

Expert Perspectives on the Tardive Dyskinesia (TD) Patient Journey: From Screening to Appropriate Treatment

EXPERT COMMENTARY

A Three-Expert Perspective on Tardive Dyskinesia (TD): Identifying, Distinguishing, and Assessing TD

These experts discuss the importance of screening for TD in clinical practice. Get their first-hand perspectives on practical approaches to identifying TD and assessing its impact.

TREATMENT

AUSTEDO XR in Practice: Data, Dosing, and a Clinical Perspective

Review key efficacy and safety data from clinical trials of AUSTEDO® (deutetrabenazine) tablets. These experts also share their insights on the use of AUSTEDO XR in their practices.



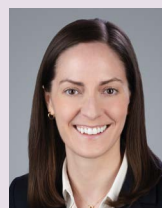
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This newsletter is produced by Teva Pharmaceuticals. Dr Richard Miller, Amber Hoberg, and Dr Christa Cooper were compensated by Teva for their insights.

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.

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A Three-Expert Perspective on Tardive Dyskinesia (TD): Identifying, Distinguishing, and Assessing TD



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Tardive dyskinesia (TD), a typically irreversible hyperkinetic movement disorder, remains underdiagnosed and undertreated despite affecting an estimated 785,000 individuals in the United States.¹⁻³ Approximately 15% of patients with TD receive a formal diagnosis, and about 5% are treated with vesicular monoamine transporter 2 (VMAT2) inhibitors, the only US Food and Drug Administration (FDA)-approved treatment.³ Routine screening and assessment are essential to help close this gap in care and support earlier identification and appropriate treatment of TD. **In this issue of News and Views, 3 experts—Richard Miller, MD, MS, a psychiatrist; Amber Hoberg, APRN, MSN, PMHNP-BC, a certified mental health nurse practitioner; and Christa Cooper, PhD, PA-C, MPH, a movement disorders physician assistant—share practical perspectives on screening for and assessing TD.**

Q: Who should be screened for TD, and how often?

Christa Cooper: Any patient with current or prior exposure to a dopamine receptor blocking agent (DRBA) should be screened for TD, including those receiving antipsychotics or other DRBAs such as metoclopramide, a prokinetic agent.^{1,4-7} Clinicians who prescribe these agents should counsel patients about the risk of developing TD and should regularly screen for abnormal involuntary movements.

Ongoing screening is critical because many individuals with TD remain undiagnosed. Therefore, patients taking antipsychotics should be screened for abnormal movements at every clinical encounter.⁸ A structured assessment, such as the

Abnormal Involuntary Movement Scale (AIMS), should be conducted at baseline, at least every 6 months in high-risk patients, **at least every 12 months in patients with a history of DRBAs**, or if new or worsening movements are observed.^{8,9}

Amber Hoberg: All patients with current or prior exposure to a DRBA should be screened for TD. This includes patients taking first- or second-generation antipsychotics. Patients are still at risk even after these medications have been discontinued, so a history of exposure remains important.^{1,4-7}

The key is to be proactive: consistent screening, patient

IMPORTANT SAFETY INFORMATION (CONTINUED)

Contraindications: AUSTEDO XR® (deutetrabenazine) extended-release tablets and AUSTEDO® (deutetrabenazine) tablets 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.

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education about the possible signs of TD, and timely follow-up can support earlier recognition.

Richard Miller: In psychiatric practice, screening for TD is required across inpatient and outpatient settings.

It should be a standard part of care, particularly because effective treatments for TD are available.

In my practice, I screen at every encounter.⁸ In addition, I perform a formal AIMS at the initiation of antipsychotic treatment and then

every 6 months for many patients, because they are at elevated risk due to substantial cumulative exposure to antipsychotics, including long-term or high-dose treatment, often in the setting of severe, persistent underlying psychiatric illness.^{8,9}

Q: In clinical practice, who can screen for TD?

Amber Hoberg: In clinical practice, screening for TD should be viewed as a team responsibility. **Anyone on the care team can observe a patient for abnormal involuntary movements and report concerns to the prescribing or diagnosing clinician.** That is different from performing a formal structured assessment, such as the AIMS.

