

HD TREATMENT INFORMATION

For the treatment of Huntington's disease (HD) chorea in adults

ONCE-DAILY
Austedo® 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®** (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 XR and AUSTEDO 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.

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 18-19 and click [here](#) or visit www.AUSTEDO.com to read or print the **Medication Guide** for AUSTEDO XR

teva



WHAT IS HUNTINGTON'S DISEASE (HD) CHOREA?

IMPORTANT SAFETY INFORMATION

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

UNDERSTANDING HD CHOREA

What is HD chorea?

HD is a hereditary neurological disorder that affects nerve cells in the brain. For people with HD, an abnormal increase in the release of dopamine (the brain chemical responsible for movement) can cause chorea.

Chorea is one of the most visible symptoms of HD and can be treated

Chorea can affect daily life for people with HD as well as their care partners. Care partners reported chorea as the most impactful symptom of HD.

What HD chorea signs look like:



Flicking the fingers



Flailing arms or legs



Shrugging shoulders



Grimacing



Twisting or jerking



Irregular eye movements or blinking

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.

THE IMPACT OF HD CHOREA

How HD chorea can affect daily activities:



Make walking and climbing stairs difficult



Affect your ability to brush teeth or bathe



Make getting dressed challenging



Affect your ability to eat or chew



Make it difficult to speak clearly

People with chorea cannot stop these movements on their own and the movements may worsen with stress. Over time, these movements cause a loss of independence.

IMPORTANT SAFETY INFORMATION (CONTINUED)

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

- 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.



ABOUT TREATMENT

GO ABOUT YOUR DAY WITH REDUCED INVOLUNTARY MOVEMENTS

*In a 12-week clinical study, AUSTEDO® (deutetrabenazine) tablets significantly reduced HD chorea**

People taking AUSTEDO saw more than 2x reduction in HD chorea vs placebo.†



*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.

†4.4-point improvement in people taking AUSTEDO vs 1.9 in people taking placebo based on Total Maximal Chorea (TMC) score. The TMC score is used to measure HD chorea movements in the face, mouth, trunk, both arms, and both legs.

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.



In a separate long-term study, AUSTEDO® (deutetrabenazine) tablets has
ESTABLISHED SAFETY RESULTS FOR
~3 YEARS

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)

Do not take AUSTEDO® XR (deutetrabenazine) extended-release tablets 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.

SYMPTOM IMPROVEMENT

People with HD chorea on AUSTEDO® (deutetrabenazine) tablets reported improvement in their ability to perform daily activities like*:



Climbing stairs / Bending, kneeling, or stooping
Lifting/carrying groceries / Walking / Dressing
Bathing / Moderate to vigorous activities

People taking AUSTEDO achieved greater improvement in the SF-36[†] Physical Functioning Score at 12 weeks vs placebo.

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[†]SF-36=Short-form 36-item survey assessing health-related quality of life.

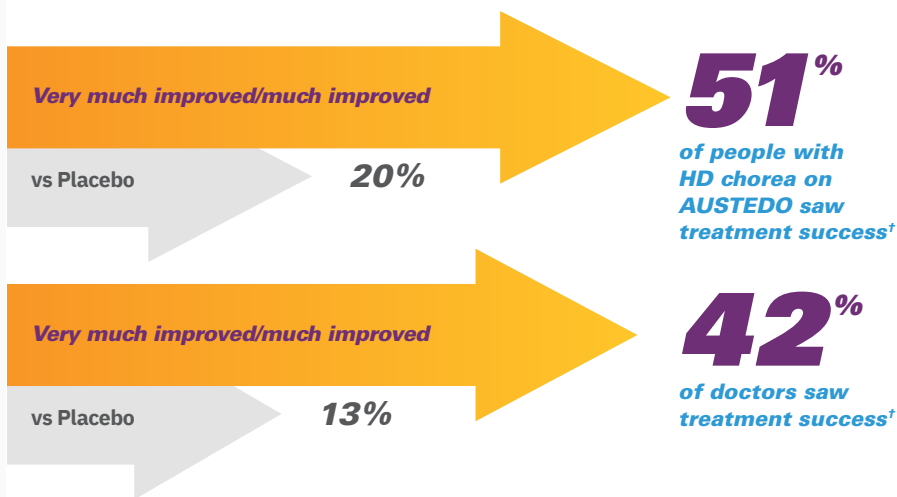
IMPORTANT SAFETY INFORMATION (CONTINUED)

