

# TD TREATMENT INFORMATION

For the treatment of tardive dyskinesia (TD) in adults

ONCE-DAILY  
**Austedo<sup>®</sup> XR**  
(deutetrabenazine)  
extended-release  
6 mg, 12 mg, 24 mg, 30 mg, 36 mg,  
42 mg, and 48 mg tablets

## AS YOU GO WITH **AUSTEDO<sup>®</sup>** (deutetrabenazine) tablets

*AUSTEDO XR. One pill, once daily across a range of effective doses.\**



\*Once-daily AUSTEDO XR contains the same active ingredient as twice-daily AUSTEDO. Data on this page is based on twice-daily dosing.

### **APPROVED USE**

AUSTEDO<sup>®</sup> XR (deutetrabenazine) extended-release tablets and AUSTEDO<sup>®</sup> (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).

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

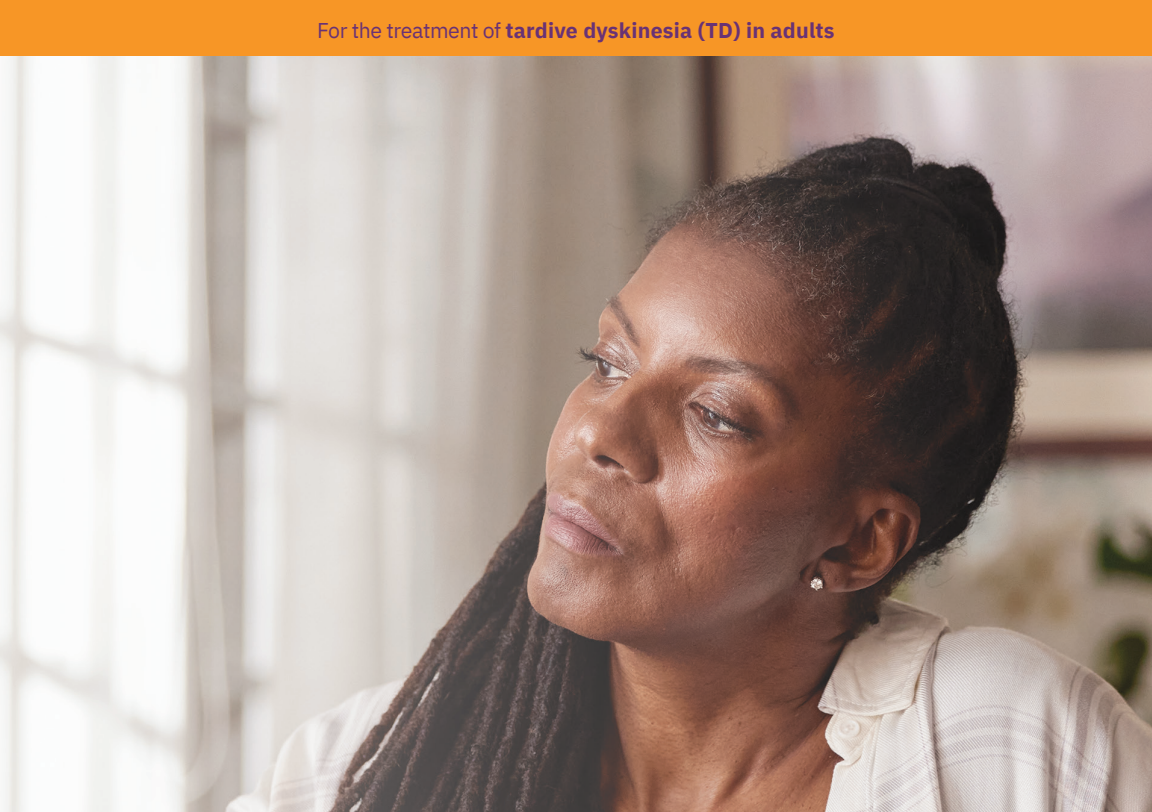
### **IMPORTANT SAFETY INFORMATION**

**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.

Please read **Important Safety Information** on pages 20-21 and click [here](#) or visit [www.AUSTEDO.com](http://www.AUSTEDO.com) to read or print the **Medication Guide** for AUSTEDO XR.

