Xenazine® (tetrabenazine) Treatment Form

Questions? 1-888-882-6013 Fax form to 1-866-341-5601

Xenazine® (tetrabenazine) 12.5 and 25 mg Tablets

Step 1: Patient Information

Name: _____
(First) (Middle) (Last)

Sex: ❑ Male ❑ Female DOB: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Cell Phone: _____

Best Time to Call: _____ E-mail: _____

Preferred Contact Person: _____

Phone: _____ Cell Phone: _____

Ship to: (If different from above) ❑ Skilled Nursing Facility ❑ Hospital ❑ Other _____

Facility Name (if applicable): _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Contact Person: _____

Special Shipping Instructions: _____

Step 2: Patient Insurance—complete the information below OR include copies of insurance cards

Primary Insurance

Name of Medical Plan: _____ Phone: _____

Relationship to Cardholder: ❑ Self ❑ Spouse ❑ Child ❑ Other: _____

Cardholder Name: _____ Plan Number: _____

Group Number: _____ ID Number: _____

Secondary Insurance

Cardholder Name: _____ Plan Number: _____

Group Number: _____ ID Number: _____

Employer: _____ Phone: _____

Prescription Insurance

Name of Prescription Plan: _____ Phone: _____

Rx BIN: _____ Rx PCN: _____

Rx ID #: _____ Group #: _____

Step 3: Patient Authorization–HIPAA Release

The information provided about patient status is complete and accurate to the best of my knowledge. I will update the Xenazine Information Center promptly if such status should change.

I authorize my healthcare providers and health plans to disclose personal and medical information related to my use or potential use of tetrabenazine to Lundbeck and its agents and contractors ("Lundbeck") and I authorize Lundbeck to use and disclose this information 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 tetrabenazine to me; and 4) evaluate the effectiveness of tetrabenazine's education programs. I agree that using the contact information I provide, Lundbeck may get in touch with me for reasons related to the Xenazine Information Center and may leave messages for me that disclose that I take tetrabenazine.

I understand that once my health information has been disclosed to Lundbeck, privacy laws may no longer restrict its use or disclosure; however, Lundbeck agrees to protect my information by using and disclosing it only for the purposes described above or as required by law. I further understand I may refuse to sign this authorization and that if I refuse, my eligibility for health plan benefits and treatment by my doctor will not change, but I will not have access to the Xenazine support services described herein. I may also cancel this authorization in the future by notifying Lundbeck in writing and submitting it by fax to 1-866-341-5601 or by calling 1-888-882-6013. If I cancel, Lundbeck will cease using or disclosing my information for the purposes listed above, except as required by law or as necessary for the orderly termination of my participation in the Xenazine Information Center. I am entitled to a copy of this signed authorization, which expires 10 years from the date it is signed by me.

I authorize Lundbeck to release information provided in this enrollment form to the Xenazine Information Center for the provision of education, training, and ongoing support on the use of Xenazine. I authorize Lundbeck to use and give out my information to send me information or materials related to Xenazine (or any other related products or services in which I might be interested), to contact me by phone by a Registered Nurse to discuss my treatment, to contact me occasionally to get my feedback (for market research purposes) about Xenazine or the Xenazine Information Center to operate (and improve the quality of) the Xenazine Information Center otherwise as required or permitted by law. I understand that if I do not wish to receive information related to Xenazine (or any related products or services) or to be contacted occasionally for market research purposes, that I may call the Xenazine Information Center's number 1-888-882-6013 at any time.

I understand that my pharmacy provider(s) will disclose to Lundbeck and/or its representatives, agents, and subcontractors certain personal health information regarding the dispensing of my tetrabenazine prescription and that such disclosure will result in remuneration to my pharmacy provider(s).

