



May 15, 2023

Dear HD community,

We are excited to share that Teva's recently FDA-approved once-daily AUSTEDO® XR (deutetrabenazine) extended-release tablets are now available in the United States for adults with tardive dyskinesia (TD) or chorea associated with Huntington's disease (HD).

Here's some important information about AUSTEDO XR:

- AUSTEDO XR is dosed once-daily whereas AUSTEDO is dosed twice-daily.
- AUSTEDO XR comes in different tablet strengths—6 mg, 12 mg and 24 mg.
- AUSTEDO XR can be taken with or without food.

We hope that this updated regimen can help reduce overall pill count and offer flexibility for daily medication intake.

For more information, I have included Frequently Asked Questions (FAQ) below around how to access the newly available AUSTEDO XR. If you have any further questions, please don't hesitate to reach out to Shared Solutions at 1-800-887-8100.

+++

### **Frequently Asked Questions (FAQ)**

**1. How can I obtain AUSTEDO XR?**

It is important to speak with your healthcare provider to determine if AUSTEDO XR could be the right treatment regimen for you.

**2. How much will AUSTEDO XR cost?**

Teva is committed to helping people who have been prescribed AUSTEDO XR access their medication.

If you have been prescribed AUSTEDO XR, you can enroll in Teva Shared Solutions at [MySharedSolutions.com](https://www.mysharedsolutions.com), which offers nursing support as well as financial, insurance and prescription assistance to start and stay on treatment.

It is important to note that savings on out-of-pocket costs may vary depending on your insurance provider and eligibility for participation in the co-pay assistance program.

Close to 90% of existing patients on AUSTEDO pay \$10 or less per month.

+++

### **APPROVED USES**

AUSTEDO® XR (deutetrabenazine) extended-release tablets and AUSTEDO® (deutetrabenazine) tablets are prescription medicines that are used to treat:

- movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).
- the involuntary movements (chorea) of Huntington's disease. AUSTEDO XR and AUSTEDO do not cure the cause of the involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

It is not known if AUSTEDO XR and AUSTEDO are safe and effective in children.

## **IMPORTANT SAFETY INFORMATION**

**AUSTEDO XR and AUSTEDO can cause serious side effects in people with Huntington's disease, including: depression, suicidal thoughts, or suicidal actions. Do not** start taking AUSTEDO XR or AUSTEDO if you are depressed (have untreated depression or depression that is not well controlled by medicine) **or** have suicidal thoughts. Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts or feelings. This is especially important when AUSTEDO XR or AUSTEDO is started and when the dose is changed. Call your healthcare provider right away if you become depressed, have unusual changes in mood or behavior, or have thoughts of suicide.

### **Do not take AUSTEDO XR or AUSTEDO if you:**

- have Huntington's disease and are depressed or have thoughts of suicide.
- have liver problems.
- are taking reserpine. **Do not** take medicines that contain reserpine with AUSTEDO XR or AUSTEDO. If your healthcare provider plans to switch you from taking reserpine to AUSTEDO XR or AUSTEDO, you must wait at least 20 days after your last dose of reserpine before you start taking AUSTEDO XR or AUSTEDO.
- are taking a monoamine oxidase inhibitor (MAOI) medicine. **Do not** take an MAOI within 14 days after you stop taking AUSTEDO XR or AUSTEDO. **Do not** start AUSTEDO XR or AUSTEDO if you stopped taking an MAOI in the last 14 days. Ask your healthcare provider or pharmacist if you are not sure.
- are taking tetrabenazine. If your healthcare provider plans to switch you from tetrabenazine to AUSTEDO XR or AUSTEDO, take your first dose of AUSTEDO XR or AUSTEDO on the day after your last dose of tetrabenazine.
- are taking valbenazine.

### **Other possible serious side effects include:**

- **Irregular heartbeat (QT prolongation).** AUSTEDO XR and AUSTEDO increases your chance of having certain changes in the electrical activity in your heart. These changes can lead to a dangerous abnormal heartbeat. Taking AUSTEDO XR or AUSTEDO with certain medicines may increase this chance.
- **Neuroleptic Malignant Syndrome.** Call your healthcare provider right away and go to the nearest emergency room if you develop these signs and symptoms that do not have another obvious cause: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, or increased sweating.
- **Restlessness.** You may get a condition where you feel a strong urge to move. This is called akathisia.
- **Parkinsonism.** Symptoms include: slight shaking, body stiffness, trouble moving, trouble keeping your balance, or falls.

**Sleepiness (sedation) is a common side effect of AUSTEDO XR and AUSTEDO.** While taking AUSTEDO XR or AUSTEDO, do not drive a car or operate dangerous machinery until you know how AUSTEDO XR or AUSTEDO affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking AUSTEDO XR or AUSTEDO may increase any sleepiness caused by AUSTEDO XR and AUSTEDO.

**The most common side effects of AUSTEDO in people with Huntington's disease include** sleepiness (sedation), diarrhea, tiredness, and dry mouth.

**The most common side effects of AUSTEDO in people with tardive dyskinesia include** inflammation of the nose and throat (nasopharyngitis) and problems sleeping (insomnia).

The most common side effects of AUSTEDO XR are expected to be similar to AUSTEDO in people with Huntington's disease or tardive dyskinesia.

These are not all the possible side effects of AUSTEDO XR or AUSTEDO. Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Please read the accompanying [Medication Guide](#).

Sincerely,  
Teva

©2023 Teva Neuroscience, Inc.

AUS-45740  
April 2023