ONCE-DAILY

Austedo XR®

(deutetrabenazine) extended-release

6 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42 mg, and 48 mg tablets

See Norma's journey to symptom improvement inside

For your adult LTC residents with TD or HD chorea[1]

MAKE A MOVE THAT MATTERS

WITH ONE PILL, ONCE-DAILY AUSTEDO XR®

LTC, long-term care.

INDICATIONS AND USAGE

AUSTEDO XR® and AUSTEDO® are indicated in adults for the treatment of tardive dyskinesia (TD) and for the treatment of chorea associated with Huntington's disease (HD).

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

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TD remains underdiagnosed despite high risk in LTC[2]

>700,000 residents in LTC facilities receive an antipsychotic drug as part of their treatment regimen[2]*

- Individuals exposed to first-generation/typical and/or second-generation/atypical antipsychotics have a mean TD prevalence of ~25%[3,4]
- 1% of residents in LTC taking antipsychotics have a TD diagnosis[2]*

Unnecessary antipsychotic use is the focus of several CMS initiatives (F605, F757, and F841)[5,6]

Reducing or discontinuing antipsychotic drugs can unmask TD[7]

Untreated TD can impact a facility's star rating[5]

- CMS Quality Measures include:
  - Percentage of residents whose ability to walk independently worsened
  - Percentage of residents whose need for help with ADLs has increased
  - Percentage of residents experiencing one or more falls with major injury
  - Number of outpatient ED visits
- Increased burden on nursing staff may contribute to turnover

Residents with TD treated with a VMAT2 inhibitor have fewer falls and ED visits.[2,8†]

APA recommends treating TD with a VMAT2 inhibitor.

Use the TD Estimator Tool to calculate how many residents in your facility may have TD

ADL, activity of daily living; APA, American Psychiatric Association; CMS, Centers for Medicare & Medicaid Services; ED, emergency department; VMAT2, vesicular monoamine transporter 2.
*According to PointClickCare® database.[2]
†Versus those treated with a non-VMAT2 inhibitor.[2]

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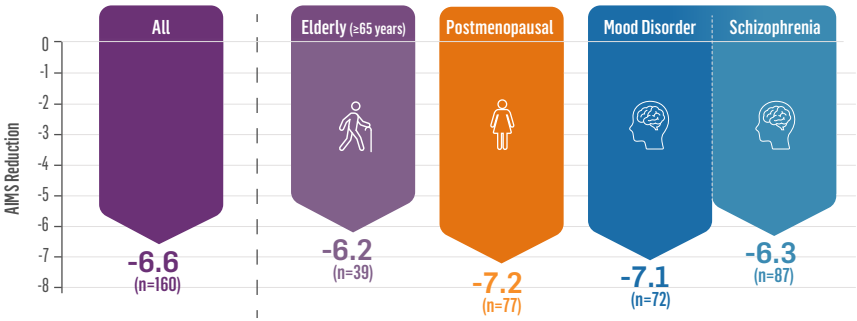
Significant and meaningful reduction of TD severity at Week 12 in pivotal studies[1,9,10]

- -3.3 vs -1.4 AIMS reduction in AIM-TD (36 mg/day, *P*=0.001)
- -3.0 vs -1.6 AIMS reduction in ARM-TD (~38 mg/day,* *P*=0.019)

Only with AUSTEDO XR:

Consistent 3-year results in patients at increased risk for TD[2,11-15]

Mean Change From Baseline in AIMS Total Score at Week 145[11,13-15†]



Patients in the AUSTEDO trials had a range of psychiatric and comorbid conditions[2]

- Gastrointestinal disorders
- Cardiovascular disorders
- Metabolism/nutritional disorders, including diabetes
- Lipid disorders
- General liver disorders‡

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,11]

AIMS, Abnormal Involuntary Movement Scale.
*Mean total dose.[9]
†Data from post hoc analyses of the RIM-TD open-label extension (OLE) study.[13-15]
‡Patients with hepatic impairment were excluded from studies. Hepatic impairment is defined as a loss of core functions, such as drug clearance, in patients with cirrhosis (stage 4 fibrosis). ~1% of residents in LTC taking antipsychotics have moderate-to-severe liver disease according to PointClickCare® database.[2,16,17]
Please see study designs at AUSTEDOhcp.com.

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.