**teva**



***“It felt good to know that I had a name to put with what I was experiencing, and I felt like I wasn’t alone because other people were going through the same thing.”***

**—Sherland, living with TD.**  
*Individual results may vary.*

**IMPORTANT SAFETY INFORMATION (CONTINUED)**

**Do not take AUSTEDO® XR (deutetrabenazine) extended-release tablets or AUSTEDO® (deutetrabenazine) tablets if you:**

- have Huntington’s disease and are depressed or have thoughts of suicide.
- have liver problems.



# WHAT IS TARDIVE DYSKINESIA (TD)?



## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

**Do not take AUSTEDO® XR (deutetrabenazine) extended-release tablets or AUSTEDO® (deutetrabenazine) tablets if you:**

- 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.

## **SYMPTOMS OF TD**

TD causes repetitive and uncontrollable movements in the face, arms, legs, and trunk that appear as twitching, shaking, or jerking.

Certain prescription medications used to treat mental health or gastrointestinal conditions can cause TD. Tardive dyskinesia is more than a side effect of using these medications—it's a real condition with its own diagnosis and treatment plan.

### ***The unintentional and uncontrollable movements of TD can:***

- **Be mistaken for being drunk or on drugs**
- **Make it difficult to speak clearly**
- **Attract unwanted attention when you're out in public**
- **Affect your ability to read or write**
- **Make cutting your food or holding your drink challenging**

***If any of these feel familiar, you may want to ask your healthcare provider to evaluate you for TD.***

### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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***“I had these movements and I became really self-conscious. I like to control my environment, my body, but I had no self-control over those movements.”***

**—Sherland, living with TD**  
*Individual results may vary.*

**IMPORTANT SAFETY INFORMATION (CONTINUED)**

**Do not take AUSTEDO® XR (deutetrabenazine) extended-release tablets or AUSTEDO® (deutetrabenazine) tablets if you:**

- 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.

## **THE IMPACT OF TD**

Having TD can be frustrating and overwhelming. Uncontrollable movements make it difficult to perform everyday tasks and activities and affect you in ways others may not see, such as causing increased anxiety in social settings.

***TD is not your fault and can be treated.***

**Sharing your experience with uncontrollable movements is an important step in finding help to manage them.**

### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

**Do not take AUSTEDO® XR (deutetrabenazine) extended-release tablets or AUSTEDO® (deutetrabenazine) tablets if you:**

- 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 a MAOI in the last 14 days. Ask your healthcare provider or pharmacist if you are not sure.



# ABOUT TREATMENT



# **BENEFITS OF AUSTEDO® XR (DEUTETRABENAZINE) EXTENDED-RELEASE TABLETS**

- 1 /** With AUSTEDO XR, you don't have to choose between maintaining your mental health and treating TD because AUSTEDO XR can be taken with most mental health medications.
- 2 /** In clinical studies, AUSTEDO® (deutetrabenazine) tablets **effectively reduced the involuntary movements** of TD.\*
- 3 /** AUSTEDO has established safety results over 3 years.
- 4 /** **Cost shouldn't stand in the way of starting treatment** for TD. Whether you have insurance or not, AUSTEDO XR has a financial program that can help.

\*Once-daily AUSTEDO XR contains the same active ingredient as twice-daily AUSTEDO. Data on this page is based on twice-daily dosing.

## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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

- 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.



# HOW AUSTEDO® XR (DEUTETRABENAZINE) EXTENDED-RELEASE TABLETS MAY HELP

*In a 12-week clinical study, some people taking AUSTEDO® (deutetrabenazine) tablets saw:*

**>2X REDUCTION**  
*in TD movements vs placebo\*†*

*Response for some as early as*  
**2 WEEKS**

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†AUSTEDO reduced the Abnormal Involuntary Movement Scale (AIMS) total score by 3.3 points vs 1.4 points with placebo. For participants taking AUSTEDO, this represents a 33% reduction in AIMS total score vs a 14% reduction for those taking placebo.

## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

**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.



*In a separate long-term study,*  
**AUSTEDO® (deutetrabenazine) tablets has**  
**ESTABLISHED SAFETY RESULTS OVER**  
**3 YEARS<sup>†</sup>**

<sup>†</sup>This was an open-label study, which is a drug trial in which all participants are aware of the drug being tested.

**IMPORTANT SAFETY INFORMATION (CONTINUED)**

**Other possible serious side effects include:**

- **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.



# ABOUT THE CLINICAL STUDIES\*

AUSTEDO® (deutetrabenazine) tablets were studied in a diverse population with the goal of identifying the change in involuntary movements—as measured by the Abnormal Involuntary Movement Scale (AIMS) total score—from the beginning to the end of the 12-week studies.

## A closer look at the data

**98%** of people in one study were taking at least one mental health drug, including:

### Antidepressants:

54%

ANTIDEPRESSANTS  
AT BASELINE

### Antipsychotics:

62%

ATYPICAL  
ANTIPSYCHOTICS

14%

TYPICAL OR COMBINATION  
ANTIPSYCHOTICS

24%

NO ANTIPSYCHOTICS  
AT BASELINE

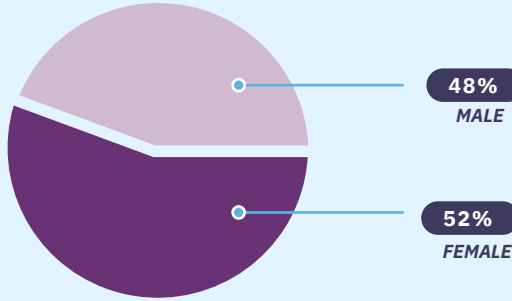
## Understanding the AIMS score

The AIMS test uses a checklist to assess the severity of involuntary movements and can also be used to track changes in the movements over time. The test rates movements over multiple areas of the body, scoring the severity of involuntary movements in each area from 0 to 4, with 0 = no movements and 4 = severe movements.

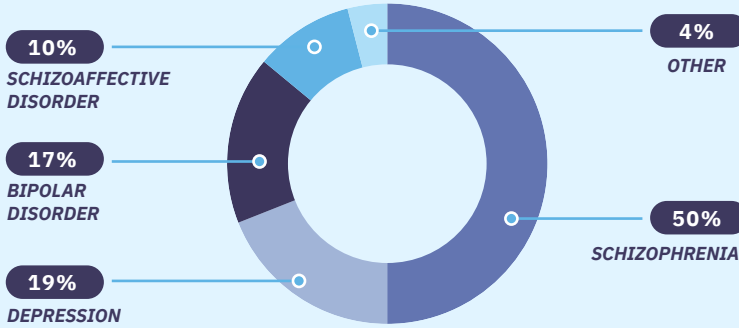
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# ADDITIONAL STUDY INFORMATION

## Sex



## Underlying mental health conditions







## COMMON SIDE EFFECTS

***In one study with AUSTEDO® (deutetrabenazine) tablets, the most common side effects included\*†:***

- Inflammation of the nose and throat (nasopharyngitis)
- Problems sleeping (insomnia)

4% of participants taking AUSTEDO had to lower their dose due to side effects vs 2% taking placebo.

**Other side effects of AUSTEDO included** depression, restlessness, agitation, and a strong urge to move (akathisia).

\*Once-daily AUSTEDO® XR (deutetrabenazine) extended-release tablets contain the same active ingredient as twice-daily AUSTEDO. Data on this page is based on twice-daily dosing.

†Adverse reactions with AUSTEDO XR are expected to be similar to AUSTEDO.

### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

**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.



**STARTING  
TREATMENT**

## ONCE-DAILY DOSING FOR TARDIVE DYSKINESIA (TD)



Keep your day going with once-daily dosing of AUSTEDO® XR (deutetrabenazine) extended-release tablets.

### AUSTEDO XR should be taken:



With water



Whole (do not crush or break)



With or without food

If you cannot swallow AUSTEDO XR/AUSTEDO® (deutetrabenazine) tablets whole, tell your healthcare provider. You may need a different medication.

### IMPORTANT SAFETY INFORMATION (CONTINUED)

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



# START AT NO COST WITH TWO CONVENIENT OPTIONS



Packaging not to scale.

To guide you through your first month with AUSTEDO® XR (deutetrabenazine) extended-release tablets, **your doctor will choose either:**

**A Sample Titration Kit to take home**

**or**

**A Prescription Titration Kit to pick up**

After that, enroll in Teva **Shared Solutions**® patient support to continue to get your prescription at the lowest cost possible.

## **IMPORTANT SAFETY INFORMATION (CONTINUED)**

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

## PERSONALIZED DOSING PROCESS

**Once-daily AUSTEDO® XR (deutetrabenazine) extended-release tablets offer a personalized approach to dosing.**

Your healthcare provider will start you at a low dose and gradually increase your dose over time. This approach allows your body to get used to the medication and can help with side effects as movements are reduced. This way, your doctor can find a dose that works for you. **This process is called titration.**



Because everyone is different, your maintenance dose will be the one that works specifically for you.



### Starting dose

Your doctor will start you on a low dose of AUSTEDO XR and will work with you to find your maintenance dose.

### Maintenance dose

Once you reach a dose that provides effective movement reduction and is tolerated, that will become your maintenance dose. If you want to increase your dose, you and your doctor can discuss more dosing options.

### IMPORTANT SAFETY INFORMATION (CONTINUED)

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



***“With AUSTEDO® (deutetrabenazine) tablets, I started seeing real progress with the involuntary movements. Now I smile again. I take video calls, I see friends and family in person. I’m back in my groove and I’m once again the chattiest person in the room.”***

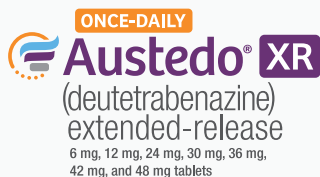
**—Sherland, living with TD**  
*Individual results may vary.*

No clinical trials have been conducted to suggest treating with AUSTEDO affects these outcomes.

**IMPORTANT SAFETY INFORMATION (CONTINUED)**

**AUSTEDO® XR (deutetrabenazine) extended-release tablets 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.**





## APPROVED USE

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).

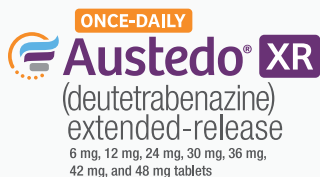
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### Do not take AUSTEDO XR or AUSTEDO if you:

- 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.



## IMPORTANT SAFETY INFORMATION (CONTINUED)

### Other possible serious side effects include:

- **Irregular heartbeat (QT prolongation).** AUSTEDO XR and AUSTEDO® (deutetrabenazine) tablets increase 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**.

# SUPPORT & RESOURCES







Shared Solutions®

## REACH OUT TO US, WE'LL REACH FOR SOLUTIONS TOGETHER

**Teva Shared Solutions® is a patient support program that can help you every step of the way.**

With Teva **Shared Solutions®**, you'll have the benefit of a Patient Access Specialist for insurance and pharmacy questions as well as nurse support for treatment and dosing guidance. Your **Shared Solutions** team are dedicated professionals in their field, so you'll get real help from real people.



### Take advantage of support services

**teva** | Shared Solutions  
**Your go-to resource for financial assistance, nurse support, and benefits coverage.**



**1-800-887-8100**

Monday-Friday  
from 8 AM to 8 PM CT

Or visit **MySharedSolutions.com**



Shared Solutions®

## COST SHOULDN'T STAND IN THE WAY OF TREATMENT

*Teva Shared Solutions® will help you navigate coverage and explore your financial options.*



Whether you're insured, underinsured, or not insured at all, we'll verify coverage and work through financial assistance options to help make treatment affordable.

