Project Overview for HCPs: Movement Disorder Treatment and Titration

Building a library for future medical education and promotional materials

This project aims to collect patient and long-term care resident video footage that demonstrates reductions in movements with AUSTEDO XR® (deutetrabenazine) extended-release tablets and/or AUSTEDO® (deutetrabenazine) tablets for use in future medical education and promotional materials. The intent is to build a library of real-world examples that can help healthcare professionals better understand what they can expect when choosing AUSTEDO XR for their adult patients with TD.

To support this effort, you are being asked to identify patients or residents who may be appropriate and willing to participate. For this request, your nomination should include

Demographics

- Patients you may see in practice or a resident in a long-term care facility
- Age groups: 18-48, 49-64, and ≥65 years
- Female or Male

Treatment

When assessing impact of treatment, please avoid hyperbolic language and remember to connect the impact to reductions in movements. Consider these sample questions to help uncover key aspects of the patient experience on treatment.

- Pretreatment baseline: AIMS score (total and per region) and symptom impact
  - Before starting treatment, what part of your body did you notice involuntary movements the most?
  - How did these movements affect everyday activities?
  - Have the movements caused any physical limitations, safety concerns, or difficulty maintaining parts of your routines?

INDICATIONS AND USAGE

AUSTEDO XR® (deutetrabenazine) extended-release tablets and AUSTEDO® (deutetrabenazine) tablets are indicated in adults for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia.

IMPORTANT SAFETY INFORMATION

Depression and Suicidality in Patients with Huntington's Disease: AUSTEDO XR and AUSTEDO can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Balance the risks of depression and suicidality with the clinical need for treatment of chorea. Closely monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior. Inform patients, their caregivers, and families of the risk of depression and suicidality and instruct them 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. AUSTEDO XR and AUSTEDO are contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression.

Please see additional Important Safety Information continued on the next page.

- Treatment titration: Reduction in movements with AUSTEDO XR or AUSTEDO during titration and maintenance and the resulting effects on other aspects of daily life
  - Since starting AUSTEDO XR, what changes have you noticed in your involuntary movements?
  - How has the severity of your movements changed over time with treatment?
  - Are there activities that you are better able to do now compared to before starting treatment with AUSTEDO XR?
  - How has the reduction in movements affected your confidence or comfort in social situations?
  - How would you describe the dosage modification (titration) process with AUSTEDO XR?

If you have a patient/resident that fulfills these criteria, next steps include:

1. Review the information with your patient/resident to get their agreement to participate
2. Begin the nomination process by completing a short form to send out consent and HIPAA authorization forms
3. Once all consent and HIPAA authorization forms have been signed, complete the nomination form
4. Submit a brief video (<1 minute) that shows why your patient/resident is a good fit. Please reference the sample interview questions within this document when conducting your patient or resident video recordings

For full details on the nomination process, please review the Nomination Process to submit a nomination that fulfills this request by accessing InPractice.com. If you have any questions, please contact getinpractice@hlxusa.com.

We appreciate your participation in this initiative.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Contraindications: AUSTEDO XR and AUSTEDO are contraindicated in patients with Huntington's disease who are suicidal, or have untreated or inadequately treated depression. AUSTEDO XR and AUSTEDO are also contraindicated in: patients with hepatic impairment; patients taking reserpine or within 20 days of discontinuing reserpine; patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of discontinuing MAOI therapy; and patients taking tetrabenazine or valbenazine.

Clinical Worsening and Adverse Events in Patients with Huntington's Disease: AUSTEDO XR and AUSTEDO may cause a worsening in mood, cognition, rigidity, and functional capacity. Prescribers should periodically re-evaluate the need for AUSTEDO XR or AUSTEDO in their patients by assessing the effect on chorea and possible adverse effects.

QTc Prolongation: AUSTEDO XR and AUSTEDO may prolong the QT interval, but the degree of QT prolongation is not clinically significant when AUSTEDO XR or AUSTEDO is administered within the recommended dosage range. AUSTEDO XR and AUSTEDO should be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

Please see additional Important Safety Information continued on the next page.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Neuroleptic Malignant Syndrome (NMS), a potentially fatal symptom complex reported in association with drugs that reduce dopaminergic transmission, has been observed in patients receiving tetrabenazine. The risk may be increased by concomitant use of dopamine antagonists or antipsychotics. The management of NMS should include immediate discontinuation of AUSTEDO XR and AUSTEDO; intensive symptomatic treatment and medical monitoring; and treatment of any concomitant serious medical problems.

Akathisia, Agitation, and Restlessness: AUSTEDO XR and AUSTEDO may increase the risk of akathisia, agitation, and restlessness. The risk of akathisia may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops akathisia, the AUSTEDO XR or AUSTEDO dose should be reduced; some patients may require discontinuation of therapy.

Parkinsonism: AUSTEDO XR and AUSTEDO may cause parkinsonism in patients with Huntington's disease or tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. The risk of parkinsonism may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops parkinsonism, the AUSTEDO XR or AUSTEDO dose should be reduced; some patients may require discontinuation of therapy.

Sedation and Somnolence: Sedation is a common dose-limiting adverse reaction of AUSTEDO XR and AUSTEDO. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, until they are on a maintenance dose of AUSTEDO XR or AUSTEDO and know how the drug affects them. Concomitant use of alcohol or other sedating drugs may have additive effects and worsen sedation and somnolence.

Hyperprolactinemia: Tetrabenazine elevates serum prolactin concentrations in humans. If there is a clinical suspicion of symptomatic hyperprolactinemia, appropriate laboratory testing should be done and consideration should be given to discontinuation of AUSTEDO XR and AUSTEDO.

Binding to Melanin-Containing Tissues: Deutetrabenazine or its metabolites bind to melanin-containing tissues and could accumulate in these tissues over time. Prescribers should be aware of the possibility of long-term ophthalmologic effects.

Common Adverse Reactions: The most common adverse reactions for AUSTEDO (>8% and greater than placebo) in a controlled clinical study in patients with Huntington's disease were somnolence, diarrhea, dry mouth, and fatigue. The most common adverse reactions for AUSTEDO (4% and greater than placebo) in controlled clinical studies in patients with tardive dyskinesia were nasopharyngitis and insomnia. Adverse reactions with AUSTEDO XR extended-release tablets are expected to be similar to AUSTEDO tablets.

Please click here or visit www.AUSTEDOhcp.com to read/print the full Prescribing Information, including Boxed Warning, for AUSTEDO XR.

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