

# TD TREATMENT INFORMATION

ONCE-DAILY  
**Austedo XR**<sup>®</sup>  
(deutetrabenazine)  
extended-release  
6 mg, 12 mg, 18 mg, 24 mg, 30 mg,  
36 mg, 42 mg, and 48 mg tablets

For the treatment of **Tardive Dyskinesia (TD)** in adults,

**AUSTEDO XR** reduces  
TD movements and can be  
taken with most mental  
health medications

**ONE PILL**  
**ONCE-DAILY**  
EXTENDED-RELEASE

**AS YOU GO WITH AUSTEDO XR**



## **APPROVED USE**

AUSTEDO XR<sup>®</sup> (deutetrabenazine) extended-release tablets and AUSTEDO<sup>®</sup> (deutetrabenazine) tablets are prescription medicines that are used to treat the 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 8-9 and click [here](#) or visit [www.AUSTEDO.com](http://www.AUSTEDO.com) to read or print the Medication Guide for AUSTEDO XR.

**teva**

## What is Tardive Dyskinesia (TD)?

### **SYMPTOMS AND CAUSES OF TD**

TD is repetitive and uncontrollable movements in the face, arms, legs, and trunk that appear as twitching, shaking, or jerking. **TD symptoms may appear as:**



Finger movements that may look like piano or guitar playing



Facial grimacing or puckering



Shoulder shrugging



Lip smacking or other mouth movements, such as chewing and sucking



Rapid eye blinking or brow wrinkling



Pelvic rocking

Long-term and even short-term use of certain prescription medications used to treat mental health or gastrointestinal conditions can cause TD. In fact, TD can even develop after these medications are stopped, changed, or their dose is reduced. TD is more than a side effect of these medications—**it's a real condition with its own diagnosis and treatment plan.**



**Medications that can cause TD include antipsychotics, antidepressants, and antiemetics.**

**If you're taking these medications and experiencing uncontrollable movements, ask your healthcare provider to evaluate you for TD**

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

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

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

## What is Tardive Dyskinesia (TD)?

### THE IMPACT OF TD

*The repetitive and uncontrollable movements of TD in the body can be a frustrating struggle both physically and emotionally.*

#### **TD movements:**

- ✓ 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



**TD is not your fault and can be treated.**  
Talk to your healthcare provider about AUSTEDO XR

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

**Do not take AUSTEDO XR or AUSTEDO 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.

## About treatment

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



AUSTEDO XR reduces TD movements with **a once-daily, extended-release pill.\***



With AUSTEDO XR, you don't have to choose between maintaining your mental health and treating TD. **AUSTEDO XR can be taken with most mental health medications.**



With **personalized dosing** from AUSTEDO XR, your healthcare provider can find the proper dose to help you reduce TD movements.



Visit **[AUSTEDO.com](https://www.austedo.com)** to view the common side effects of AUSTEDO XR.

\*Once-daily AUSTEDO XR contains the same active ingredient as twice-daily AUSTEDO (deutetrabenazine) tablets. 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 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.

## About treatment

# HELP GAIN CONTROL OF TD MOVEMENTS

**>70%** of adults reduced  
**TD MOVEMENTS**  
with AUSTEDO.†

†In a 12-week clinical study, people taking AUSTEDO had at least a 10% reduction based on the total motor Abnormal Involuntary Movement Scale (AIMS) score at Week 12.

**AUSTEDO XR can reduce  
TD MOVEMENTS WITH  
SOME SEEING A RESPONSE  
AS EARLY AS 2 WEEKS.**

**96%** of adults in clinical trials  
continued with their  
**AUSTEDO XR dose without needing  
to reduce it due to side effects.**

**Nearly 9 out of 10 people are satisfied with AUSTEDO XR\***

\*Based on a survey analysis from 131 people on AUSTEDO XR.

### **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.

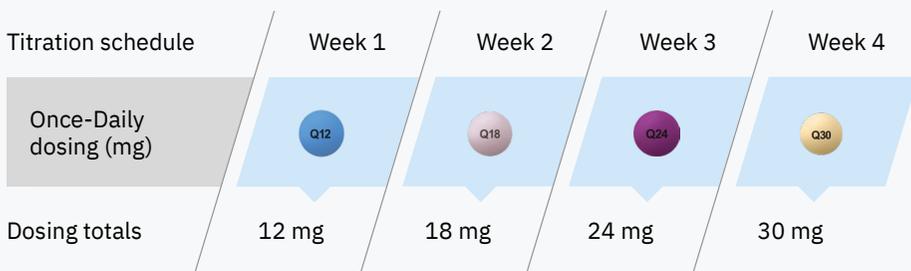


## How to get started

# PERSONALIZED DOSING FOR TD

**One pill, once-daily AUSTEDO XR offers a personalized approach to dosing with a Titration Kit.**

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 TD movements are reduced. This way, your healthcare provider can find a dose that works for you. This process is called titration.