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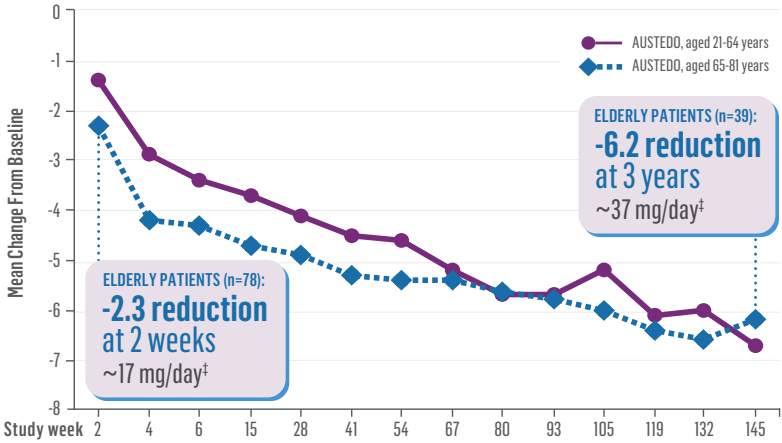
Rapid response as early as Week 2[9,10]*

Increasing improvement observed over 3 years in the longest TD clinical trial to date (OLE)[2,11,12]†

Sustained Results for Elderly and Younger Patients: AIMS Score Reduction in RIM-TD[2,13]



Consistent treatment results across elderly patients (aged 65-81 years) and younger patients (aged 21-64 years)[13§]:

- Similar dose and response at 3 years (>36 mg/day)‡
- Similar safety and tolerability profile
- Similar percentage of patients remained in the study at 3 years

***Largest elderly population* of any TD clinical study (n=78)[13,18]**

*Response observed as early as Week 2 in placebo-controlled studies.[9,10]
†71% of patients at Week 145 saw improvement relative to Week 15.[2]
‡Mean total dose.[2]
§In a post hoc subgroup analysis of the RIM-TD OLE.[13]
Please see study designs at **AUSTEDOhcp.com**.

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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In a real-world survey of 209 individuals with TD taking AUSTEDO XR, the **majority of individuals reported movement reduction** (>90%)[2]

As a result of movement reduction with AUSTEDO XR, surveyed individuals reported improvements in daily living[2]

☑ Emotional well-being

- Less embarrassment (~73%)
- Improved self-esteem (~68%)
- Lowered anxiety (~62%)

☑ Social well-being

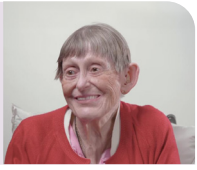
- Spending time with family and friends (~79%)
- Increased comfort speaking to others (~76%)

☑ Physical well-being & productivity

- Improved overall physical health (~58%)

Individuals reported overall satisfaction with AUSTEDO XR—regardless of previous treatment status or age[2,19*†]

Click here to discover how Norma, a real resident taking AUSTEDO XR, saw movement reduction



*Consistent survey results across individuals previously treated with valbenazine (n=54) or with no prior TD treatment (n=100).[19] No head-to-head studies comparing deutetrabenazine and valbenazine have been conducted. These patient survey results should not be construed to imply differences in safety, efficacy, or clinical outcome.

†Consistent survey results across elderly and younger subgroups.[2]

IMPORTANT SAFETY INFORMATION (Continued)

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.

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Average number of medications per resident at time of TD diagnosis is ~15[2]*

Only with AUSTEDO XR: ability to increase once-daily dose in residents taking strong CYP inhibitors and inducers[1,20†]

With AUSTEDO XR[1]:

Residents can reach a dose with statistically significant results, including‡

- Those taking strong CYP3A4/5 inhibitors or inducers
- Poor CYP2D6 metabolizers or those taking strong CYP2D6 inhibitors

No clinically significant QT prolongation up to the maximum dose (48 mg/day)§

AUSTEDO XR has few restrictions related to drug-drug interactions (DDIs)[1]

Drug coadministered with VMAT2 inhibitor	Recommended Dosing	
	AUSTEDO XR[1,21,22]	Valbenazine/Valbenazine Sprinkle[20]
Strong CYP3A4/5 inducer	**No dose restriction**	**Concomitant use is not recommended**
Strong CYP3A4/5 inhibitor	**No dose restriction**	**40 mg/day** lowest dose available
Strong CYP2D6 inhibitor (or if resident is a poor CYP2D6 metabolizer)	**Up to 36 mg/day**	**40 mg/day** lowest dose available
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 difference in safety, efficacy, or clinical outcome.