Many members of the care team may be in a position to notice abnormal movements first. Nurses, medical assistants, reception staff, case managers, social workers,

and other support staff can all help identify possible signs of TD when they are trained to observe for them.

This is especially important across care settings such as outpatient clinics, group homes, and long-term care environments, where different staff members may see the patient in different contexts. Sometimes movements are more apparent during everyday activities or periods of stress, so broad awareness among staff can improve early recognition and prompt timely follow-up.

Richard Miller: I completely agree that this is a team responsibility. In my clinic, screening begins in the waiting room, before the patient enters the exam room. Front-desk staff, support staff, case managers, and other team members who interact with patients regularly are often the first to notice a change or observe abnormal movements. They are not responsible for completing a formal AIMS assessment or diagnosing TD, but they should know when to elevate concerns to the prescriber or clinician for further evaluation.

Q: How do you screen for movements?

Amber Hoberg: I screen for TD by combining observation with targeted questioning. I observe patients while they are seated, speaking, and moving naturally, and I ask direct questions about unwanted movements involving the face, jaw, tongue, trunk, and extremities.⁹⁻¹¹ If screening raises concern for possible TD, I then perform a more formal evaluation, such as the AIMS.

Richard Miller: Building on that, in psychiatry it is important to observe patients during routine interaction, when they may be less aware that abnormal movements are being assessed. Some individuals, often because of embarrassment, may consciously or unconsciously suppress or hide their movements. Many of my patients are at increased risk for TD, so I also use the AIMS examination at their follow-up visits to guide a more structured head-to-toe assessment for abnormal movements.^{12,13}

Christa Cooper: From the neurology side, once those movements are identified, patients are referred to my movement disorders practice. My role is to confirm TD and differentiate it from other movement disorders. In that setting, I focus on the clinical history, the pattern of movements, and the neurologic examination to determine whether the presentation is consistent with TD or another movement disorder.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

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Q: How do you train your staff to recognize possible signs of TD in clinical practice?

Amber Hoberg: I keep staff training simple. **I teach team members what common TD movements may look like**—such as excessive blinking, brow furrowing, lip or jaw movements, tongue movements, finger movements, or repetitive trunk shifting—and encourage them to report anything that appears abnormal or repetitive.^{2,14}

Richard Miller: I take a similar approach. Staff education focuses on helping team members recognize visible, potentially abnormal movements. **The goal is not for everyone to become an expert in movement disorders, but to help them recognize when something appears unusual or concerning.** Over time, repeated exposure and practical education help staff become

more comfortable recognizing when further assessment is needed.

Christa Cooper: That makes sense—my clinic is a bit different. In my movement disorders clinic, patients typically present with some form of abnormal movement, and distinguishing TD from other movement disorders is the responsibility of the clinician rather than the staff.

Q: What are the most common movement disorders you encounter in your clinical practice, and how do you differentiate TD from them?

Richard Miller: The movement disorders I encounter most often in psychiatric practice are TD and drug-induced parkinsonism (DIP). Differentiating them requires a clinical examination and careful review of the patient's medical history and medication exposure. Key considerations include the pattern of movements, the timing of symptom onset, and any history of antipsychotic use.¹⁵ **Accurate diagnosis is critical because TD and DIP require different treatment approaches, and appropriate treatment for one condition may exacerbate the other.**¹⁵⁻¹⁹

Christa Cooper: I agree—careful history and physical examination are both essential to differentiating TD from DIP. During physical examination, **when assessing for DIP, I look first for bradykinesia, which is the core clinical feature of parkinsonism.**¹⁵ **Rigidity and resting tremor may also be present, although not in every patient. These features are not typical of TD, which presents as hyperkinetic, nonrhythmic movements affecting the face, mouth, tongue, or limbs.**¹⁵

Amber Hoberg: In addition to TD and DIP, the other movement disorders I most commonly encounter are akathisia and dystonia. In some cases, patients may have more than one movement disorder, which can make the evaluation more complex.¹⁵

Differentiating them requires careful attention to the type of movement and the patient's description of the experience. Akathisia is characterized more by internal restlessness with a need to move.^{15,16} Dystonia tends to involve sustained contractions or abnormal posturing.¹⁶

Q: Why is it important to assess the impact of TD, and how do you evaluate that impact in your patients?