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

- are taking valbenazine.

SYMPTOM IMPROVEMENT

Both doctors and people with HD chorea on AUSTEDO rated overall symptoms as "very much improved" or "much improved" at 12 weeks with AUSTEDO.*



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†Treatment success is measured by perceived improvement in TMC score.

AUSTEDO XR/AUSTEDO does not cure the cause of the involuntary movements, and it does not treat the other symptoms of HD, such as problems with thinking or emotions.

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.

ABOUT THE CLINICAL STUDY

A clinical study measured the effects of AUSTEDO® (deutetrabenazine) tablets in people with HD chorea*

First goal of the study:

To evaluate the effects of AUSTEDO on:

- HD chorea symptoms using the Total Maximal Chorea (TMC) score
- TMC score progress before, during, and at the end of the 12-week study

Second goal of the study:

To evaluate the effects of AUSTEDO on:

- Overall HD symptoms, as reported by people and their doctors
- Limitations on people's ability to perform daily activities

About the study:

90 people with HD chorea were studied for 12 weeks.



45 people were selected to take AUSTEDO and 45 people were selected to take placebo (inactive tablets).



Involuntary movements were measured at the beginning and end of the study, with movements also being observed at intervals throughout the 12-week period.

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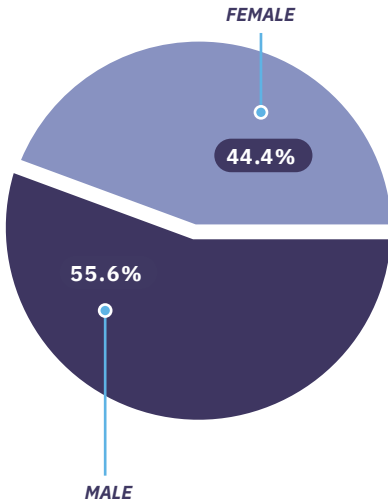
IMPORTANT SAFETY INFORMATION (CONTINUED)

Other possible serious side effects include:

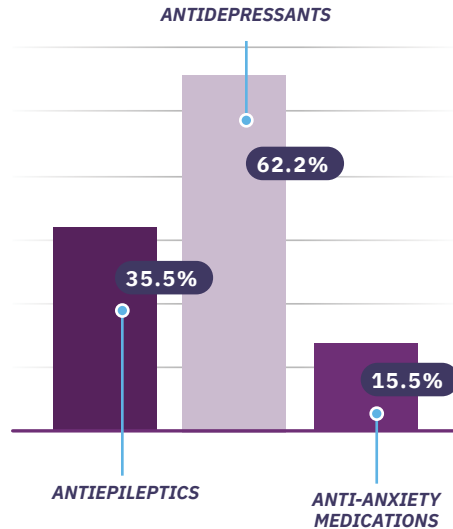
- **Neuroleptic Malignant Syndrome.** Call your healthcare provider right away and go to the nearest emergency room if you develop these signs and symptoms that do not have another obvious cause: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, or increased sweating.

ABOUT THE CLINICAL STUDY*

Sex of people in study:



Medications people continued†:



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†Medications people taking AUSTEDO were able to continue throughout the trial.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Other possible serious side effects include:

- **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.

