTHERA.com.

NORTHERA Treatment Form

HIPAA RELEASE

Patient Authorization for Use and Disclosure of Personal Health Information

I authorize my healthcare providers (including pharmacy providers) and health plans to disclose my personal health information related to this prescription form or my use or potential use of NORTHERA, including my personal contact information on this form (collectively, my "Information"), to the patient support program called the NORTHERA Support Center (the "Program") so that the Program may use and disclose the Information in order to: (1) establish my benefit eligibility; (2) communicate with my healthcare providers and health plans about my benefit and coverage status and my medical care; (3) provide support services, including facilitating the provision of NORTHERA to me, as well as any information or materials related to such services or Lundbeck products, including promotional or educational communications; (4) evaluate the effectiveness of NORTHERA support programs; (5) report safety information, including in communications with the US Food and Drug Administration and other government authorities; (6) contact me regarding this prescription form or my use or potential use of NORTHERA and provide me with related patient support communications, including through messages left for me that disclose that I take or may take NORTHERA; and (7) allow Lundbeck to analyze the usage patterns and the effectiveness of Lundbeck products, services, and programs and help develop new products, services, and programs, and for other Lundbeck general business and administrative purposes.

I understand that my pharmacy provider(s) may receive remuneration in exchange for the provision of my Information as authorized above, and that once my Information has been disclosed to the Program, federal privacy law may no longer restrict its use or disclosure and that it may be redisclosed to others. I also understand, however, that the Program plans to use and disclose my Information only for the purposes described above or as required by law.

I understand that if I refuse to sign this Authorization, that will not affect my right to treatment or payment benefits for health care. I also understand that if I sign, I may later withdraw this Authorization by sending written notice of my withdrawal from the Program to the NORTHERA Support Center Coordinating Center at PO Box 7526, Gaithersburg, MD 20898, and that such withdrawal will not affect any uses and disclosures of my Information prior to the Program's receipt of the notice. I am entitled to a copy of this signed Authorization, which expires 10 years from the date it is signed by me or such timeframe as allowed by law.

AUTHORIZED REPRESENTATIVE CONSENT (OPTIONAL)

I further authorize the NORTHERA Support Center to discuss my treatment with the following authorized representative(s).

AUTHORIZED REPRESENTATIVE (1) NAME (PLEASE PRINT):

RELATIONSHIP TO PATIENT: ☐ Spouse ☐ Child ☐ Other: _____

AUTHORIZED REPRESENTATIVE (2) NAME (PLEASE PRINT):

RELATIONSHIP TO PATIENT: ☐ Spouse ☐ Child ☐ Other: _____

PATIENT HIPAA

PATIENT/GUARDIAN SIGNATURE:	**PATIENT/GUARDIAN NAME (PLEASE PRINT):**	**DATE:**

RELATIONSHIP TO PATIENT: ☐ Self ☐ Spouse ☐ Other[a] _____

[a]Please note documentation proving Power of Attorney may be required.

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NORTHERA Treatment Form

1 Patient Information

PATIENT NAME:		**MAILING ADDRESS:**		
DOB (MM/DD/YYYY):	**GENDER:** ☐ M ☐ F	**CITY:**	**STATE:**	**ZIP CODE:**
PRIMARY PHONE: ( )	☐ Home ☐ Cell ☐ Work	☐ **CHECK HERE IF PATIENT IS IN THE HOSPITAL. DISCHARGE DATE:** _____		
SECONDARY PHONE: ( )	☐ Home ☐ Cell ☐ Work	EMAIL:		
PREFERRED CONTACT TIME: ☐ Morning ☐ Afternoon ☐ Evening		**PATIENT TO READ AND SIGN HIPAA AUTHORIZATION ON PAGE 1.**		

2 Patient Insurance Attach copies of both sides of patient's pharmacy benefit card(s) OR complete the following

PRIMARY INSURANCE COMPANY:	**ID NUMBER:**
PHONE: ( )	CARDHOLDER NAME:
PLAN NUMBER:	GROUP NUMBER:

RELATIONSHIP TO CARDHOLDER: ☐ Self ☐ Spouse ☐ Child ☐ Other:

☐ **CHECK IF NO COVERAGE**

3 Clinical Information

Has a clinical evaluation of the patient's current medications been performed to evaluate for any medications that may precipitate hypotension?	☐ Yes ☐ No
ATTACH PATIENT'S CURRENT MEDICATIONS AND KNOWN DRUG ALLERGIES	
Will the patient be monitored for supine hypertension prior to and during treatment?	☐ Yes ☐ No
Does the patient have any contraindications to the use of NORTHERA (eg, hypersensitivity to NORTHERA or any of its components)?	☐ Yes ☐ No

WHAT IS THE PATIENT'S PRIMARY DIAGNOSIS? (CHECK ONE OF THE FOLLOWING):

- ☐ G20 Parkinson's disease (PD)
- ☐ G23.2 Striatonigral degeneration
- ☐ G99.0 Autonomic neuropathy in diseases classified elsewhere
- ☐ G90.9 Disorder of the autonomic nervous system, unspecified
- ☐ G90.3 Multi-system degeneration of the autonomic nervous system
- ☐ Dopamine beta-hydroxylase (DBH) deficiency
  Attach chart notes supporting the clinical diagnosis.
- ☐ Non-diabetic autonomic neuropathy (NDAN)
  Attach chart notes supporting the clinical diagnosis.
- ☐ Other (Include ICD code): _____
  Attach chart notes supporting the clinical diagnosis.

