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

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.

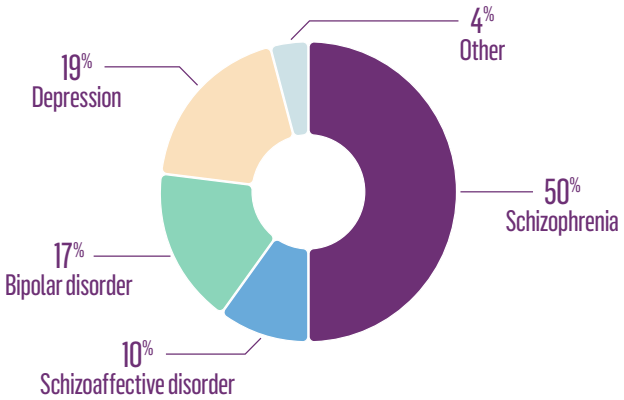
teva

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

Studied in a patient population with a range of psychiatric and other comorbid conditions[2,3]

The efficacy and safety of AUSTEDO were evaluated in adult patients with TD, up to 81 years of age[1,3]

Underlying psychiatric conditions in the pivotal study[2]



Other comorbid conditions[3]

- Gastrointestinal disorders
- Cardiovascular disorders
- Metabolism/nutritional disorders, including diabetes
- Lipid disorders

98% of patients were taking at least 1 concomitant medication, including antidepressants and antipsychotics[2,3]

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.

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.

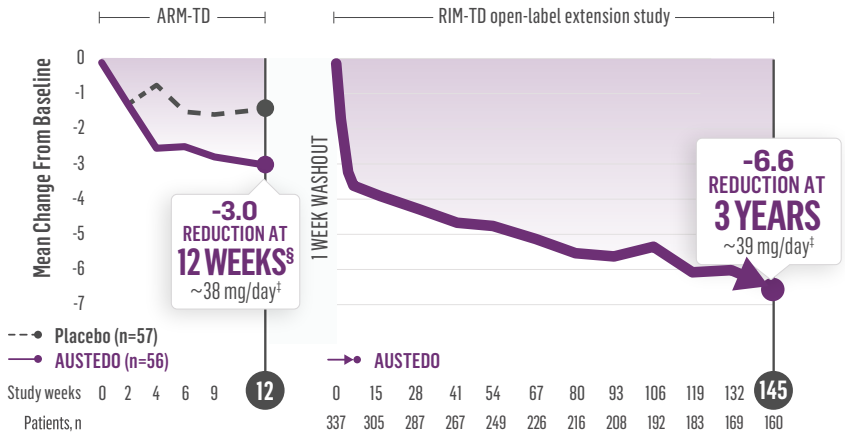
Rapid response as early as Week 2[2,4*]

Increasing improvement observed over 3 years in an OLE study[5†]

Significant response at Week 12 vs placebo in pivotal studies[1,2,4]

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

AIMS Score Reduction in Pivotal and OLE Studies[3-5]



Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,5]

†71% of patients at Week 145 saw improvement relative to Week 15.[3]
3% of patients did not complete the study due to lack of efficacy.[5]

Comparable tolerability to pivotal trials, with no new safety signals[5]	50% or more reduction in AIMS score for the majority of patients[5]
Consistent results across mood disorder and schizophrenia subgroups[6]	90% mean compliance rate[3‖]

Explore more pivotal and 3-year data at **AUSTEDOhcp.com**

AIMS, Abnormal Involuntary Movement Scale; OLE, open-label extension.
*Response observed as early as Week 2 in placebo-controlled studies.[2,4]
‡Mean total dose.[3,4]
§Versus -1.6 with placebo (*P*=0.019).[1,4]
‖Overall compliance based on pill counts.[3]
Please see study designs at AUSTEDOhcp.com.

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

Average dose remained stable from Week 15 through Week 145 in RIM-TD[5]

- Average dose was ~39 mg/day from Week 15 through Week 145
- Mean dose at Week 145 was similar for younger (aged <55 years) and older (aged ≥55 years) patients[7]
- Mean dose at Week 145 was similar for schizophrenia and mood disorder subgroups[6]

Patients in the RIM-TD study received the AUSTEDO BID formulation.[1,5]

Click here to see Charlene's treatment journey over 2+ years

Please see study design for RIM-TD at AUSTEDOhcp.com.

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.

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.

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.

Interim results from a real-world survey of 118 patients to assess satisfaction and experience with AUSTEDO XR[3]

As a result of TD movement reduction with AUSTEDO XR, patients reported:

Improved social and emotional well-being

- Greater self-esteem (~66%) and less embarrassment (73%)
- Less anxiety (~59%) and better overall emotional well-being (~77%)
- Feeling more comfortable in social settings (~80%)

Improved ability to do daily activities

- Hold things, like a glass or fork (~51%)
- Feed themselves (~49%)
- Dress themselves (~38%)

98% of patients said taking AUSTEDO XR is easy

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.