Christa Cooper: It is important to assess impact because **the visible severity of TD does not always reflect how much it affects a patient's daily life.** Even relatively

subtle movements can interfere with function, confidence, and social engagement.²⁰ I usually ask specific questions about discomfort, embarrassment, social withdrawal,

or difficulty with particular tasks, rather than simply asking whether the movements are bothersome. That approach tends to reveal the true burden more clearly.

IMPORTANT SAFETY INFORMATION (CONTINUED)

QTc Prolongation: AUSTEDO XR® (deutetrabenazine) extended-release tablets and AUSTEDO® (deutetrabenazine) tablets 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.

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Amber Hoberg: Providers should assess the impact of TD because **APA guidelines recommend treating TD when it is clinically impactful to the patient—regardless of the severity of movements.**⁸

The IMPACT-TD scale can be a valuable tool for evaluating the impact of TD, which can help inform treatment decisions in clinical practice.²¹

Richard Miller: I agree. Assessing the impact of TD is important because the effects on a patient's daily life may not be apparent unless they are explored. Patients often do not volunteer this information unless they are asked directly with targeted questions.

Q: Can you share an example of how TD has affected one of your patients, and how you addressed it in clinical practice?

Amber Hoberg: One patient with mild TD had been told by 2 previous providers that her movements were not severe enough to treat. However, **the decision to treat should not be based on the AIMS score alone, but on the impact TD has on the patient's daily life.**⁸ By asking more detailed questions, I learned that her mild oral movements were affecting her speech, undermining her confidence, and substantially impairing her work as an attorney. She had also begun withdrawing from family events because of her movements. Based on the significant impact TD was having on her life, I initiated treatment.

Richard Miller: One of my patients with TD had been actively trying to hide the movements, including by wearing heavy, bulky clothing year-round. **Once I was able to get him to talk about his movements, it became clear that TD was affecting much more than his appearance**—he was withdrawing socially and avoiding routine activities outside the home. I approached the conversation carefully and used a shared decision-making approach rather than pushing treatment too aggressively. Once he agreed to treatment, his movements improved substantially, and so did his comfort with social interaction and day-to-day functioning.

Christa Cooper: One patient I treated became increasingly isolated because of social embarrassment related to TD and concern that others would notice or judge the movements. This is common in patients with TD, particularly given that many also have underlying mental health disorders that may be further affected by TD. This case reinforced for me that even movements that appear mild can have a profound effect on quality of life and should not be dismissed.

Q: What are the key considerations, challenges, and best practices for assessing TD in a virtual setting?

Christa Cooper: Virtual assessment requires patience from both the clinician and the patient, but TD screening should remain part of telemedicine care. The main challenge is camera positioning, which may limit what movements can be observed. At a minimum, facial movements are often assessable by video, and with

guidance, patients can reposition the camera or move farther back so the upper body and extremities can also be evaluated.²²

Amber Hoberg: The first 7 items of the AIMS examination provide a full-body assessment of a patient's movements. **In most telepsychiatry visits, 6 of the**

7 items can be evaluated with a waist-up view. With camera repositioning, all 7 items can often be assessed.^{12,22}

It is also important to ask targeted questions and, when appropriate, involve a caregiver or family member who may be able to provide additional observations about movements in everyday settings.

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.

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Richard Miller: Most of my practice is in person, but I do some telehealth, particularly in residential or inpatient settings where patients may be seen remotely. Virtual assessment of TD can be challenging because subtle

movements may be easier to miss on video than during an in-person visit. In this setting, it is especially important to have experienced, well-trained onsite staff who can help observe the patient and report any abnormal

movements that may not be fully appreciated virtually.²² When needed, I follow up with staff after the visit to confirm what was observed and determine whether further in-person assessment is warranted.²²

Q: How do you adapt the AIMS examination for patients who are bed- or wheelchair-bound or who have cognitive impairment?

Amber Hoberg: The key is to assess what you can rather than assuming the exam cannot be done. **Even when patients are bed- or wheelchair-bound, it is still possible to observe abnormal movements while the patient is seated or lying down and to complete key components of the assessment with appropriate positioning and support.** To help ensure patient safety, I have a nurse or another staff member assist during the examination.

