Austedo®
(deutetrabenazine)
6 mg, 9 mg, and 12 mg tablets

Teva

cordially invites you to a presentation & discussion entitled:

Update for Healthcare Professionals: Management of TD and Chorea Associated with HD

Moderated by:

AMBER HOBERG, NP
Psychiatric Mental Health Nurse Practitioner

On
Thursday, October 11, 2018 at **6:30 PM**

At

Palmer's Restaurant
218 Moore Street
San Marcos, TX 78666
(512) 353-3500

Please RSVP to:
Kristin Caddell– (318) 426-2424

In accordance with the PhRMA Code on Interactions with Healthcare Professionals, attendance at this program is limited to healthcare professionals. Accordingly, attendance by non-clinical guests or spouses is not permitted.

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Indications and Usage

AUSTEDO® is indicated for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia in adults.

Important Safety Information

Depression and Suicidality in Patients with Huntington's Disease: 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® is contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression.

Please see Important Safety Information continued on next page and accompanying full Prescribing Information, including Boxed Warning.

Important Safety Information (continued)

Contraindications: AUSTEDO® (deutetrabenazine) tablets is contraindicated in patients with Huntington's disease who are suicidal, or have untreated or inadequately treated depression. AUSTEDO® is 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 (Xenazine®) or valbenazine (Ingrezza™).

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

QTc Prolongation: Tetrabenazine, a closely related VMAT2 inhibitor, causes an increase in the corrected QT (QTc) interval. A clinically relevant QT prolongation may occur in some patients treated with AUSTEDO® who are CYP2D6 poor metabolizers or are co-administered a strong CYP2D6 inhibitor. Dose reduction may be necessary. The use of AUSTEDO® in combination with other drugs known to prolong QTc may result in clinically significant QT prolongations. For patients requiring AUSTEDO® doses greater than 24 mg per day who are using AUSTEDO® with other drugs known to prolong QTc, assess the QTc interval before and after increasing the dose of AUSTEDO® or the other drugs. AUSTEDO® should be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

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®; intensive symptomatic treatment and medical monitoring; and treatment of any concomitant serious medical problems.

Akathisia, Agitation, and Restlessness: 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® dose should be reduced; some patients may require discontinuation of therapy.

Parkinsonism in Patients with Huntington's Disease: AUSTEDO® may cause parkinsonism in patients with Huntington's disease. The risk of parkinsonism may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops parkinsonism, the 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®. 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® 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®.

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.

Please see Important Safety Information continued on next page and accompanying full Prescribing Information, including Boxed Warning.

Important Safety Information (continued)

CYP2D6 Metabolism: In patients who are poor CYP2D6 metabolizers or are taking strong CYP2D6 inhibitors, the total daily dosage of AUSTEDO® (deutetrabenazine) tablets should not exceed 36 mg (maximum single dose of 18 mg).

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.

Please see accompanying full Prescribing Information, including Boxed Warning.