*According to PointClickCare® database.[2]
†36 mg/day maximum dose for residents taking strong CYP2D6 inhibitors (or poor CYP2D6 metabolizers); 48 mg/day maximum dose for all others.[1]
‡Statistically significant AIMS improvement in AIM-TD at Week 12 in the 24 mg/day and 36 mg/day dosing arms (-3.2 and -3.3 reduction, respectively, vs -1.4 with placebo). Patients in the pivotal studies received the AUSTEDO BID formulation.[1]
§Based on studies in healthy patients. For patients with congenital long QT syndrome or arrhythmias associated with prolonged QT interval, all VMAT2 inhibitors should be avoided. Caution should be used for patients taking drugs that prolong the QT interval.[1,20]

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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Demonstrated safety and tolerability profile in pivotal and 3-year studies[1,11]

Adverse Events Reported in ≥2% of Patients Treated With AUSTEDO in TD Pivotal Studies[1,2]

Adverse Events	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 studies received the AUSTEDO BID formulation. Adverse events with AUSTEDO XR are expected to be similar to AUSTEDO BID.[1]

Similar discontinuation and dose reduction rates vs placebo.[1,9,10]

Once patients in the pivotal trials were titrated to their maintenance dose, several adverse events were no longer reported[2]:

- Dry mouth and nausea (AIM-TD)
- Somnolence and dry mouth (ARM-TD)

Comparable safety and tolerability in the 3-year study, with no new safety signals[11]

IMPORTANT SAFETY INFORMATION (Continued)

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.

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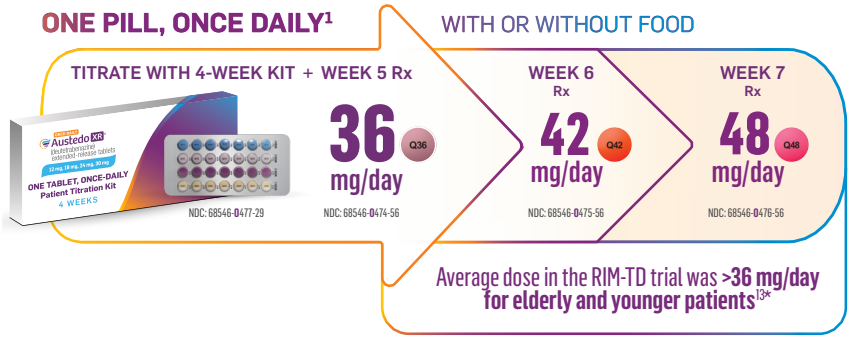
Simple start: 4-week Titration Kit or PointClickCare® Pharmacy Order Set



Flexible dosing for effective & tolerable control[1]

In pharmacokinetic studies, increased plasma levels did not correlate with higher potential for adverse events in TD[23,24]

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,11]

Image shown is not actual 4-week Titration Kit. Tablets not shown at actual size.
*Mean total dose in a post hoc subgroup analysis of the RIM-TD OLE.[2,13]
Please see study designs at **AUSTEDOhcp.com**.

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.

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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Get residents started at no cost

Prescribe the 4-week Kit and ask pharmacy to apply the 30-day Free Trial Voucher at AUSTEDOcardform.com*

OR

PointClickCare®

Prescribe with the PointClickCare Pharmacy Order Set and ask pharmacy to apply the 30-day Free Trial Voucher at AUSTEDOcardform.com*

Continue titrating weekly until symptom control is effectively and tolerably achieved (48 mg/day maximum dosage).[1]

Image shown is not actual 4-week Titration Kit.

*Certain restrictions apply. Terms and conditions on AUSTEDOcardform.com.

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For residents switching from AUSTEDO BID to one pill, once-daily AUSTEDO XR

Therapeutic equivalence allows switch from AUSTEDO BID to AUSTEDO XR at same daily dose[1,2]

Quick Reference Guide: Weekly Titration for AUSTEDO BID and AUSTEDO XR

Week	AUSTEDO BID Dose/Pill Count	AUSTEDO XR Dose/Pill Count
1	6 mg BID (14 tablets total)	12 mg once daily (7 tablets total)
2	9 mg BID (14 tablets total)	18 mg once daily (7 tablets total)
3	12 mg BID (14 tablets total)	24 mg once daily (7 tablets total)
4	15 mg BID (28 tablets total)	30 mg once daily (7 tablets total)
5	18 mg BID (28 tablets total)	36 mg once daily (7 tablets total)
6	21 mg BID (28 tablets total)	42 mg once daily (7 tablets total)
7	24 mg BID (28 tablets total)	48 mg once daily (7 tablets total)

Tablets not shown at actual size.