SYMPTOMATIC CONDITION(S) (CHECK ALL THAT APPLY):

- ☐ Neurogenic orthostatic hypotension (nOH)
- ☐ R42 Dizziness and giddiness
- ☐ I95.1 Orthostatic hypotension
- ☐ I95.89 Other hypotension
- ☐ R55 Syncope and collapse
- ☐ Other (Include ICD code): _____

Has the patient tried and failed or is intolerant to midodrine?	☐ Yes ☐ No
Has the patient tried and failed or is intolerant to fludrocortisone?	☐ Yes ☐ No

Has the patient tried any of the following non-pharmacologic interventions? (Check all that apply):

- ☐ Discontinuation of drugs, which can cause orthostatic hypotension (eg, diuretics, antihypertensive medications [primarily sympathetic blockers], anti-anginal drugs [nitrates], alpha-adrenergic antagonists, and antidepressants)
- ☐ Increased salt and water intake, if appropriate
- ☐ Raising the head of the bed 10 to 20 degrees
- ☐ Compression stockings
- ☐ Physical maneuvers to improve venous return
- ☐ Avoiding precipitating factors (eg, overexertion in hot weather, arising too quickly from supine to sitting or standing)
- ☐ Other: _____

Your patient will not be automatically enrolled in the NORTHERA Support Center Nurse Program.

☐ Check here if you choose to enroll your patient in the NORTHERA Support Center Nurse Program.

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Northera® (droxidopa) capsules 100 mg • 200 mg • 300 mg

NORTHERA Treatment Form

4 Prescriber Information

PRESCRIBER NAME:	**SPECIALTY:** ☐ Neurologist ☐ Cardiologist ☐ Nephrologist ☐ Other: _____		
PRACTICE/FACILITY NAME:		**NPI #:**	**STATE ID:**
		OFFICE CONTACT NAME:	
MAILING ADDRESS:		**OFFICE CONTACT PHONE:** ( )	
CITY:	***STATE:** **ZIP CODE:**	**OFFICE CONTACT FAX:** ( )	
PRESCRIBER EMAIL:			

5 Prescription Information

PATIENT NAME:		**MAILING ADDRESS:**		
DOB (MM/DD/YYYY):	**PATIENT PHONE:** ( )	**CITY:**	**STATE:**	**ZIP CODE:**

*Please **choose one** option below. Please complete with instructions reflecting a 30-day supply schedule.*

☐ A — NORTHERA 24-HOUR TITRATION SCHEDULE

Dispense: NORTHERA 100 mg capsules (30-day supply) Sig: To be filled by the pharmacy to reflect indicated titration schedule. Refills = 0

Administer 3 times daily: when you get up in the morning, at midday, and in late afternoon (at least 3 hours before bed)

Day 1	Day 2	Day 3	Day 4	Day 5	Day 6-30[a]
100 mg	200 mg	300 mg	400 mg	500 mg	600 mg

Additional instructions:

☐ B — NORTHERA 48-HOUR TITRATION SCHEDULE

Dispense: NORTHERA 100 mg capsules (30-day supply) Sig: To be filled by the pharmacy to reflect indicated titration schedule. Refills = 0

Administer 3 times daily: when you get up in the morning, at midday, and in late afternoon (at least 3 hours before bed)

Days 1 and 2	Days 3 and 4	Days 5 and 6	Days 7 and 8	Days 9 and 10	Days 11-30[a]
100 mg	200 mg	300 mg	400 mg	500 mg	600 mg

Additional instructions:

☐ C — NORTHERA CUSTOM TITRATION SCHEDULE

Dispense: NORTHERA 100 mg capsules (30-day supply) Sig: To be filled by the pharmacy to reflect indicated titration schedule. Refills = 0

Day(s) ___-___	Day(s) ___-___	Day(s) ___-___	Day(s) ___-___	Day(s) ___-___	Day(s) ___-___	Day(s) ___-___
100 mg ____ times daily	____ mg ____ times daily	____ mg ____ times daily	____ mg ____ times daily	____ mg ____ times daily	____ mg ____ times daily	____ mg ____ times daily

Additional instructions:

☐ D — NORTHERA FIXED SCHEDULE

The quantity will be calculated at the pharmacy based upon indicated schedule for a 30-day supply. Refills = 0

Dispense: NORTHERA ☐ 100 mg capsules ☐ 200 mg capsules ☐ 300 mg capsules Sig: Take _____ mg _____ time(s) daily

Additional instructions:

[a]Continued effectiveness of NORTHERA should be assessed periodically.