➔ **Patient/Guardian Signature:** _____ Date: _____

Step 4: Prescriber Information

Prescriber Name: _____
(First) (Last)

Specialty: ❑ Neurology ❑ Other: _____

Prescriber Address: _____

Prescriber Address #2: _____

City: _____ State: _____ Zip Code: _____

Phone: _____ Fax: _____ NPI #: _____

Physician Office Contact: _____ Phone: _____

Step 5

℞ **Xenazine® (tetrabenazine)** Date: _____

❑ 12.5-mg tablets 30 Day Supply Quantity: _____ 90 Day Supply Quantity: _____

❑ 25-mg tablets 30 Day Supply Quantity: _____ 90 Day Supply Quantity: _____

Refills: _____

Titration schedule (per week)

Week 1: _____

Week 2: _____

Week 3: _____

Week 4: _____

ICD-10 Code: ❑ G10 Huntington's Disease

Prescriber Signature - STAMP SIGNATURE NOT ALLOWED

➔ Dispense as written* _____ Date: _____

➔ Product Substitution Permitted _____ Date: _____

*requirements for DAW may vary by state

Contact XIC at (888) 882-6013 if you need assistance

Step 6: By filling out this form, your HD chorea patient is automatically enrolled into the WithinREACH Patient Support Program

❑ **Check here if you choose not to enroll this patient into WithinREACH**

Step 7: Prescriber Authorization

I certify that Xenazine therapy is medically necessary and that this information is accurate to the best of my knowledge. Furthermore, the signing of the Xenazine Treatment Form represents an unsolicited request for reimbursement assistance including the procurement of any disease-specific clinical evidence in support thereof.

I authorize TheraCom LLC, acting as the Xenazine Information Center, to be my designated agent and to act as my business associate (as defined in 45 CFR 160.103) to use and disclose any information in this form to the insurer of the above-named patient and to obtain any information about the patient, including any protected health information (as defined in 45 CFR 160.103), from the insurer, including eligibility and other benefit coverage information, for my payment and/or healthcare operation purposes for which this drug is being prescribed. As my business associate, TheraCom is required to comply with, and by its signature hereto, agrees that it will comply with, the applicable requirements of 45 CFR 164.504(e) regarding business associates, and that it will safeguard any protected health information that it obtains on my behalf, and will use and disclose this information only for the purposes specified herein or as otherwise permitted by law.

I understand that no clinical information except that which is provided by the physician office will be used in the securing of product access by TheraCom.

➔ **Prescriber Signature:** _____ Date: _____

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XENAZINE® (tetrabenazine) Tablets

Indications and Usage:

XENAZINE is indicated for the treatment of chorea associated with Huntington's disease.

Important Safety Information:

WARNING: DEPRESSION AND SUICIDALITY

See full prescribing information for complete boxed warning.

- **Increases the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease.**
- **Balance risks of depression and suicidality with the clinical need for control of chorea when considering the use of XENAZINE.**
- **Monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior.**
- **Inform patients, caregivers, and families of the risk of depression and suicidality and instruct to report behaviors of concern promptly to the treating physician.**
- **Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation.**
- **XENAZINE is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.**