Pills are for illustration only and not actual size or likeness.

### Starting dose

Your healthcare provider 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 TD movement reduction and is tolerated, that will become your maintenance dose. If you want to increase your dose, you and your healthcare provider can discuss more dosing options.



**Your TD treatment needs are unique to you, and AUSTEDO XR has different dosing strengths so your healthcare provider can find the dose that works for you**



## 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.

## How to get started

# HOW TO TAKE YOUR MEDICATION



Once daily



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.

## HOW YOU'LL BEGIN TREATMENT



Not an actual image of the free Titration Kit.

**The AUSTEDO XR Titration Kit gradually increases your medication to find the proper dose to help reduce your TD movements.**

**Your healthcare provider may provide a FREE Titration Kit to either:**  
**Take home from their office — OR — Pick up at your pharmacy\***

The Titration Kit will guide you through your first month with AUSTEDO XR.

\*With prescription and a free trial voucher at [AUSTEDOCARDFORM.COM](http://AUSTEDOCARDFORM.COM). Terms and conditions apply.

### 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.

## **APPROVED USE**

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

### **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 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**.

## Teva Shared Solutions<sup>®</sup> patient support program

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

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

**Shared Solutions<sup>®</sup>** helps with financial, insurance, and prescription assistance so you can receive treatment sooner and stay on treatment

## FINANCIAL SUPPORT

Whether you're insured, underinsured, or not insured at all, **Shared Solutions<sup>®</sup>** will verify coverage and work through financial assistance options to help make treatment affordable. Plus, we'll help you navigate the paperwork so nothing falls through the cracks.



**More than 90% of people pay \$10 or less per month for AUSTEDO XR\***

\*Patients can start AUSTEDO XR for \$0 with a 30-day Free Trial Voucher. Additional financial assistance support is available for eligible patients. Certain restrictions apply. Terms and conditions on [AUSTEDOcardform.com](https://www.austedo.com/AUSTEDOcardform.com).

### IMPORTANT SAFETY INFORMATION (CONTINUED)

#### Other possible serious side effects include:

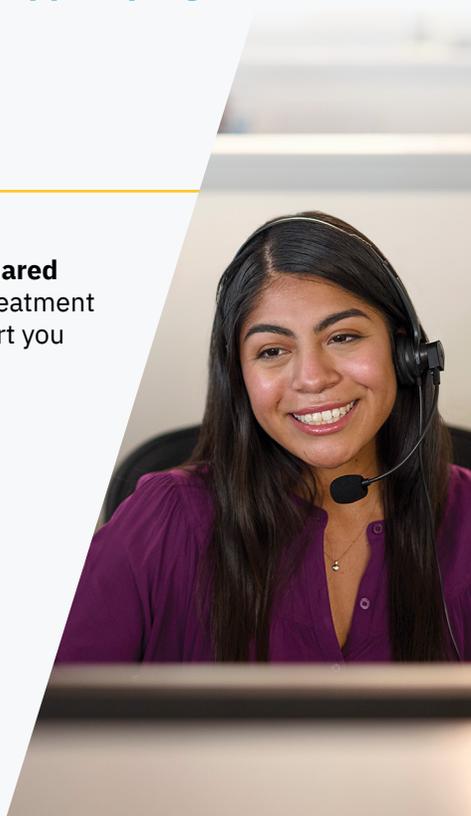
- **Irregular heartbeat (QT prolongation).** AUSTEDO XR<sup>®</sup> and AUSTEDO<sup>®</sup> (deutetrabenazine) tablets increase your chance of having certain changes in the electrical activity in your heart. These changes can lead to a dangerous abnormal heartbeat. Taking AUSTEDO XR or AUSTEDO with certain medicines may increase this chance.

## Teva Shared Solutions® patient support program

### **NURSE SUPPORT**

While taking AUSTEDO XR® (deutetrabenazine) extended-release tablets with support from **Shared Solutions®**, you will receive calls throughout treatment from our nurses to see how we can best support you in reaching your goals. They can help you with:

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



**teva** | Shared Solutions

*Start your enrollment today!*



**1-800-887-8100**

Monday-Friday  
from 8 AM to 8 PM CT

Or visit **MySharedSolutions.com**

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

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## START AUSTEDO XR TO REDUCE TD MOVEMENTS

- Some people saw a response as early as 2 weeks\*†
- Get personalized dosing with one pill, once-daily AUSTEDO XR
- Eligible patients may pay as little as \$0 per month‡
- Get support through Teva Shared Solutions<sup>®</sup> patient support program



Visit [AUSTEDO.com](https://www.austedo.com)

to access other resources.  
Escanee estecódigo para  
acceder a otros recursos.

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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.

‡Offer is only available to patients with commercial insurance. Offer is NOT available to patients 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 at [AUSTEDOcardform.com](https://www.austedo.com).

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