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

Demonstrated safety and tolerability profile for a broad range of patients with TD[1-3]

- Studied in older and younger patients (ages 21-81)
- Studied across a range of underlying conditions
- Patients were taking a variety of concomitant medications

Adverse Events Reported in ≥2% of Patients Treated With AUSTEDO in TD Studies[1,3]

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%

Once patients in the pivotal trials were titrated to their maintenance dose, **several adverse events were no longer reported[3]:**

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

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:

- Discontinuation due to adverse reactions occurred in up to 4% of patients taking AUSTEDO vs 3% of patients taking placebo[2,4]
- Dose reduction due to adverse reactions was required in 4% of patients taking AUSTEDO vs 2% of patients taking placebo[1]

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.

Consider the potential for drug-drug interactions when choosing a VMAT2 inhibitor

No dose restrictions up to 36 mg/day for patients starting AUSTEDO XR[1]

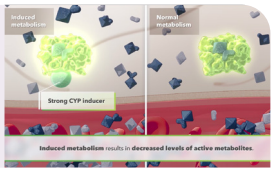
Drug coadministered with VMAT2 inhibitor	Recommended Maximum Therapeutic Dose	
	AUSTEDO XR[1]	Ingrezza® (valbenazine) and Ingrezza® sprinkle (valbenazine)[8]
Strong CYP3A4/5 inducer	No dose restriction	Concomitant use is not recommended
Strong CYP3A4/5 inhibitor		40 mg/day
Strong CYP2D6 inhibitor	36 mg/day	40 mg/day
Poor CYP2D6 metabolizer		

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

- In pharmacokinetic studies, increased plasma levels correlated with higher potential for TD treatment success, but **not** higher potential for adverse events[9,10]*
- **Additionally, no dose adjustments are required when taking AUSTEDO XR with P-gp substrates** (eg, calcium channel blockers, statins, and antimicrobials)[1,3,11,12]

Average number of medications per resident with TD ranges from ~4 to ~17[13]

Click here to watch: Understanding the connection between metabolic pathways and drug-drug interactions



Patients in the pivotal studies received the AUSTEDO BID formulation.[1]

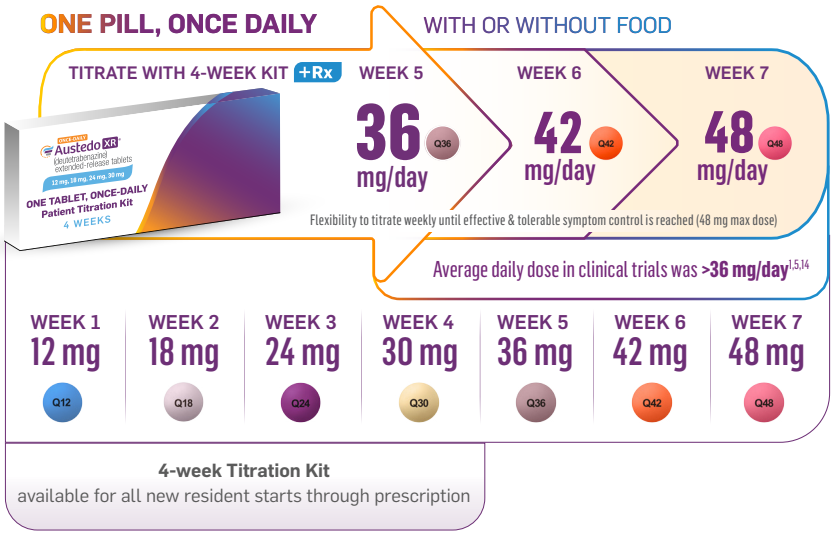
VMAT2, vesicular monoamine transporter 2.
*Treatment success defined as "much improved" or "very much improved" based on Patient Global Impression of Change and Clinical Global Impression of Change.[9]
AUSTEDO XR is metabolized primarily through CYP2D6, with minor contributions from CYP3A4/5.[1]
The brands listed are registered trademarks of their respective owners.

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.

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

Flexible dosing for effective & tolerable control[1]



4-week Titration Kit
available for all new resident starts through prescription

Residents can start at no cost with the easy-to-use 4-week Titration Kit[3]

Prescribe Titration Kit
with 30-day Free Trial Voucher applied*
+ prescribe 36 mg/day for Week 5

Pharmacy will dispense prescribed kit and apply 30-day Free Trial Voucher.

