HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use AUSTEDO XR or AUSTEDO safely and effectively. See full prescribing information for AUSTEDO XR and AUSTEDO.

AUSTEDO® XR (deutetrabenazine) extended-release tablets, for oral use
AUSTEDO® (deutetrabenazine) tablets, for oral use
Initial U.S. Approval: 2017

WARNING: DEPRESSION AND SUICIDALITY IN PATIENTS WITH HUNTINGTON'S DISEASE
See full prescribing information for complete boxed warning.

- **Increases the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease (5.1)**
- **Balance risks of depression and suicidality with the clinical need for treatment of chorea when considering the use of AUSTEDO XR or AUSTEDO (5.1)**
- **Monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior (5.1)**
- **Inform patients, caregivers, and families of the risk of depression and suicidality and instruct to report behaviors of concern promptly to the treating physician (5.1)**
- **Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation (5.1)**
- **AUSTEDO XR and AUSTEDO are contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression (4, 5.1)**

RECENT MAJOR CHANGES

AUSTEDO XR (added throughout the Prescribing Information)	2/2023
Dosage and Administration (2.1)	5/2022
Dosage and Administration (2.1, 2.2)	2/2023

INDICATIONS AND USAGE

AUSTEDO XR and AUSTEDO are vesicular monoamine transporter 2 (VMAT2) inhibitors indicated in adults for the treatment of:

- Chorea associated with Huntington's disease (1)
- Tardive dyskinesia (1)

DOSAGE AND ADMINISTRATION

	AUSTEDO XR	AUSTEDO
Recommended Starting Dosage	12 mg once daily (12 mg per day)	6 mg twice daily (12 mg per day)

- Titrate at weekly intervals by 6 mg per day based on reduction of chorea or tardive dyskinesia, and tolerability, up to a maximum recommended daily dosage of 48 mg (2.1)
- Administer AUSTEDO XR with or without food in once-daily doses (2.1)
- Administer AUSTEDO with food and administer total daily dosages of 12 mg or above in two divided doses (2.1)
- Swallow tablets whole; do not chew, crush, or break (2.1)
- If switching patients from tetrabenazine, discontinue tetrabenazine and initiate AUSTEDO XR or AUSTEDO the following day. See full prescribing information for recommended conversion table (2.2)
- Maximum recommended dosage of AUSTEDO XR or AUSTEDO in poor CYP2D6 metabolizers is 36 mg per day (2.4, 8.7)

DOSAGE FORMS AND STRENGTHS

Extended-release tablets: 6 mg, 12 mg, and 24 mg (3)
Tablets: 6 mg, 9 mg, and 12 mg (3)

CONTRAINDICATIONS

- Suicidal, or untreated/inadequately treated depression in patients with Huntington's disease (4, 5.1)
- Hepatic impairment (4, 8.6, 12.3)
- Taking reserpine, MAOIs, tetrabenazine, or valbenazine (4, 7.2, 7.3, 7.6)

WARNINGS AND PRECAUTIONS

- QT Prolongation: Avoid use in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval (5.3)
- Neuroleptic Malignant Syndrome (NMS): Discontinue if this occurs (5.4)
- Akathisia, agitation, restlessness, and parkinsonism: Reduce dose or discontinue if this occurs (5.5, 5.6)
- Sedation/somnolence: May impair the patient's ability to drive or operate complex machinery (5.7)

ADVERSE REACTIONS

Most common adverse reactions (>8% of AUSTEDO-treated patients with Huntington's disease and greater than placebo): somnolence, diarrhea, dry mouth, and fatigue (6.1)

Most common adverse reactions (that occurred in 4% of AUSTEDO-treated patients with tardive dyskinesia and greater than placebo): nasopharyngitis and insomnia (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Teva Pharmaceuticals at 1-888-483-8279 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

DRUG INTERACTIONS

- Concomitant use of strong CYP2D6 inhibitors: Maximum recommended dose of AUSTEDO XR or AUSTEDO is 36 mg per day (2.3, 7.1)
- Alcohol or other sedating drugs: May have additive sedation and somnolence (7.5)

USE IN SPECIFIC POPULATIONS

Pregnancy: Based on animal data, may cause fetal harm (8.1)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 2/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: DEPRESSION AND SUICIDALITY IN PATIENTS WITH HUNTINGTON'S DISEASE

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: 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. Anyone considering the use of AUSTEDO XR or AUSTEDO must 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. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician.

Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington's disease. AUSTEDO XR and AUSTEDO are contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression *[see Contraindications (4) and Warnings and Precautions (5.1)].*

1 INDICATIONS AND USAGE

AUSTEDO® XR and AUSTEDO® are indicated in adults for the treatment of:

- chorea associated with Huntington's disease *[see Clinical Studies (14.1)]*
- tardive dyskinesia *[see Clinical Studies (14.2)]*

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information

The dose of AUSTEDO XR and AUSTEDO is determined individually for each patient based on reduction of chorea or tardive dyskinesia and tolerability. Table 1 displays the recommended dosage and important administration instructions of AUSTEDO XR and AUSTEDO when first prescribed to patients who are not being switched from tetrabenazine (a related VMAT2 inhibitor).

Table 1: Recommended Dosage and Important Administration Instructions for AUSTEDO XR and AUSTEDO

	AUSTEDO XR extended-release tablet	**AUSTEDO tablet**
Recommended Starting Dosage	12 mg once daily (12 mg per day)	6 mg twice daily (12 mg per day)
Recommended Dose Titration	The dosage of AUSTEDO XR or AUSTEDO may be increased at weekly intervals in increments of 6 mg per day based on reduction of chorea or tardive dyskinesia, and tolerability, up to a maximum recommended daily dosage of 48 mg *[see Clinical Trials (14.1, 14.2)]*.	
Important Administration Instructions	• Administer AUSTEDO XR with or without food *[see Clinical Pharmacology (12.3)]*. • Swallow AUSTEDO XR whole. Do not chew, crush, or break tablets. • Administer AUSTEDO XR once daily.	• Administer AUSTEDO with food *[see Clinical Pharmacology (12.3)]*. • Swallow AUSTEDO whole. Do not chew, crush, or break tablets. • Administer AUSTEDO total daily dosages of 12 mg or above in two divided doses.
Switching Between AUSTEDO and AUSTEDO XR	When switching between AUSTEDO tablets (twice daily) and AUSTEDO XR extended-release tablets (once daily), switch to the same total daily dosage.	

2.2 Switching Patients from Tetrabenazine to AUSTEDO XR or AUSTEDO

Discontinue tetrabenazine and initiate AUSTEDO XR or AUSTEDO the following day. The recommended initial dosing regimen of AUSTEDO XR or AUSTEDO in patients switching from tetrabenazine to AUSTEDO XR or AUSTEDO is shown in Table 2.

Table 2: Recommended Initial Dosing Regimen when Switching from Tetrabenazine to AUSTEDO XR or AUSTEDO

Current tetrabenazine daily dosage	Initial regimen of AUSTEDO XR extended-release tablet	Initial regimen of AUSTEDO tablet
12.5 mg	6 mg once daily	6 mg once daily
25 mg	12 mg once daily	6 mg twice daily
37.5 mg	18 mg once daily	9 mg twice daily
50 mg	24 mg once daily	12 mg twice daily
62.5 mg	30 mg once daily	15 mg twice daily
75 mg	36 mg once daily	18 mg twice daily
87.5 mg	42 mg once daily	21 mg twice daily
100 mg	48 mg once daily	24 mg twice daily

After patients are switched to AUSTEDO XR or AUSTEDO, the dose may be adjusted at weekly intervals *[see Dosage and Administration (2.1)]*.

2.3 Dosage Adjustment with Strong CYP2D6 Inhibitors

In patients receiving strong CYP2D6 inhibitors, the total daily dosage of AUSTEDO XR or AUSTEDO should not exceed 36 mg *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)]*.

2.4 Dosage Adjustment in Poor CYP2D6 Metabolizers

In patients who are poor CYP2D6 metabolizers, the total daily dosage of AUSTEDO XR or AUSTEDO should not exceed 36 mg *[see Use in Specific Populations (8.7)]*.

2.5 Discontinuation and Interruption of Treatment

Treatment with AUSTEDO XR or AUSTEDO can be discontinued without tapering. Following treatment interruption of greater than one week, AUSTEDO XR or AUSTEDO therapy should be re-titrated when resumed. For treatment interruption of less than one week, treatment can be resumed at the previous maintenance dose without titration.

3 DOSAGE FORMS AND STRENGTHS

AUSTEDO XR extended-release tablets are available in the following strengths:

- The 6 mg extended-release tablets are round, grey-coated tablets, with “Q6” printed in black ink on one side.
- The 12 mg extended-release tablets are round, blue-coated tablets, with “Q12” printed in black ink on one side.
- The 24 mg extended-release tablets are round, purple-coated tablets, with “Q24” printed in black ink on one side.

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