HD TREATMENT INFORMATION

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

**YOU OWN THE DAY**

Take charge of HD chorea with once-daily AUSTEDO XR (deutetrabenazine) extended-release tablets.

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**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.

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 to read the Medication Guide for this treatment.
WHAT IS HUNTINGTON’S DISEASE (HD) CHOREA?
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

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

How HD chorea can affect daily activities:

- Make walking and climbing stairs difficult
- Make getting dressed challenging
- Affect your ability to brush teeth or bathe
- 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.
ABOUT TREATMENT
OWN YOUR DAY WITH MORE THAN 2X MOVEMENT REDUCTION

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 contains 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 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.
TAKE CHARGE OF YOUR HD CHOREA WITH LONG-LASTING SYMPTOM IMPROVEMENT

Take charge of your HD chorea
With long-lasting symptom improvement

Another study showed symptom improvement was sustained 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.

*Mean TMC score changed minimally from Week 8 to Week 132 (or end of treatment).

IMPORTANT SAFETY INFORMATION
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 an MAOI in the last 14 days. Ask your healthcare provider or pharmacist if you are not sure.
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 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.

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.
SYMPTOM IMPROVEMENT

Both doctors and people with HD chorea on AUSTEDO® (deutetrabenazine) tablets rated overall symptoms as “very much improved” or “much improved” at 12 weeks with AUSTEDO.*

Very much improved/much improved

vs Placebo

20%

51% of people with HD chorea on AUSTEDO saw treatment success†

Very much improved/much improved

vs Placebo

13%

42% of doctors saw treatment success†

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

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.
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**

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

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

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**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.

*Once-daily AUSTEDO® XR (deutetrabenazine) extended-release tablets 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)

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.

*Once-daily AUSTEDO XR contains the same active ingredient as twice-daily AUSTEDO. Data on this page is based on twice-daily dosing.
For the treatment of chorea associated with Huntington’s disease (HD) in adults

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.

STARTING TREATMENT
DOSING FOR HD CHOREA

**OWNCE DAILY**

*Own more of your day with once-daily dosing of AUSTEDO® XR (deutetrabenazine) extended-release tablets*

**AUSTEDO XR should be taken:**

- **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.

**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.
WHAT IS TITRATION?

Once-daily AUSTEDO® XR (deutetrabenazine) extended-release tablets is a titrated medication, which means your doctor will adjust your dose up or down until you find the dose that provides effective movement reduction while ensuring the medicine is well tolerated.

Sample Titration Kit
Given to you at your doctor’s office

Prescription Titration Kit
Prescription given to you to be filled at your pharmacy. Participating pharmacies will apply a 30-day Free Trial Voucher* to your prescription so it is no cost to you.

*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.

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.
**TITRATING YOUR MEDICATION**

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

<table>
<thead>
<tr>
<th>Titration Schedule</th>
<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Once Daily Dosing (mg)</strong></td>
<td>12 mg</td>
<td>18 mg</td>
<td>24 mg</td>
<td>30 mg</td>
</tr>
</tbody>
</table>

AUSTEDO XR is available in 6 mg, 12 mg, and 24 mg extended-release tablets and can be combined up to a daily maximum strength of 48 mg. In one clinical study, the average dose of AUSTEDO® (deutetrabenazine) tablets after treatment was ~38 mg daily.*

*Once-daily AUSTEDO XR contains the same active ingredient as twice-daily AUSTEDO. Data on this page is based on twice-daily dosing. Pills are for illustration only and not actual size or likeness.

Once you reach a dose that provides effective movement reduction and is well tolerated, that will become your **maintenance dose**—the dose you stay on moving forward.

It’s important to take AUSTEDO XR exactly as prescribed by your doctor. If you experience a change in symptoms, share these details with your doctor as they may decide to adjust your dose.

**IMPORTANT SAFETY INFORMATION (CONTINUED)**

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.
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.

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

IMPORTANT SAFETY INFORMATION

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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) 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 click here or visit www.AUSTEDO.com to read or print the Medication Guide for AUSTEDO XR.
For the treatment of chorea associated with Huntington’s disease (HD) in adults.

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.

SUPPORT & RESOURCES
For the treatment of chorea associated with Huntington’s disease (HD) in adults

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.

REACH OUT TO US, WE’LL REACH FOR SOLUTIONS TOGETHER

With Teva 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

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.
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 per month*†

AUSTEDO XR (deutetrabenazine) extended-release tablets 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.
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

IMPORTANT SAFETY INFORMATION (CONTINUED)

AUSTEDO XR and AUSTEDO (deutetrabenazine) tablets 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.
GETTING YOUR PRESCRIPTION IS EASIER WITH TEVA SHARED SOLUTIONS®

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

**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.
For the treatment of chorea associated with Huntington's disease (HD) in adults

Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.

Sign up for 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
TREAT NOW. OWN MORE MOMENTS.

- More than 2x movement reduction at 12 weeks vs placebo.†
- Once-daily dosing
- Start at no cost
- Get support through Teva Shared Solutions®

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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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Please read Important Safety Information on pages 18-19 and click here to read the Medication Guide for this treatment.
What is the most important information I should know about AUSTEDO XR and AUSTEDO?