- XENAZINE is also contraindicated in patients who have impaired hepatic function or are taking monoamine oxidase inhibitors (MAOIs) or reserpine. XENAZINE should not be used in combination with an MAOI, or within a minimum of 14 days of discontinuing therapy with an MAOI. At least 20 days should elapse after stopping reserpine before starting XENAZINE.
- Prescribers should periodically re-evaluate the need for XENAZINE in their patients by assessing the beneficial effect on chorea and possible adverse effects, including worsening mood, cognition, rigidity, and functional capacity. XENAZINE should be titrated slowly over several weeks for a dose that is appropriate for each patient.
- Before a dose greater than 50 mg/day is administered, the patient's CYP2D6 metabolizer status should be determined. Do not exceed 50 mg/day or 25 mg/dose if XENAZINE is administered with a strong CYP2D6 inhibitor.
- XENAZINE therapy should be re-titrated if there is a treatment interruption of greater than 5 days, or a treatment interruption occurring due to a change in the patient's medical condition or concomitant medications.
- A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with XENAZINE. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac dysrhythmia). Additional signs may include elevated creatinine phosphokinase, myoglobinuria, rhabdomyolysis, and acute renal failure. The management of NMS should include immediate discontinuation of XENAZINE and other drugs not essential to concurrent therapy.
- XENAZINE can also cause other serious side effects, including: akathisia, restlessness, agitation, parkinsonism, and sedation/somnolence. These side effects may require a dose reduction or discontinuation of XENAZINE. Monitoring of vital signs on standing should be considered in patients who are vulnerable to hypotension. Dysphagia has also been reported with use of XENAZINE; some cases of dysphagia were associated with aspiration pneumonia.
- QT prolongation–related arrhythmias have been reported with use of XENAZINE. XENAZINE should not be used in combination with drugs known to prolong QTc (which in certain circumstances can lead to torsades de pointes and/or sudden death), in patients with congenital long QT syndrome, or in patients with a history of cardiac arrhythmias. A potentially irreversible syndrome of involuntary, dyskinetic movements called tardive dyskinesia (TD) may develop in patients treated with neuroleptic drugs. If signs and symptoms of TD appear in a patient treated with XENAZINE, drug discontinuation should be considered. The risk of parkinsonism, NMS, and akathisia may be increased by concomitant use of XENAZINE and dopamine antagonists or antipsychotics.
- XENAZINE elevates serum prolactin concentrations. XENAZINE may induce sedation/somnolence which may impair the ability to drive or operate dangerous machinery. Alcohol or other sedating drugs can worsen sedation/somnolence.
- Some adverse events, such as depression, fatigue, insomnia, sedation/somnolence, parkinsonism, and akathisia, may be dose-dependent. If the adverse effect does not resolve or decrease, consideration should be given to lowering or discontinuing XENAZINE. The most commonly reported adverse events with XENAZINE compared to placebo were sedation/somnolence (31% vs 3%), fatigue (22% vs 13%), insomnia (22% vs 0%), depression (19% vs 0%), akathisia (19% vs 0%), anxiety (15% vs 3%), and nausea (13% vs 7%).

For more information, please see the full Prescribing Information, including Boxed Warning, the Medication Guide, or go to www.xenazineusa.com.

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Lundbeck

www.XenazineUSA.com

Xenazine® (tetrabenazine)
12.5 and 25 mg Tablets

Healthcare Professional: Tear off and give to patient or caregiver

Welcome to Xenazine® (tetrabenazine) Treatment

Your doctor just prescribed Xenazine for you. This sheet describes the next steps as you start your Xenazine treatment

Read the Medication Guide that comes with Xenazine before you start taking it and each time you refill the prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What to expect next

1. Verification of your medical insurance information

- ⇢ After completing this form with your doctor, it will be faxed to the Xenazine Information Center
- ⇢ The Xenazine Information Center will:
  - – Contact your insurance company to see if Xenazine is covered under your plan
  - – Work with your doctor to submit any paperwork needed for you to get Xenazine

2. Talking about your co-pay

- ⇢ The Xenazine Information Center will contact you about your co-pay
- ⇢ If you need help paying for your medication, ask the Xenazine Information Center about REACH™

3. Prescription delivery

- ⇢ The first Xenazine prescription will be delivered by the fifth business day after your doctor sends in a completed prescription form*
- ⇢ All refills will be sent by a specialty pharmacy (Accredo, Advanced Care Scripts [ACS], CVS Caremark, or CuraScript)

Remember to return all calls from the Xenazine Information Center and your specialty pharmacy to help make sure your Xenazine prescription is filled on time.

Your Xenazine initial dosing schedule

You or your doctor can write down your initial dosing schedule here. He or she will give you specific instructions on how much Xenazine you should take and how often.

	Xenazine Dose			
Time of Day	Week 1	Week 2	Week 3	Week 4

Please carefully read the Important Safety Information, including Boxed Warning about the increased risk of depression and suicidality, on the back. Please refer to the accompanying Xenazine full Prescribing Information and Medication Guide for more information.