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

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,5,14]
Image shown is not actual 4-week Titration Kit. Tablets not shown at actual size.
*Certain restrictions apply. Terms and conditions on AUSTEDOcardform.com.
Please see study designs at AUSTEDOhcp.com.

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.

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.

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[1,3]

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)

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

See more information on billing codes for all formulations on page 10

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

Billing codes

ICD-10 CM Diagnosis Codes: G24.01 Tardive Dyskinesia (TD) and G10 Huntington's Chorea (HD)

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	Q12	68546-471-56	68546-0471-56
18 mg	Q18	68546-479-56	68546-0479-56
24 mg	Q24	68546-472-56	68546-0472-56
30 mg	Q30	68546-473-56	68546-0473-56
36 mg	Q36	**68546-474-56**	**68546-0474-56**
42 mg	Q42	**68546-475-56**	**68546-0475-56**
48 mg	Q48	**68546-476-56**	**68546-0476-56**
AUSTEDO BID Dosage		**10-digit NDC**	**11-digit NDC**
6 mg	SD 6	**68546-170-60**	**68546-0170-60**
9 mg	SD 9	**68546-171-60**	**68546-0171-60**
12 mg	SD 12	**68546-172-60**	**68546-0172-60**

TD 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.

Click here to learn about Norma, a real resident on her treatment journey with AUSTEDO XR

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.

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.

Resident access & affordability with AUSTEDO XR[3]

Preferred coverage

AUSTEDO XR has preferred coverage across a majority of national Medicare Part D plans.

93% of patients pay $10 or less for AUSTEDO XR*

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 prior authorization process, affordability programs, payer coverage, and reimbursement pathway

Contact your local sales representative or request a visit from an Access & Reimbursement Manager at AUSTEDOhcp.com

CoverMyMeds is a registered trademark of CoverMyMeds LLC.
*Time period: 01/2024 through 09/2024.[3]
†Certain restrictions apply. Terms and conditions on AUSTEDOcardform.com.

IMPORTANT SAFETY INFORMATION (Continued)

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.

References

1. AUSTEDO XR® (deutetrabenazine) extended-release tablets and AUSTEDO® current Prescribing Information. Parsippany, NJ: Teva Neuroscience, Inc. **2.** 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. **3.** Data on file. Parsippany, NJ: Teva Neuroscience, Inc. **4.** 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. **5.** 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. **6.** 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. **7.** Sajatovic M, Finkbeiner S, Wilhelm A, et al. Long-term safety and efficacy of deutetrabenazine in younger and older patients with tardive dyskinesia. *Am J Geriatr Psychiatry.* 2022;30(3):360-371. **8.** Ingrezza® (valbenazine) capsules. Prescribing Information. San Diego, CA: Neurocrine Biosciences, Inc. **9.** 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. **10.** Levi M, Schneider F, Gosselin NH, et al. Population pharmacokinetic and exposure safety analyses of deutetrabenazine in patients with moderate to severe tardive dyskinesia. Presented at: American Conference on Pharmacometrics. October 20-23, 2019; Orlando, FL. **11.** Zhou SF. Structure, function and regulation of P-glycoprotein and its clinical relevance in drug disposition. *Xenobiotica.* 2008;38(7-8):802-832. **12.** 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. **13.** Jokanovic N, Tan EC, Dooley MJ, Kirkpatrick CM, Bell JS. Prevalence and factors associated with polypharmacy in long-term care facilities: a systematic review. *J Am Med Dir Assoc.* 2015;16(6):535.e1-535.e12. **14.** Frank S, Testa C, Edmondson MC, et al. The safety of deutetrabenazine for chorea in Huntington disease: an open-label extension study. *CNS Drugs.* 2022;36(11):1207-1216.

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

EFFECTIVE *AND* EASY[1,3]

INCREASING IMPROVEMENT OBSERVED OVER TIME (OLE)*

Significant response at Week 12 in TD pivotal studies.
Results through 3 years in RIM-TD open-label extension study.[2,4,5,8]

FLEXIBILITY FOR EFFECTIVE & TOLERABLE CONTROL

Flexible one pill, once-daily dosing, including for patients taking medications metabolized by CYP3A4/5 or CYP2D6, or P-gp substrates.[1,3,8]

CONSISTENT RESULTS ACROSS PATIENT TYPES

Comparable AIMS reduction and tolerability data across age and underlying condition subgroups in the 3-year RIM-TD study.[5-7]

ACCESS & AFFORDABILITY

Preferred coverage across a majority of national Medicare Part D plans.[3]

Only with AUSTEDO XR

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,5]
*71% of patients at Week 145 saw improvement relative to Week 15.[3]

IMPORTANT SAFETY INFORMATION (Continued)

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.

teva