This chart follows the standard titration schedule for AUSTEDO and AUSTEDO XR.
Not all residents will follow the same schedule, so be sure to confirm residents' current dose with their providers.

Additional dosing and administration information[1]

- Administer AUSTEDO XR in once-daily doses
- Administer AUSTEDO XR with or without food
- Swallow AUSTEDO XR whole. Do not chew, crush, or break tablets

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.

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Billing codes

ICD-10-CM	Diagnosis Codes	
Tardive dyskinesia (TD)	**G24.01**	
Huntington's chorea	**G10**	
Assessment	**CPT code**	
AIMS assessment	96127	
AUSTEDO XR Dosage	**10-digit NDC**	**11-digit NDC**
4-week Titration Kit	**68546-477-29**	**68546-0477-29**
12 mg	68546-471-56	68546-0471-56
18 mg	68546-479-56	68546-0479-56
24 mg	68546-472-56	68546-0472-56
30 mg	68546-473-56	68546-0473-56
36 mg	**68546-474-56**	**68546-0474-56**
42 mg	**68546-475-56**	**68546-0475-56**
48 mg	**68546-476-56**	**68546-0476-56**
AUSTEDO BID Dosage	**10-digit NDC**	**11-digit NDC**
6 mg	**68546-170-60**	**68546-0170-60**
9 mg	**68546-171-60**	**68546-0171-60**
12 mg	**68546-172-60**	**68546-0172-60**

The ICD-10 code G24.01 is for drug-induced subacute dyskinesia and is applicable to tardive dyskinesia.
Tablets not shown at actual size.

For residents with TD, tardive dyskinesia should be listed as the primary diagnosis, along with the resident's baseline AIMS score

Please note that for some prior authorization submissions, an AIMS score may be required.

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Comprehensive coverage and affordability

Preferred coverage

AUSTEDO XR has preferred coverage across a majority of Medicare Part D plans.[2]

93% of patients pay $10 or less[2]*

93%

Residents can start AUSTEDO XR for $0 with 30-day Free Trial Voucher. Additional financial assistance support available for eligible residents.†

Access & Reimbursement Managers are available through CoverMyMeds® to educate on PA process, affordability programs, payer coverage, and the reimbursement pathway.

Click here to contact your local LTC Account Manager or Access & Reimbursement Manager for more information

PA, prior authorization.
CoverMyMeds is a registered trademark of CoverMyMeds LLC.
*Time period: 01/2025 through 09/2025.[2]
†Certain restrictions apply. Terms and conditions on **AUSTEDOcardform.com**.