MORE DETAILS ABOUT THE STUDY*

AGE RANGE:

23-74

MEAN CAG REPEAT LENGTH:

36 / 59
MIN / MAX

TMC SCORE AT THE START
OF STUDY:

8.0 / 21.5
MIN / MAX

Understanding the TMC score

The TMC score is used to determine the effectiveness of HD chorea treatment. Seven parts of the body—including the face, mouth, arms, and legs—are scored from 0 to 4, with 0 indicating no chorea. A complete TMC score ranges from 0 to 28. **The lower the score, the less chorea, or involuntary movements, exhibited by the person.**



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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.

COMMON SIDE EFFECTS*

In the clinical study, the most common side effects of AUSTEDO (deutetrabenazine) tablets included:

- **Sleepiness (sedation)**
- **Diarrhea**
- **Dry mouth**
- **Tiredness**

Adverse reactions with AUSTEDO XR (deutetrabenazine) extended-release tablets are expected to be similar to AUSTEDO.

These are not all the possible side effects of AUSTEDO XR/AUSTEDO. Tell your healthcare provider if you have any side effects that bother you or that do not go away.

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.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Using AUSTEDO XR or AUSTEDO with certain other medicines may cause side effects. **Do not start any new medicines while taking AUSTEDO XR or AUSTEDO without talking to your doctor first.**

In the clinical study, AUSTEDO provided significant and meaningful control of HD chorea with demonstrated safety and tolerability. AUSTEDO XR/AUSTEDO does not cure the cause of the involuntary movements, and it does not treat the other symptoms of HD, such as problems with thinking or emotions.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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



**STARTING
TREATMENT**

ONCE-DAILY DOSING FOR HUNTINGTON'S DISEASE (HD) CHOREA



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 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.

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)

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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.

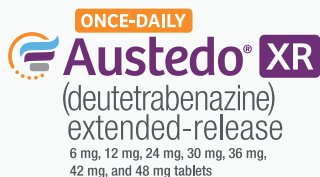
Maintenance dose

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)

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- 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.



APPROVED USE

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.

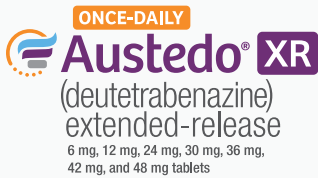
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- have liver problems.
- are taking reserpine. **Do not** take medicines that contain reserpine with AUSTEDO XR or AUSTEDO. If your healthcare provider plans to switch you from taking reserpine to AUSTEDO XR or AUSTEDO, you must wait at least 20 days 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 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.

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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 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 **Shared Solutions**, 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** 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**

COST SHOULDN'T STAND IN THE WAY OF TREATMENT

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

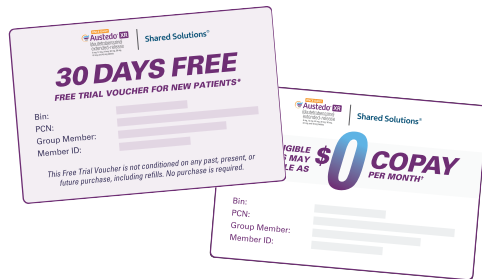


Whether you're insured, underinsured, or not insured at all, we'll verify coverage and work through financial assistance options to help make treatment affordable.

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 is free for your first 30 days with our Free Trial Voucher,† then you may be eligible for \$0 copay per month.*



*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.

†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.



Shared Solutions®

NURSE SUPPORT

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 HD chorea and AUSTEDO XR
- ✓ Starting a treatment plan, dosing, and even managing your refills, to keep you on track and on treatment
- ✓ Understanding how to take and 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

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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 AT EVERY STEP



Sign up for Teva Shared Solutions®

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**



START TREATMENT. REDUCE HD CHOREA.

- **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® patient support program**

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†4.4-point improvement in people taking AUSTEDO vs 1.9 in people taking placebo based on Total Maximal Chorea (TMC) score. The TMC score is used to measure HD chorea movements in the face, mouth, trunk, both arms, and both legs.

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