**Close to 90% of people taking AUSTEDO® (deutetrabenazine) tablets pay \$10 or less per month for their prescription.**

### Treatment for as little as \$0

AUSTEDO XR (deutetrabenazine) extended-release tablets are free for your first 30 days with our Free Trial Voucher,\* then you may be eligible for \$0 copay per month.†



\*The 30-day Free Trial Voucher is only for new patients. Voucher is good for up to 4 weeks of titration or 30 days of medication.

† 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 review complete **Terms and Conditions** at AUSTEDO.com.



Shared Solutions®

## NURSE SUPPORT

***Teva Shared Solutions® nurses provide ongoing support to help you reach your treatment goals with AUSTEDO XR (deutetrabenazine) extended-release tablets.***

**Shared Solutions nurses can help you with things like:**

- ✓ Learning about TD and AUSTEDO XR
- ✓ Starting a treatment plan, reaching your appropriate AUSTEDO XR dose, and even managing your refills
- ✓ How to take and how to remember to take your AUSTEDO XR
- ✓ Providing tools and resources to help you stay on track



**“I’m proud to be a Shared Solutions nurse; I can go into work knowing I’m taking a potentially stressful situation and making it as smooth of a transition as possible.”**

**—Shared Solutions nurse**

### **IMPORTANT SAFETY INFORMATION (CONTINUED)**

**The most common side effects of AUSTEDO® (deutetrabenazine) tablets 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.





Shared Solutions®

## GETTING YOUR PRESCRIPTION IS EASIER WITH TEVA SHARED SOLUTIONS®

**Your healthcare provider can send your AUSTEDO XR (deutetrabenazine) extended-release tablets prescription in 1 of 2 ways:**

**teva** | **With** Shared Solutions

Once you or your doctor enrolls you in **Shared Solutions**, our patient support program, here's what to expect:

Your prescription can be sent directly to Shared Solutions. They will confirm that it can be sent to the preferred pharmacy, identify financial assistance options, help make treatment affordable, and assist in navigating Medicare Part D.

Your pharmacy will ship your prescription (and future refills) to you. Once you start your prescription, a Shared Solutions nurse will call you to provide ongoing support throughout your treatment and support with future refills.

**Without** Shared Solutions

If you are not enrolled when AUSTEDO XR is prescribed, here's what to expect:

Your prescription can be sent directly to the preferred pharmacy.

You and your doctor are responsible for identifying financial assistance options, navigating Medicare Part D, and identifying a different pharmacy if the preferred pharmacy is out of network.

Your pharmacy will ship your prescription (and future refills) to you. You will not receive **Shared Solutions** nurse support, and you are responsible for the future refills process.

Navigating insurance and billing information can be overwhelming. Teva **Shared Solutions**, our patient support program, can help ease the process by handling it for you. Call **1-800-887-8100** to find out more.



Shared Solutions®

**YOU'RE NOT ALONE, WE'RE HERE TO SUPPORT YOU EVERY STEP OF THE WAY**

**Sign up for Teva Shared Solutions®**

**teva** | Shared Solutions  
**Your go-to resource for financial assistance, nurse support, and benefits coverage.**



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Monday-Friday  
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42 mg, and 48 mg tablets



## **START TREATMENT. REDUCE TD MOVEMENTS.**

- **More than 2x movement reduction at 12 weeks vs placebo\*\*†**
- **One pill, once daily across a range of effective doses**
- **Start treatment at no cost**
- **Get support through the Teva Shared Solutions<sup>®</sup> patient support program**

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†AUSTEDO reduced the AIMS total score by 3.3 points vs 1.4 points with placebo. For participants taking AUSTEDO, this represents a 33% reduction in AIMS total score vs a 14% reduction for those taking placebo.

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