Additional resources for managing residents' TD

Click here to learn about TD-related topics from experts in one central hub

Click here to explore additional resources for treating TD in LTC

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References

1. AUSTEDO XR® (deutetrabenazine) extended-release tablets and AUSTEDO® current Prescribing Information. Parsippany, NJ: Teva Neuroscience, Inc. **2.** Data on file. Parsippany, NJ: Teva Neuroscience, Inc. **3.** Cloud LJ, Zutshi D, Factor SA. Tardive dyskinesia: therapeutic options for an increasingly common disorder. *Neurotherapeutics*. 2014;11(1):166-176. **4.** Carbon M, Hsieh C-H, Kane JM, Correll CU. Tardive dyskinesia prevalence in the period of second-generation antipsychotic use: a meta-analysis. *J Clin Psychiatry*. 2017;78(3):e264-e278. **5.** Centers for Medicare & Medicaid Services. Design for Care Compare Nursing Home Five-Star Quality Rating System: Technical Users' Guide. Centers for Medicare & Medicaid Services; January 2025. **6.** Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. State Operations Manual: Appendix PP—Guidance to Surveyors for Long Term Care Facilities. Centers for Medicare & Medicaid Services; 2024. **7.** Caroff SN, Hurford I, Lybrand J, Campbell EC. Movement disorders induced by antipsychotic drugs: implications of the CATIE schizophrenia trial. *Neurol Clin*. 2011;29(1):127-148. **8.** American Psychiatric Association. *Practice Guideline for the Treatment of Patients With Schizophrenia*. 3rd ed. American Psychiatric Association; 2021. **9.** Fernandez HH, Factor SA, Hauser RA, et al. Randomized controlled trial of deutetrabenazine for tardive dyskinesia: the ARM-TD study. *Neurology*. 2017;88(21):2003-2010. **10.** Anderson KE, Stamler D, Davis MD, et al. Deutetrabenazine for treatment of involuntary movements in patients with tardive dyskinesia (AIM-TD): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Psychiatry*. 2017;4(8):595-604. **11.** Hauser RA, Barkay H, Fernandez HH, et al. Long-term deutetrabenazine treatment for tardive dyskinesia is associated with sustained benefits and safety: a 3-year, open-label extension study. *Front Neurol*. 2022;13:773999. **12.** Marder SR, Singer C, Lindenmayer JP, et al. A phase 3, 1-year, open-label trial of valbenazine in adults with tardive dyskinesia. *J Clin Psychopharmacol*. 2019;39(6):620-627. **13.** Sajatovic M, Gandhi P, Konings M, et al. Long-term safety and efficacy of deutetrabenazine in patients aged ≥65 years with tardive dyskinesia. Poster presented at: American Association for Geriatric Psychiatry; March 14-17, 2025; Phoenix, AZ. **14.** Hauser RA, Barkay H, Fernandez HH, et al. Effects of long-term deutetrabenazine treatment in patients with tardive dyskinesia and underlying psychiatric or mood disorders. Poster presented at: Psych Congress; October 29-November 1, 2021; San Antonio, TX. **15.** Nasrallah H, Chen M, Barkay H, Gordon MF, Finkbeiner S. Long-term efficacy and safety of deutetrabenazine in postmenopausal women with tardive dyskinesia. Poster presented at: American Psychiatric Association; May 21-25, 2022; New Orleans, LA. **16.** Ravenstijn P, Chetty M, Manchandani P, Elmeliegy M, Qosa H, Younis I. Design and conduct considerations for studies in patients with hepatic impairment. *Clin Transl Sci*. 2023;16(1):50-61. **17.** Smith A, Baumgartner K, Bositis C. Cirrhosis: diagnosis and management. *Am Fam Physician*. 2019;100(12):759-770. **18.** Sajatovic M, Alexopoulos GS, Jen E, et al. Improvements over time with valbenazine in elderly adults (≥65 years) with tardive dyskinesia: post hoc analyses of 2 long-term studies. *J Clin Psychiatry*. 2025;86(2):24m15550. **19.** Jain R, Konings M, Driessen MT, Kotak S, Gandhi P. Patient experience with once-daily deutetrabenazine extended-release tablets for the treatment of tardive dyskinesia in individuals with prior valbenazine use. Poster presented at: Psych Congress 2025; September 17-21, 2025; San Diego, CA. **20.** Ingrezza® (valbenazine) capsules. Prescribing Information. San Diego, CA: Neurocrine Biosciences, Inc. **21.** Zhou SF. Structure, function and regulation of P-glycoprotein and its clinical relevance in drug disposition. *Xenobiotica*. 2008;38(7-8):802-832. **22.** Ahmed Juvale II, Abdul Hamid AA, Abd Halim KB, Che Has AT. P-glycoprotein: new insights into structure, physiological function, regulation and alterations in disease. *Heliyon*. 2022;8(6):e09777. **23.** Singh R, Sunzel EM, Kang DK, et al. Assessment of the deutetrabenazine exposure-response relationships for patients with moderate-to-severe tardive dyskinesia. Poster presented at: Psych Congress; September 17-20, 2022; New Orleans, LA. **24.** Levi M, Schneider F, Gosselin NH, et al. Population pharmacokinetic and exposure safety analyses of deutetrabenazine in patients with moderate to severe tardive dyskinesia. Poster presented at: American Conference on Pharmacometrics; October 20-23, 2019; Orlando, FL.

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EFFECTIVE *AND* EASY[1,2]

3 YEARS of results

CONSISTENT RESULTS IN PATIENTS AT INCREASED TD RISK (OLE)[1,2,9-15]

- Rapid response as early as 2 weeks (exploratory)
- Significant results at 12 weeks (pivotal)
- Increasing improvement observed over 3 years (OLE)*

FEW DOSE RESTRICTIONS RELATED TO DDIs[1,20]

Ability to increase once-daily dose in residents taking strong CYP inhibitors and inducers

SIMPLE START

Residents can start with the 4-week Kit or with the PointClickCare® Pharmacy Order Set. Apply 30-day Free Trial Voucher to start at no cost†

Only with AUSTEDO XR

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,11]

*71% of patients at Week 145 saw improvement relative to Week 15.[2]

†Certain restrictions apply. Terms and conditions on **AUSTEDOcardform.com**.

IMPORTANT SAFETY INFORMATION

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 see additional Important Safety Information throughout and click here to visit www.AUSTEDOhcp.com to read/print the full Prescribing Information, including Boxed Warning, for AUSTEDO XR.

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