For patients with cognitive impairment, I often model the

requested movements so the patient can mimic them. Many patients can follow simple, demonstrated instructions.

Richard Miller: I agree—**flexibility is key.** These situations can be challenging, and there is no one-size-fits-all approach to performing the AIMS examination. The key is to adapt the assessment to the patient's abilities and clinical presentation and obtain the best information possible under the circumstances.

Christa Cooper: In one patient who was wheelchair-bound and unable to respond reliably because of cognitive impairment, I was still able to observe and score the abnormal movements without modification, as the movements were sufficiently severe to be assessed visually, although gait could not be evaluated. Caregiver input was essential in providing additional context about the patient's movements and their impact on daily functioning.

Q: Once TD is diagnosed, what is your approach to initiating treatment for your patients?

Christa Cooper: I first review the medication list carefully, including whether the patient is taking an anticholinergic, since that can worsen TD. From there, my approach is to initiate treatment with a VMAT2 inhibitor, given the available efficacy data and FDA approval for TD.^{8,15,16,19}

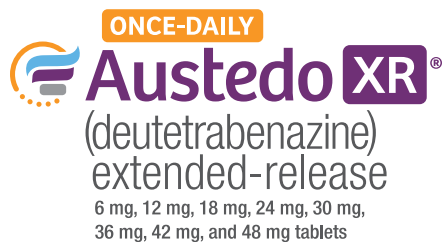
Richard Miller: I discuss treatment promptly, with emphasis on education, trust, and shared decision-making. I explain what TD is, why it occurs, and what treatment may help. In psychiatry, patient engagement is especially important. Some patients are hesitant to add

another medication, particularly if they already feel burdened by prior treatment experiences. Taking time to educate the patient and allowing them to participate meaningfully in the decision can make a major difference in whether treatment is started and maintained. ■

IMPORTANT SAFETY INFORMATION (CONTINUED)

Akathisia, Agitation, and Restlessness: AUSTEDO XR® (deutetrabenazine) extended-release tablets and AUSTEDO® (deutetrabenazine) tablets 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.

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TREATMENT

AUSTEDO XR in Practice: Data, Dosing, and a Clinical Perspective

AUSTEDO XR is a one-pill, once-daily vesicular monoamine transporter 2 (VMAT2) inhibitor approved in adults for the treatment of tardive dyskinesia (TD) and chorea associated with Huntington's disease.¹ This article highlights key findings from the pivotal clinical trials of AUSTEDO, reviews initiation and dosing considerations, and shares clinician perspectives on treatment in practice.

Key Findings From Clinical Trials for AUSTEDO: ARM-TD, AIM-TD, and RIM-TD

The efficacy and safety profile of AUSTEDO was established in two 12-week, randomized, double-blind, placebo-controlled pivotal studies in adults with TD: Aim to Reduce Movements in Tardive Dyskinesia (ARM-TD), a flexible-dose study, and Addressing Involuntary Movements

in Tardive Dyskinesia (AIM-TD), a fixed-dose study.¹⁻³ The primary efficacy endpoint in both studies was change in Abnormal Involuntary Movement Scale (AIMS) total score from baseline to Week 12.^{2,3}

In the placebo-controlled studies, patients receiving AUSTEDO demonstrated improvement as early as Week 2 and achieved significant and meaningful reductions in TD severity at Week 12.¹⁻³ In ARM-TD, a 3.0-point reduction in AIMS total score from baseline to Week 12 was observed in patients receiving AUSTEDO, while a 1.6-point reduction was observed in the placebo group.^{1,3} Long-term results through approximately 3 years were collected in the Reducing Involuntary Movements in Participants With Tardive Dyskinesia (RIM-TD) open-label extension study, in which

patients were titrated to a dose that effectively reduced movements and was tolerated by the patient.⁴

Increasing improvement in AIMS total score was observed over 3 years, with 71% of patients at Week 145 showing improvement relative to Week 15 (**Figure 1**).^{4,5} Consistent results were observed across a broad range of patient populations, including older adults, postmenopausal women, and patients with mood or psychotic disorders.⁶⁻⁸



"The 3-year results are particularly meaningful to me because they show continued improvement over time.⁴ In my experience, treatment response with AUSTEDO XR has been consistent with those findings." – *Christa Cooper, PhD, PA-C, MPH*