The Xenazine Information Center is here to help

If you have questions about your insurance coverage and/or how you will be sent the Xenazine prescribed by your doctor, please call the Xenazine Information Center toll-free at 1-888-882-6013.

For more information, you can also visit www.XenazineUSA.com. There you will find the latest Xenazine Medication Guide and other helpful resources.

*Program not available in all states.

Xenazine®
(tetrabenazine)
12.5 and 25 mg Tablets

XENAZINE® (tetrabenazine) Tablets

Indications and Usage:

XENAZINE is a medicine that is used to treat the involuntary movements (chorea) of Huntington's disease. XENAZINE does not cure the cause of the involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

It is not known whether XENAZINE is safe and effective in children.

Important Safety Information:

- **XENAZINE can cause serious side effects, including:**
  - **depression**
  - **suicidal thoughts**
  - **suicidal actions**
- You should not start taking XENAZINE if you are depressed (have untreated depression or depression that is not well controlled by medicine) **or** have suicidal thoughts.
- Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings, or worsening depression. This is especially important when XENAZINE is started and when the dose is changed.
- Do not take XENAZINE if you have liver problems or are taking monoamine oxidase inhibitors (MAOIs) or reserpine. Ask your doctor or pharmacist if you are not sure. **At least 20 days should pass after stopping reserpine before starting XENAZINE.**
- Tell your doctor if you are pregnant or plan to become pregnant, breast-feeding, have breast cancer or a history of breast cancer, or have heart disease or an irregular heartbeat.
- **Tell your doctor about all the medicines you take. Do not start any new medicines while taking XENAZINE without talking to your doctor first.**
- **Take XENAZINE exactly as prescribed by your doctor.** The need for therapy should be evaluated on an ongoing basis with your doctor. The dose of XENAZINE should be adjusted slowly over several weeks for a dose that is appropriate for you. Tell your doctor if you stop taking XENAZINE for more than **5** days. **Do not take another dose until you talk to your doctor. If your doctor thinks you need to take more than 50 mg of XENAZINE each day, you will need to have a blood test to see if a higher dose is right for you.**
- Neuroleptic Malignant Syndrome (NMS) is a potentially fatal side effect reported with XENAZINE. Call your doctor right away and go to the nearest emergency room if you develop these signs and symptoms that do not have another obvious cause: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, or increased sweating. XENAZINE should be stopped immediately if NMS is diagnosed.
- XENAZINE can also cause other serious side effects, including: parkinsonism (slight shaking, body stiffness, trouble moving, or keeping your balance), restlessness (akathisia), trouble swallowing, irregular heartbeat, and dizziness due to blood pressure changes when you change position (orthostatic hypotension). Trouble swallowing may increase the risk of pneumonia. Uncontrolled movements called tardive dyskinesia (TD) may also develop in patients treated with XENAZINE. It is possible that the TD will not go away.
- The risk of side effects, such as irregular heartbeat, parkinsonism, NMS, and restlessness (akathisia), may be increased when using XENAZINE with other drugs (e.g., dopamine antagonists or antipsychotics).
- Sleepiness is a common side effect of XENAZINE; **do not drive a car or operate dangerous machinery until you know how XENAZINE affects you.** Alcohol and other drugs may increase sleepiness caused by XENAZINE.
- Some side effects, such as depression, tiredness, trouble sleeping, sleepiness, parkinsonism, agitation, and restlessness (akathisia), may be dose-dependent. If the side effects don't stop or lessen, your doctor should consider lowering the dose or stopping your XENAZINE. The most commonly reported side effects in studies with XENAZINE were sleepiness, trouble sleeping, depression, tiredness, anxiety, restlessness, agitation, and nausea.

For more information, please see the full Prescribing Information, including Boxed Warning, the Medication Guide, or go to www.xenazineusa.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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