- AUSTEDO XR and AUSTEDO can cause serious side effects in people with Huntington's disease, including:
  - depression
  - suicidal thoughts
  - suicidal actions
- Do not start taking AUSTEDO XR or AUSTEDO if you have Huntington's disease and 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 or have any of the following symptoms, especially if they are new, worse, or worry you:

- feel sad or have crying spells
- lose interest in seeing your friends or doing things you used to enjoy
- sleep a lot more or a lot less than usual
- feel unimportant
- feel guilty
- feel hopeless or helpless
- feel more irritable, angry, or aggressive than usual
- feel more or less hungry than usual or notice a big change in your body weight
- have trouble paying attention
- feel tired or sleepy all the time
- have thoughts about hurting yourself or ending your life

What are AUSTEDO XR and AUSTEDO?

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.
- 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.

Who should not take AUSTEDO XR or AUSTEDO?

Do not take AUSTEDO XR or AUSTEDO if you:

- have Huntington's disease and are depressed or have thoughts of suicide. See "What is the most important information I should know about AUSTEDO XR and AUSTEDO?"
- 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.

Before taking AUSTEDO XR or AUSTEDO, tell your healthcare provider about all of your medical conditions, including if you:

- have emotional or mental problems (for example, depression, nervousness, anxiety, anger, agitation, psychosis, previous suicidal thoughts or suicide attempts).
- have liver disease.
- have an irregular heart rhythm or heartbeat (QT prolongation, cardiac arrhythmia) or a heart problem called congenital long QT syndrome.
- have low levels of potassium or magnesium in your blood (hypokalemia or hypomagnesemia).
- have breast cancer or a history of breast cancer.
- have an irregular heart rhythm or heartbeat (QT prolongation, cardiac arrhythmia) or a heart problem called congenital long QT syndrome.
- are pregnant or plan to become pregnant. It is not known if AUSTEDO XR or AUSTEDO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if AUSTEDO XR or AUSTEDO passes into breast milk.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking 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 healthcare provider first.

How should I take AUSTEDO XR or AUSTEDO?

- Take AUSTEDO XR or AUSTEDO exactly as your healthcare provider tells you to take it.
- If you take AUSTEDO XR, take your dose by mouth one time each day, with or without food.
- If you take AUSTEDO, take your dose by mouth and with food. If your dose of AUSTEDO is 12 mg or more each day, take AUSTEDO tablets 2 times a day in equal doses.
- Swallow AUSTEDO XR or AUSTEDO tablets whole with water. Do not chew, crush, or break AUSTEDO XR or AUSTEDO tablets before swallowing. If you cannot swallow AUSTEDO XR or AUSTEDO tablets whole, tell your healthcare provider. You may need a different medicine.
- Your healthcare provider may increase your dose of AUSTEDO XR or AUSTEDO each week for several weeks, until you and your healthcare provider find the right dose for you.
- Tell your healthcare provider if you stop taking AUSTEDO XR or AUSTEDO for more than 1 week. Do not take another dose until you talk to your healthcare provider.

continued
What should I avoid while taking AUSTEDO XR or AUSTEDO?
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.

What are the possible side effects of AUSTEDO XR and AUSTEDO?
AUSTEDO XR and AUSTEDO can cause serious side effects, including:

- Depression and suicidal thoughts or actions in people with Huntington’s disease. See “What is the most important information I should know about AUSTEDO XR and AUSTEDO?”
- 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 (NMS). 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
  ◦ increased sweating
- Restlessness. You may get a condition where you feel a strong urge to move. This is called akathisia.
- Parkinsonism. Symptoms of parkinsonism include: slight shaking, body stiffness, trouble moving, trouble keeping your balance, or falls.

The most common side effects of AUSTEDO in people with Huntington’s disease include:
- sleepiness (sedation)
- tiredness
- diarrhea
- dry mouth

The most common side effects of AUSTEDO in people with tardive dyskinesia include:
- inflammation of the nose and throat (nasopharyngitis)
- 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 may report side effects to FDA at 1-800-FDA-1088.

How should I store AUSTEDO XR and AUSTEDO?
- Store AUSTEDO XR and AUSTEDO tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed to protect AUSTEDO XR and AUSTEDO from light and moisture.
- Do not throw away the desiccant canister in the bottle until the last dose of AUSTEDO XR or AUSTEDO is taken.

General information about the safe and effective use of AUSTEDO XR and AUSTEDO.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AUSTEDO XR or AUSTEDO for a condition for which it was not prescribed. Do not give AUSTEDO XR or AUSTEDO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about AUSTEDO XR and AUSTEDO that is written for health professionals.

What are the ingredients in AUSTEDO XR and AUSTEDO?
AUSTEDO XR:
Active ingredient: deutetrabenazine
Inactive ingredients: ammonium hydroxide, black iron oxide, butyl alcohol, butylated hydroxyanisole, butylated hydroxytoluene, cellulose acetate, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, magnesium stearate, polyethylene glycol, polyethylene glycol 3350, polyethylene oxide, polyvinyl alcohol, propylene glycol, shellac, sodium chloride, t alc, titanium dioxide, FD&C blue #2 lake, and FD&C red #40 lake. The 6 mg and 12 mg extended-release tablets also contain FD&C yellow #6 lake.

AUSTEDO:
Active ingredient: deutetrabenazine
Inactive ingredients: ammonium hydroxide, black iron oxide, n-butyl alcohol, butylated hydroxyanisole, butylated hydroxytoluene, magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, polyethylene oxide, polysorbate 80, polyvinyl alcohol, povidone, propylene glycol, shellac, t alc, titanium dioxide, and FD&C blue #2 lake. The 6 mg tablets also contain FD&C red #40 lake. The 12 mg tablets also contain FD&C yellow #6 lake.

Manufactured for:
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For more information, go to www.AUSTEDO.com or call 1-888-483-8279.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: February 2023