



#### For the treatment of Tardive Dyskinesia (TD) in adults

#### The Treatment Tracker will help you:

- Set TD treatment goals
- Use helpful tips to stay on track with treatment
- ✓ Track your progress
- **Discuss your treatment journey** with your healthcare provider



#### APPROVED USES

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

- 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.
- 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 <u>here</u> or or visit www.AUSTEDO.com to read print the Medication Guide for AUSTEDO XR.

# TARDIVE DYSKINESIA (TD) TREATMENT GOALS

You and your healthcare team have worked together to develop a plan to treat your TD that includes once-daily AUSTEDO XR® (deutetrabenazine) extended-release tablets. **To help you stay on track with your treatment plan, it's important to first define your goals**.

#### Here are a few questions to get you started.

Write answers in the spaces provided and share them with your healthcare team, family members, and/or care partners:

1	What uncontrollable movements are you hoping may improve with treatment?
2	What other personal treatment goals have you and/or your healthcare team set?
3	What steps have you, your healthcare team, family members, and/or care partners identified to help you achieve your treatment goals?
4	What would your day-to-day look like with reduced TD movements?

## IMPORTANT SAFETY INFORMATION (CONTINUED)

Do not take AUSTEDO XR or AUSTEDO if you:

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



# TAKE YOUR MEDICATION AS PRESCRIBED

Life can get busy, and it's not always easy to remember all your healthcare provider's instructions. However, it is important that you continue to take once-daily AUSTEDO XR® (deutetrabenazine) extended-release tablets exactly as prescribed.



If you cannot swallow AUSTEDO XR tablets whole, tell your healthcare provider. You may need a different medicine.

AUSTEDO XR tablets can be taken with most mental health medications.\*

\*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 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.





## STAYING ON TRACK

It's important to take once-daily AUSTEDO XR® (deutetrabenazine) extended-release tablets as prescribed. Use these tips to help you stay on track:

#### Have a plan



- Before starting AUSTEDO XR, talk to your healthcare provider about what to do if you miss a dose
- Add your dosing schedule to your other daily routines so you will be less likely to miss a dose
- Tell your healthcare provider if you stop taking AUSTEDO XR for more than 1 week. Do not take another dose until you talk to your healthcare provider



#### Set a routine

- Follow the dosing schedule exactly as prescribed by your healthcare provider
- Set an alarm as a treatment reminder
- Keep your AUSTEDO XR tablets in the same place so you know where they are



#### Record your treatment

 Use the Progress Tracker and Activity Log included in this guide to record when AUSTEDO XR is taken and any questions you have for your healthcare provider





- Work with your healthcare provider to find the dose of AUSTEDO XR that works for you
- It's important to take AUSTEDO XR exactly as your healthcare provider prescribes it
- Your healthcare provider may adjust your dose up or down in the first few weeks of treatment based on reduction of movements and how well the medicine is tolerated

### **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.







This is the dosing schedule for the Titration Kit. Upon completion of the kit, your healthcare provider will write you a prescription for AUSTEDO XR® (deutetrabenazine) extended-release tablets and determine what daily dose is right for you.

Titration schedule	/ Week 1	Week 2	Week 3	Week 4
Once-Daily dosing (mg)	Q12	Q18	Q24	Q30
Dosing totals	12 mg	18 mg	24 mg	30 mg

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

## **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.





## FREQUENTLY ASKED QUESTIONS

It's normal to have questions when starting a new medication.

Here are some questions from people living with Tardive Dyskinesia (TD), with answers provided by a healthcare professional:

- O: Why am I being prescribed AUSTEDO XR® (deutetrabenazine) extended-release tablets?
- A: Your healthcare provider has diagnosed your uncontrollable movements as TD. In clinical studies, AUSTEDO® (deutetrabenazine) tablets effectively reduced TD body movements.\* And, in the clinical studies, people taking AUSTEDO were able to continue with their mental health medications.
- Q: Will taking AUSTEDO XR affect my other medications?
- A: In clinical studies, people taking AUSTEDO were able to continue with their mental health medications like antipsychotics or antidepressants. Tell your healthcare provider about all your medical conditions and all of the medicines you take, including prescription and over-the-counter medications, vitamins, and herbal supplements.\*
- Q: How will I know if AUSTEDO XR is working?
- A: TD affects everyone differently, so treatment results may vary from person to person. In a study, >70% of adults experienced a reduction in TD movements.<sup>†</sup>

## **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.



<sup>\*</sup>Once-daily AUSTEDO XR extended-release tablets contain the same active ingredient as AUSTEDO tablets. Data on this page is based on twice-daily dosing.

<sup>&</sup>lt;sup>†</sup>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.

