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.

teva

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*

Residents taking antipsychotics have a range of comorbidities, including ~1% with moderate-to-severe liver disease.*

Unnecessary antipsychotic use is the focus of several CMS initiatives[3,4]

Resident health and safety inspections evaluate antipsychotic use through F-tags

- F605: Resident has right to be treated with respect and dignity
- F757: Drug regimen is free from unnecessary drugs
- F841: Physician serves as a medical director and is responsible for resident care and medical care coordination

Reducing or discontinuing antipsychotic drugs can unmask TD[2,5]

However, residents taking antipsychotic drugs are more commonly and quickly diagnosed with EPS than TD

- ~6% of residents have a diagnosis of EPS vs ~1% having a TD diagnosis
- TD takes longer to diagnose than EPS (581 days vs 389 days on average)

Untreated TD can impact CMS quality ratings[3]

- Increased burden on nursing staff may contribute to turnover
- Physical health of residents with TD can impact facility reputation

APA recommends treating TD with a VMAT2 inhibitor.

Residents with TD treated with a VMAT2 inhibitor have fewer falls and ED visits.[2,6†]

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

APA, American Psychiatric Association; CMS, Centers for Medicare & Medicaid Services; ED, emergency department; EPS, extrapyramidal symptoms; VMAT2, vesicular monoamine transporter 2.
*According to PointClickCare® database.[2]
†Versus those treated with a non-VMAT2 inhibitor.[2]
PointClickCare® is a registered trademark of *PointClickCare Technologies Inc.*

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AUSTEDO was studied in a diverse patient population[2,7]

Results across elderly patients (aged ≥65 years) and younger patients (aged 21-64 years)[1,2]

- Elderly and younger patients with TD (ages 21-81) included in pivotal studies[1,2]
- Consistent treatment results across elderly and younger patients in open-label extension study[2]
  - Largest elderly population of any TD clinical study (n=78)

Patients had a range of psychiatric and comorbid conditions[2]

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

Patients were taking concomitant medications, including those metabolized by CYP3A4/5 and CYP2D6[2,8]

- Antidepressants at baseline: 54% of patients[2,7]
- Antipsychotics[2,7]
  - Atypical: 62% of patients
  - Typical or combination: 14% of patients
  - None at baseline: 24% of patients

*Patients with hepatic impairment were excluded from studies.[1,2]

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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Significant AIMS reduction at Week 12 vs placebo in pivotal studies[1,7,9]

- -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)

RIM-TD OLE: 3x longer than any other TD extension study[2,10-12]

- Patients saw a -6.6 reduction in AIMS score (~39 mg/day*) at Week 145 in the full RIM-TD population
- **11-point mean reduction at Week 145** for patients with >14-point baseline AIMS score in a post hoc analysis of RIM-TD (n=40)
  - Percentage reduction from baseline was comparable for patients with ≤14-point baseline AIMS score (~56%) and >14-point baseline AIMS score (~60%)
- Comparable tolerability to pivotal trials, with no new safety signals
- 90% mean compliance rate†

Learn more about the only TD clinical study with 3 years of sustained results[2,10,11] at AUSTEDOhcp.com

Patients in the pivotal and long-term studies received the AUSTEDO BID formulation.[1,11]
AIMS, Abnormal Involuntary Movement Scale; OLE, open-label extension.
*Mean total dose.[2,9]
†Overall compliance based on pill counts.[2]
Please see study designs for AIM-TD, ARM-TD, and RIM-TD 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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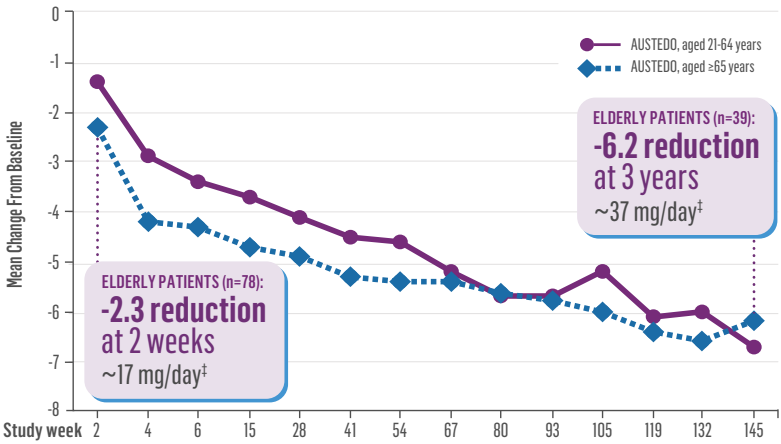
Largest elderly population of any TD clinical study (n=78)[13,14]

Rapid response as early as Week 2[7,9]*

Increasing improvement observed over 3 years in an OLE study[11†]

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



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

- Similar dose and response at Week 145 (>36 mg/day)‡
- Similar safety and tolerability profile
- Similar percentage of patients remained in the study at Week 145

*Response observed as early as Week 2 in placebo-controlled studies.[7,9]
†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 design 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.