"I have a few people who have been on AUSTEDO XR for a couple of years now, and my experience has been consistent with what was observed in the placebo-controlled and open-label extension studies.^{1,4,8} I see consistent improvement in my patients, and their side effects are consistent with the established safety and tolerability profile of the drug." – *Richard Miller, MD, MS*

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

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Demonstrated Safety and Tolerability Profile

The most common adverse reactions occurring in >3% of patients treated with AUSTEDO® (deutetrabenazine) tablets and greater than placebo were nasopharyngitis and insomnia (**Table 1**).¹ No new safety signals were identified in the 3-year extension study, and the safety profile remained generally consistent with that observed in the pivotal studies.^{4,8}

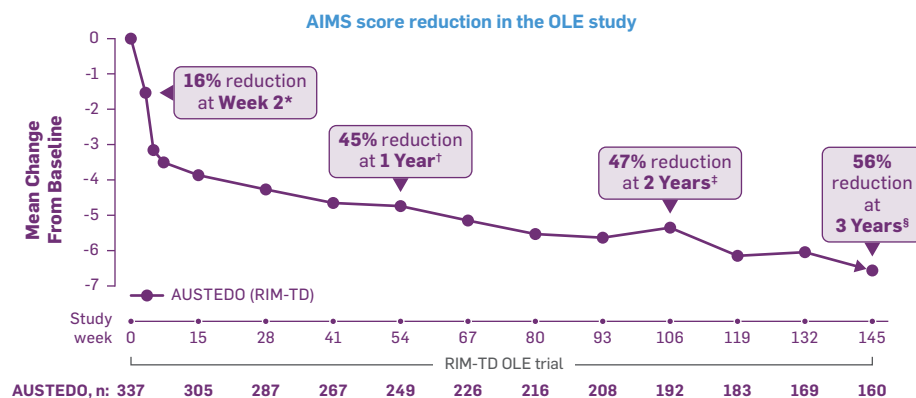


"Many of my patients take multiple medications, so safety is always an important consideration. AUSTEDO XR® (deutetrabenazine) extended-release tablets has an established safety profile, with no new safety signals observed in the 3-year study."^{1,4,8} – *Amber Hoberg, APRN, MSN, PMHNP-BC*

Few Restrictions Related to Drug-Drug Interactions

Patients with TD often take multiple medications to manage psychiatric and nonpsychiatric comorbidities. AUSTEDO XR has a metabolic profile that allows for few restrictions related to drug-drug interactions. Only with AUSTEDO XR can the once-daily dose be increased in patients taking strong CYP inhibitors and inducers, with a maximum dose of 36 mg/day for those taking strong CYP2D6 inhibitors (or poor CYP2D6 metabolizers) and 48 mg/day for all others (**Table 2**).¹

Figure 1. Increasing Improvement Observed Over 3 Years in the Longest TD Clinical Trial to Date^{4,5}



Patients in the RIM-TD study received the AUSTEDO twice daily (BID) formulation.⁵

*Calculated based on the average AIMS score at Week 2 vs baseline.

†Calculated based on the average AIMS score at 1 year vs baseline.

‡Calculated based on the average AIMS score at 2 years vs baseline.

§Calculated based on the average AIMS score at 3 years vs baseline.

Baseline AIMS score: RIM-TD (AUSTEDO: 10.7 [SD, 4.7]).⁴

Table 1. Adverse Reactions Reported in ≥2% of Patients With TD Treated With AUSTEDO in Placebo-Controlled TD Studies^{1,5}

Adverse Reaction	AUSTEDO (n=279)	Placebo (n=131)
Headache	5%	8%
Somnolence	4%	7%
Diarrhea	4%	4%
Nasopharyngitis	4%	2%
Fatigue	4%	5%
Insomnia	4%	1%
Anxiety	4%	5%
Upper respiratory tract infection	3%	4%
Dry mouth	3%	5%
Nausea	2%	7%
Weight increased	2%	3%
Urinary tract infection	2%	2%
Depression/dysthymic disorder	2%	1%
Akathisia/agitation/restlessness	2%	1%
Arthralgia	2%	1%

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation. Adverse reactions with AUSTEDO XR are expected to be similar to AUSTEDO BID.^{1,5}