Prescriber Certification and Authorization: I certify that, to the full extent required by applicable law, I have obtained written permission from my patient named above (or from the patient's legal representative) to release to the patient support program, the NORTHERA Support Center ("the Program"), the patient's personal health information, both as provided on this form and such other personal health information as the Program may need (1) to perform a preliminary verification of the patient's insurance coverage for NORTHERA, (2) to assess the patient's eligibility for participation in the Program, (3) to enroll the patient in the Program, (4) to provide reimbursement support and other services to the patient in connection with the patient's prescription(s) on this form, and (5) for the other purposes identified on the Patient Authorization for Use and Disclosure of Personal Health Information. I authorize and appoint the Program to convey on my behalf the prescription(s) I signed for the patient and the other information included on this form to the dispensing pharmacy chosen by or for the patient. I agree that the Program may contact me, including without limitation via email, fax, and telephone, to seek additional information relating to the Program, NORTHERA, or the prescription(s) contained on this form.

I understand that any NORTHERA provided at no charge to the patient is provided on a complimentary basis. I will not submit or cause to be submitted any claims for payment or reimbursement for such products to any third-party payor, including a federal health care program. If I am or become in possession of such product, I will not resell or attempt to resell the product.

PRESCRIBER SIGNATURE (SIGN BELOW)

DISPENSE AS WRITTEN	**DATE**	**PRODUCT SUBSTITUTION PERMITTED**	**DATE**

SIGNATURE STAMPS NOT ACCEPTABLE

*The prescriber is to comply with his/her state specific prescription requirements such as e-prescribing, state specific prescription form, fax language, etc. Non-compliance with state specific requirements could result in outreach to the prescriber.

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NORTHERA® (droxidopa)

INDICATIONS AND USAGE

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 (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. Effectiveness beyond 2 weeks of treatment has not been established. The continued effectiveness of NORTHERA should be assessed periodically.

IMPORTANT SAFETY INFORMATION

WARNING: SUPINE HYPERTENSION

Monitor supine blood pressure prior to and during treatment and more frequently when increasing doses. Elevating the head of the bed lessens the risk of supine hypertension, and blood pressure should be measured in this position. If supine hypertension cannot be managed by elevation of the head of the bed, reduce or discontinue NORTHERA.

CONTRAINDICATIONS

- NORTHERA is contraindicated in patients who have a history of hypersensitivity to the drug or its ingredients.

WARNINGS AND PRECAUTIONS

- **Supine Hypertension:** NORTHERA therapy may cause or exacerbate supine hypertension in patients with nOH, which may increase the risk of cardiovascular events if not well managed, particularly stroke.
- **Hyperpyrexia and Confusion:** Cases of a symptom complex resembling neuroleptic malignant syndrome (NMS) have been reported with NORTHERA use during post-marketing surveillance. Observe patients carefully when the dosage of NORTHERA is changed or when concomitant levodopa is reduced abruptly or discontinued, especially if the patient is receiving neuroleptics. NMS is an uncommon but life-threatening syndrome characterized by fever or hyperthermia, muscle rigidity, involuntary movements, altered consciousness, and mental status changes. The early diagnosis of this condition is important for the appropriate management of these patients.
- **Ischemic Heart Disease, Arrhythmias, and Congestive Heart Failure:** NORTHERA therapy may exacerbate existing ischemic heart disease, arrhythmias, and congestive heart failure. Careful consideration should be given to this potential risk prior to initiating therapy.
- **Allergic Reactions:** Hypersensitivity reactions, including anaphylaxis, angioedema, bronchospasm, urticaria, and rash have been reported in post-marketing experience, with some resulting in emergency treatment. If a hypersensitivity reaction occurs, discontinue the drug and initiate appropriate therapy.

  This product contains FD&C Yellow No. 5 (tartrazine), which may also cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

- The most common adverse reactions (>5% and ≥3% difference compared to placebo) were headache, dizziness, nausea, and hypertension.

DRUG INTERACTIONS

- Administering NORTHERA in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension.
- Dopa-decarboxylase inhibitors may require dose adjustments for NORTHERA.
- The concomitant use of selective MAO-B inhibitors, such as rasagiline or selegiline, was permitted in the NORTHERA clinical trials. However, based on mechanism of action, the use of non-selective MAO inhibitors and linezolid should be avoided as there is a potential for increased blood pressure when taken with NORTHERA.

USE IN SPECIFIC POPULATIONS

- There are no available data on use of NORTHERA in pregnant women and risk of major birth defects or miscarriage. Because of the potential for serious adverse reactions, including reduced weight gain in breastfed infants, advise a woman not to breastfeed during treatment with NORTHERA.
- The safety and effectiveness of NORTHERA in pediatric patients have not been established. No overall differences in safety or effectiveness were observed between patients aged 75 years and older and younger patients in clinical trials, but greater sensitivity of some older individuals cannot be ruled out.
- Clinical experience with NORTHERA in patients with severe renal function impairment (GFR <30 mL/min) is limited; therefore, dosing recommendations cannot be provided for these patients.

Please see the accompanying full Prescribing Information, including Boxed Warning for supine hypertension, go to www.NORTHERA.com, or call the NSC at 844-601-0101.

Lundbeck

DRX-B-00215a(1)v2 **www.NORTHERA.com**