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Demonstrated safety and tolerability profile for a broad range of patients

Adverse Events Reported in ≥2% of Patients Treated With AUSTEDO in TD 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%

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)**

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[7,9]
- Dose reduction due to adverse reactions was required in 4% of patients taking AUSTEDO vs 2% of patients taking placebo[1]

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

Metabolic profile allows for few restrictions related to drug-drug interactions[1]

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

Drug coadministered with VMAT2 inhibitor	Recommended Dosing	
	AUSTEDO XR[1,15,16]	Valbenazine/Valbenazine Sprinkle[17]
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 patient 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

No clinically significant QT prolongation up to the maximum recommended dose of AUSTEDO (48 mg/day)[1]*

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

When a drug that strongly induces or inhibits the same CYP enzyme responsible for metabolizing a VMAT2 inhibitor is taken concurrently, active metabolite levels are impacted.[18]

- **~50% of drugs are metabolized by CYP3A4/5 enzymes**[19,20]

AUSTEDO XR is primarily metabolized by CYP2D6[1†]

- **~2x fewer drugs are metabolized by CYP2D6** than by CYP3A4/5[19,21]

In pharmacokinetic studies, increased plasma levels correlated with higher potential for TD treatment success, but not higher potential for adverse events.[22,23‡]

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.[1,17]

†Minor contributions from the CYP3A4/5 pathways.[1]

‡Treatment success defined as "much improved" or "very much improved" based on Patient Global Impression of Change (PGIC) and Clinical Global Impression of Change (CGIC).[22]

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

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

☑ Improved emotional well-being

- Improved overall emotional well-being (~79%)
- Less embarrassment (~73%)
- Improved self-esteem (~68%)

☑ Improved social well-being

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

☑ Improved physical well-being

- Improved overall physical health (~58%)

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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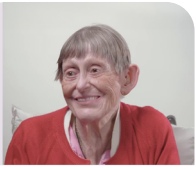
~99%

Nearly all elderly and younger patients said AUSTEDO XR is easy to take and include in their daily routine[2]

High rate of overall satisfaction (~90%) with AUSTEDO XR reported across younger (19-64 years) and elderly (≥65 years) subgroups[2]

~97% PLAN TO CONTINUE TAKING AUSTEDO XR[2]

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



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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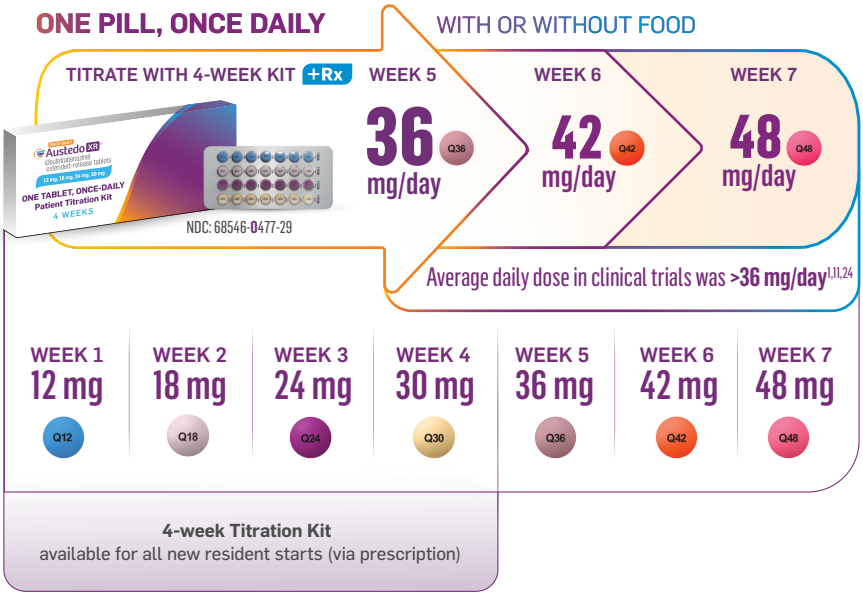
Flexible dosing for effective & tolerable control[1]



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.[1,11,24]

Image shown is not actual 4-week Titration Kit. Tablets not shown at actual size.
Please see study designs at AUSTEDOhcp.com.

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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Residents can start at no cost with the easy-to-use 4-week Titration Kit[2]

Prescribe Retail 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.

OR

Apply 30-day Free Trial Voucher* against initial 30-day prescription + prescribe 36 mg/day at Week 5

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

Pharmacy Order Templates are available for AUSTEDO and AUSTEDO XR in PointClickCare.

Image shown is not actual 4-week Titration Kit. Tablets not shown at actual size.
*Certain restrictions apply. Terms and conditions on AUSTEDOcardform.com/voucher.

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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)

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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Billing codes

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

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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Resident access & affordability with AUSTEDO XR[2]

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*

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

CoverMyMeds is a registered trademark of CoverMyMeds LLC.
*Time period: 01/2024 through 09/2024.[2]
†Certain restrictions apply. Terms and conditions on AUSTEDOcardform.com/voucher.

Additional resources as you continue to manage your residents' TD

Learn about TD-related topics from experts in one central hub at AUSTEDOhcp.com/connectd

Explore resources for treating TD in LTC at AUSTEDOhcp.com

Contact your local LTC account manager or request a visit from an Access & Reimbursement Manager at AUSTEDOhcp.com

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36 mg, 42 mg, and 48 mg tablets

References

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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[1,2]

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.[7,9,11,17]

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.[1,2,17]

CONSISTENT RESULTS ACROSS PATIENT SUBGROUPS

Consistent results and dosing across elderly and younger patients in the 3-year RIM-TD post hoc analysis.[13]

ACCESS & AFFORDABILITY

Preferred coverage across a majority of national Medicare Part D plans.[2]

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]

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.