For the treatment of the uncontrolled movements of tardive dyskinesia (TD) in adults

Approved Uses
AUSTEDO® is a prescription medicine that is used to treat:

• the involuntary movements (chorea) of Huntington's disease. AUSTEDO® does 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® is safe and effective in children.

Important Safety Information

AUSTEDO® can cause serious side effects in people with Huntington's disease, including: depression, suicidal thoughts, or suicidal actions. Do not start taking 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® 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 10-11 and the accompanying Medication Guide.
Do you have uncontrolled physical movements?

Various medical conditions can cause uncontrolled movements across different parts of the body. Uncontrolled movements may also be the result of taking certain prescription medications that treat mental health conditions or gastrointestinal issues.

Do you have any of the following:
- Uncontrolled movements in your face, mouth, tongue, arms, and/or legs?
- Trouble speaking, or being understood by others?
- Difficulty reading or writing?
- A hard time cutting your food or holding your drink?
- Movements that make you feel self-conscious?

If you’ve answered “yes” to 1 or more of the questions above, you may want to ask your doctor to evaluate you for tardive dyskinesia (TD).

Could these movements be a sign of TD?

TD causes repetitive, unintentional movements. These movements have been described as “twitchy,” “shaky,” “jittery,” and “jerky.”

Movements can be seen in the following areas:
- Face and mouth (eyes, lips, jaw, and tongue)
- Arms and hands
- Legs and feet
- Trunk (shoulder, neck, and hips)

Tardive dyskinesia (TD) affects everyone differently

The severity of TD symptoms can vary from person to person, but even mild symptoms can be bothersome.

The physical uncontrolled movements of TD can make it difficult to do everyday activities. These uncontrolled movements may also lead those with TD to distance themselves from others or from activities they enjoy.

With TD, it’s personal. Everyone’s needs and treatment goals are unique.

The first step to managing TD is recognizing the signs and discussing them with your doctor.
How AUSTEDO® (deutetrabenazine) tablets may help

AUSTEDO® is FDA approved to treat tardive dyskinesia (TD) in adults

- AUSTEDO® treats the movements in the face, tongue, or other body parts that cannot be controlled
- AUSTEDO® is believed to work with the natural chemicals in your brain to help reduce uncontrolled movements
- You may be able to take AUSTEDO® with your other medicines
  — In clinical studies of AUSTEDO®, participants with TD had various mental health conditions and were able to continue taking medicines to treat those conditions while taking AUSTEDO®, such as antipsychotics and antidepressants

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medications, vitamins, and herbal supplements.

Do not take AUSTEDO® if you are taking any of the following medicines:
- a monoamine oxidase inhibitor (MAOI) medicine. Do not take an MAOI within 14 days after you stop taking AUSTEDO®. Do not start AUSTEDO® if you stopped taking an MAOI in the last 14 days. Ask your healthcare provider or pharmacist if you are not sure.
- reserpine. Do not take medicines that contain reserpine (such as Serpalan® and Renese®-R) with AUSTEDO®. If your healthcare provider plans to switch you from taking reserpine to AUSTEDO®, you must wait at least 20 days after your last dose of reserpine before you start taking AUSTEDO®.
- tetrabenazine (Xenazine®). If your healthcare provider plans to switch you from tetrabenazine (Xenazine®) to AUSTEDO®, take your first dose of AUSTEDO® on the day after your last dose of tetrabenazine (Xenazine®).
- valbenazine (Ingrezza®).

How AUSTEDO® was studied

In 2 clinical studies, a total of 335 participants with tardive dyskinesia (TD) were studied for 12 weeks.
- A total of 220 participants took AUSTEDO® and a total of 115 participants took placebo (inactive tablets)

Primary goal

The primary goal of both studies was to identify the change in the Abnormal Involuntary Movement Scale (AIMS) total score from the beginning to the end of the 12-week studies. The AIMS total score was used to measure the uncontrolled movements of TD.

