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

Easy to start and stay on one pill, once-daily AUSTEDO XR[1,2]

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INDICATIONS AND USAGE

AUSTEDO XR® and AUSTEDO® 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.

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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Starting new patients on one pill, once-daily AUSTEDO XR

Billing codes

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

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**
Assessment		**CPT code**	
AIMS assessment		96127	

Tablets not shown at actual size.

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.

Switching patients to one pill, once-daily AUSTEDO XR[1]

Switch from:

- AUSTEDO BID to AUSTEDO XR at same total daily dose (at next fill)
- Tetrabenazine to AUSTEDO XR overnight at half total dose of tetrabenazine

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) — SD 6, SD 6	12 mg once daily (7 tablets total) — Q12
2	9 mg BID (14 tablets total) — SD 9, SD 9	18 mg once daily (7 tablets total) — Q18
3	12 mg BID (14 tablets total) — SD 12, SD 12	24 mg once daily (7 tablets total) — Q24
4	15 mg BID (28 tablets total) — SD 6, SD 6, SD 9, SD 9	30 mg once daily (7 tablets total) — Q30
5	18 mg BID (28 tablets total) — SD 9, SD 9, SD 9, SD 9	36 mg once daily (7 tablets total) — Q36
6	21 mg BID (28 tablets total) — SD 9, SD 9, SD 12, SD 12	42 mg once daily (7 tablets total) — Q42
7	24 mg BID (28 tablets total) — SD 12, SD 12, SD 12, SD 12	48 mg once daily (7 tablets total) — Q48

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

Tablets not shown at actual size.

For patients with Huntington's disease (HD) chorea:
Recommended initial dose following switch is ~50% of daily tetrabenazine dose[1]

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93% of patients pay $10 or less with financial assistance offerings[2]

New, non-sampled patients can receive their first 30 days of AUSTEDO XR for free*

Free Trial Voucher available at AUSTEDOcardform.com.

Remind pharmacy to apply.

Austedo XR® (deutetrabenazine) extended-release 6 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42 mg, and 48 mg tablets | Shared Solutions®

30 DAYS FREE

FREE TRIAL VOUCHER FOR NEW PATIENTS*

Bin:
PCN:
Group Member:
Member ID:

This Free Trial Voucher is not conditioned on any past, present, or future purchase, including refills. No purchase is required.

For questions or additional assistance, please call 1-844-308-5110

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

Patients may pay as little as $0 per month for AUSTEDO XR†

Patients must self-enroll at MySharedSolutions.com.

Visit AUSTEDOcardform.com to send a link to patients with more information.

Austedo XR® (deutetrabenazine) extended-release 6 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42 mg, and 48 mg tablets | Shared Solutions®

ELIGIBLE PATIENTS MAY PAY AS LITTLE AS $0 COPAY PER MONTH†

Bin:
PCN:
Group Member:
Member ID:

To learn more about the 30-day Free Trial Voucher and Copay Card visit **AUSTEDOcardform.com**

†Offer is only available to patients with commercial insurance. Offer is NOT available to patients eligible for Medicare, Medicaid, or any other government payer coverage. Out-of-pocket costs may vary. Exclusions and limitations apply. Please see complete Terms and Conditions.

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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Initiating a Prior Authorization (PA) for your patients starting AUSTEDO XR

Start a PA through CoverMyMeds®

1. Log in to your account or create one at **covermymeds.com**. Search "AUSTEDO XR" and dose.
2. Click "Start PA" to create a PA request:
   - Select treatment option
   - Complete all PA fields
   - Upload any additional documentation
3. Submit PA request (regularly check dashboard for updates).

To improve processing time for PAs, remember to obtain a copy of the patient's pharmacy benefits card (front and back).

Need help getting started? Chat with CoverMyMeds on **covermymeds.com** | or call 1-866-452-5017

Access & Reimbursement Managers (ARMs) are available throughout the PA process

ARMs can assist with:

- Education about the PA process (including CoverMyMeds portal)
- Information about payer coverage, PA criteria, and affordability programs
- Education on Teva **Shared Solutions**® and other patient support

Request a visit from an ARM or ask your Teva Sales Representative to connect you with your local ARM for more information

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.

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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Teva Shared Solutions® provides additional support to help your patients achieve treatment goals

Shared Solutions can help with:

Access	Affordability	Adherence[2]
Navigating patients' insurance: • Conducting benefits verification • Identifying in-network pharmacies • Supporting your patients through the Prior Authorization process	**Identifying financial assistance offerings:** • Free Trial Voucher • Copay assistance • Patient Assistance Program (PAP)	**Ongoing treatment support from a dedicated nurse:** • Adherence support • Expectation reinforcement • Dosing and titration guidance • Patient education • Tools and resources to help manage treatment

Enrolling in Shared Solutions

- You can enroll patients starting on AUSTEDO XR via the CoverMyMeds® portal or by using the PSRF (patient authorization required)
- Patient can also self-enroll at MySharedSolutions.com

For HCPs: To download the PSRF, visit **AUSTEDOhcp.com**

For Patients: For more information on patient support services, visit **MySharedSolutions.com**

PSRF, Prescription and Service Request Form.

Patient Assistance Program

For patients who are uninsured or unable to afford AUSTEDO XR/AUSTEDO, the Teva Cares Foundation may be able to help.

Teva Cares is an independent, nonprofit program that provides AUSTEDO XR/AUSTEDO at no cost to eligible patients.*

To learn more, visit TevaCares.org or call 1-877-237-4881.

*Patient must reside in the United States, meet insurance and income requirements, and have a valid prescription.

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.

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.

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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Additional information to get your patients started on one pill, once-daily AUSTEDO XR[1]

Learn more about important dosing and administration information for AUSTEDO XR

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.

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.

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