#### Q: What happens if I miss a dose?

A: Before starting AUSTEDO XR® (deutetrabenazine) extended-release tablets, talk to your healthcare provider about what to do if you forget a dose. Also, tell your healthcare provider if you stop taking AUSTEDO XR for more than 1 week. Do not take another dose until you talk to your healthcare provider. Using the Progress Tracker and Activity Log in this guide will help you remember to take your daily medication as prescribed.

#### Q: Why might my healthcare provider adjust my dose?

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

#### Q: What happens when I reach my appropriate dose?

A: Once your healthcare provider determines the dose of AUSTEDO XR that's right for you, that will become your maintenance dose. It's important to track your progress (using the Progress Tracker included in this guide) both during the initial titration period and once your maintenance dose is established, so your treatment plan can be adjusted if something changes.

#### Q: Are there side effects?

A: As with any medication, it's always important to discuss possible side effects with your healthcare provider before you start taking AUSTEDO XR. It's also important to keep your healthcare provider informed as to how you're feeling throughout treatment. If something doesn't feel right, tell your healthcare provider so your treatment plan can be adjusted as necessary.

## 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 USES

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- 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.



#### **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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

Please read the accompanying **Medication Guide**.



# PROGRESS TRACKER AND **ACTIVITY LOG**

- Use this progress tracker daily to help you achieve your treatment goals with once-daily AUSTEDO XR® (deutetrabenazine) extended-release tablets
  - Write the Week # (eg, week 1) and the month/day/year you start treatment.
  - **Check the "Titrated" box** if you are still in the process of working with your healthcare provider to find the dose that's effective for you.

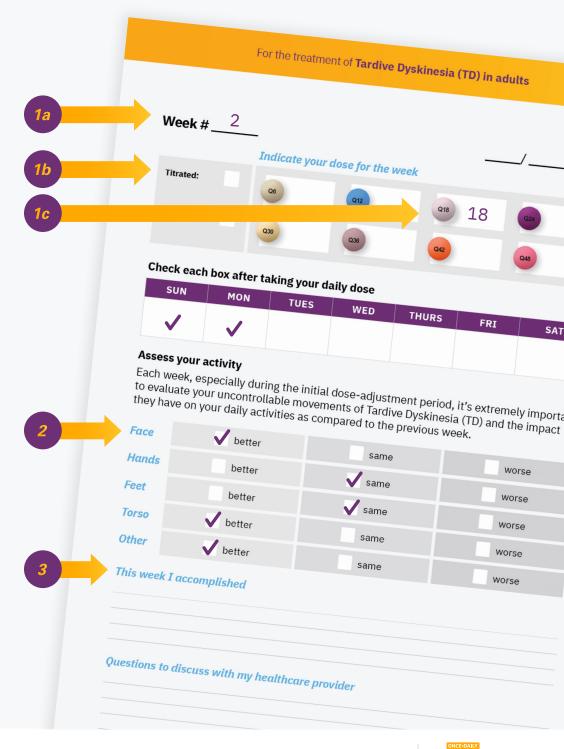
Check the "Maintenance" box if you already found your effective dose so you're able to track it over time to ensure it's the most appropriate dose for your needs.

- **Note your prescribed dose for that week** given to you by your healthcare provider. Track progress both during the titration period and with the maintenance dose so your treatment plan can be adjusted if something changes.
- Record changes in movements in the activity log **Evaluate your movements** each week and the impact they've had on your daily life as compared to the previous week.
- Keep notes to discuss with your healthcare provider during vour next visit

## DON'T FORGET REFILLS

Need additional Progress Tracker and Activity Log sheets? Download more at www.AUSTEDO.com/tardive-dyskinesia/resources. Remember to bring your completed log sheets to upcoming appointments to help you discuss your progress with your healthcare provider.









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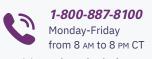


## **HEALTH INFORMATION**

AUSTEDO XR® (deutetrabenazine) extended-release tablets start date:
Primary care healthcare provider:
Phone number:
Address:
Name to winter
Neurologist:
Phone number:
Address:
Hospital:
Phone number:
Address:
Pharmacy:
Phone number:
Address:
Insurance carrier:
Phone number:
Health insurance member ID:



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## **APPOINTMENT RECORD**

Record your next appointment date in the space provided.

My next ap	ppointment	is:	My next app	pointment	is:
MONTH:			монтн:		
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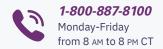
# REACH OUT TO US, WE'LL REACH FOR SOLUTIONS TOGETHER

Teva Shared Solutions<sup>®</sup> patient support program is here to help you every step of the way.



If you have any questions while you're setting goals and tracking progress with once-daily AUSTEDO XR® (deutetrabenazine) extended-release tablets, **Shared Solutions** can help achieve your treatment goals.

## Sign up for Shared Solutions





through our website anytime at MySharedSolutions.com

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