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

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Table 2. Metabolic Profile of AUSTEDO XR Allows for Few Restrictions Related to Drug-Drug Interactions^{1,9,10}

	AUSTEDO XR	Ingrezza® (valbenazine)
Strong CYP3A4/5 inducer	No dose restriction	Concomitant use is not recommended
Strong CYP3A4/5 inhibitor	No dose restriction	40 mg/day (lowest available dose)
Strong CYP2D6 inhibitor (or if a patient is a poor CYP2D6 metabolizer)	Up to 36 mg/day	40 mg/day (lowest available dose)
P-gp substrate (eg, calcium channel blockers, statins, antimicrobials, and digoxin)	No dose adjustment to P-gp substrate required	Dose adjustment to P-gp substrate may be required

These differences should not be construed to imply differences in safety, efficacy, or clinical outcome.

Figure 2. Dosing Flexibility for Effective and Tolerable Control^{1,4,5}

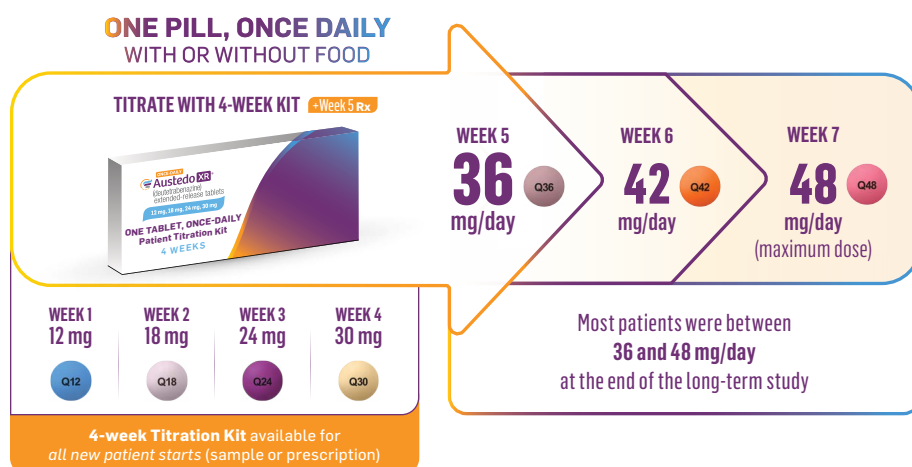


Image shown is not actual 4-week Titration Kit. Tablets not shown at actual size.

Simple Start: 4-Week Titration Kit + 36 mg/day Prescription

AUSTEDO XR is available in a range of doses, providing flexibility to help patients achieve effective and tolerable symptom control.¹ The recommended starting dose

for patients with TD is 12 mg/day and may be increased weekly by 6 mg/day (**Figure 2**).¹ The 4-Week Titration Kit is available for patients new to AUSTEDO XR through either a sample or a prescription. A prescription for 36 mg/day can be written at the same time

to help support continuity of care.⁵ Importantly, it is not necessary to modify a patient's antipsychotic dose when prescribing AUSTEDO XR.^{1,5}

AUSTEDO XR may be taken with or without food, and patients who miss a dose for less than 1 week can restart treatment at the same daily dose.



"The entire care team helps monitor response over time.

We follow patients closely after treatment initiation to assess tolerability, determine whether additional titration is needed, and understand how they are doing on therapy."

– Richard Miller, MD, MS

Key Takeaways

- Rapid response observed as early as Week 2¹⁻³
- Significant and meaningful reductions in TD severity at Week 12^{2,3}
- Increasing improvement observed over 3 years⁴
- Established safety profile with no new safety signals identified in the 3-year study^{1,4,8}
- Flexible dosing with few restrictions related to drug-drug interactions¹ ■

IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Common Adverse Reactions: The most common adverse reactions for AUSTEDO® (deutetrabenazine) tablets (>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® (deutetrabenazine) extended-release tablets are expected to be similar to AUSTEDO tablets.

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References

EXPERT COMMENTARY: A Three-Expert Perspective on Tardive Dyskinesia (TD): Identifying, Distinguishing, and Assessing TD

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TREATMENT: AUSTEDO XR in Practice: Data, Dosing, and a Clinical Perspective

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