The AIMS total score is calculated by adding scores from all of the following individual areas of the body:

- Face (including mouth, jaw, and tongue)
- Arms (including wrists, hands, and fingers)
- Trunk (hips, neck, and shoulders)
- Legs (including knees, feet, and toes)
Proven to effectively reduce tardive dyskinesia (TD)

AUSTEDO® (deutetrabenazine) tablets reduced the uncontrolled movements of TD in 2 clinical studies

Study 1: Reduction in AIMS* total score at Week 12

- In Study 1, 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 from the start of the study vs a 12% reduction for those taking placebo

  ![Graph showing reduction in AIMS* total score at Week 12](chart1.png)

- Improvement in uncontrolled movements began to be seen at 2 weeks.

Study 2: Reduction in AIMS* total score at Week 12

- In Study 2, AUSTEDO® reduced the AIMS* total score by 3.0 points vs 1.6 points with placebo
  - For participants taking AUSTEDO®, this represents an approximately 27% reduction in AIMS* total score from the start of the study vs a 16% reduction for those taking placebo

  ![Graph showing reduction in AIMS* total score at Week 12](chart2.png)

A reduction in AIMS* total score means fewer uncontrolled movements

*The Abnormal Involuntary Movement Scale (AIMS) measures uncontrolled movements of TD.

Please read Important Safety Information on pages 10-11 and the accompanying Medication Guide.
Side effects from the clinical studies of AUSTEDO® (deutetrabenzazaine) tablets

In 2 clinical studies for tardive dyskinesia (TD)

The most common side effects of AUSTEDO® included:

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

Other side effects of AUSTEDO® in the clinical studies included:

- Depression, restlessness, agitation, and a strong urge to move (akathisia).
- Sleepiness (sedation) is a common side effect of AUSTEDO®.

While taking AUSTEDO®, do not drive a car or operate dangerous machinery until you know how AUSTEDO® affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking AUSTEDO® may increase any sleepiness caused by AUSTEDO®.

These are not all the possible side effects of AUSTEDO®. Tell your doctor if you have any side effects that bother you or that do not go away.

4% of participants taking AUSTEDO® had to have their dose lowered due to side effects vs 2% taking placebo

Individualized dosing with AUSTEDO®

AUSTEDO® dosing is individualized, meaning you and your doctor can work together to find the dose that is right for you.

Your doctor may adjust your dose of AUSTEDO® each week for several weeks in order to find the dose that is appropriate for you.

AUSTEDO® tablets are available in 3 strengths: 6 mg, 9 mg, and 12 mg.

Take AUSTEDO® exactly as your healthcare provider tells you to take it.

Take AUSTEDO® with food. Swallow AUSTEDO® tablets whole with water. Do not chew, crush, or break AUSTEDO® tablets before swallowing. If you cannot swallow AUSTEDO® tablets whole, tell your healthcare provider, you may need a different medicine.
Important Safety Information

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® 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® 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® if you:**

- have Huntington’s disease and are depressed or have thoughts of suicide.
- have liver problems.
- are taking a monoamine oxidase inhibitor (MAOI) medicine. **Do not** take an MAOI within 14 days after you stop taking AUSTEDO®. **Do not** start 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 reserpine. **Do not** take medicines that contain reserpine (such as Serpalan® and Renese®-R) with AUSTEDO®. If your healthcare provider plans to switch you from taking reserpine to AUSTEDO®, you must wait at least 20 days after your last dose of reserpine before you start taking AUSTEDO®.
- are taking tetrabenazine (Xenazine®). If your healthcare provider plans to switch you from tetrabenazine (Xenazine®) to AUSTEDO®, take your first dose of AUSTEDO® on the day after your last dose of tetrabenazine (Xenazine®).
- are taking valbenazine (Ingrezza®).

**Other possible serious side effects include:**

- **Irregular heartbeat (QT prolongation).** 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® with certain medicines may increase this chance. If you are at risk of QT prolongation, your healthcare provider should check your heart before and after increasing your AUSTEDO® dose above 24 mg a day.
- **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 in people with Huntington’s disease.** Symptoms include: slight shaking, body stiffness, trouble moving, or keeping your balance.

**Sleepiness (sedation) is a common side effect of AUSTEDO®.**

While taking AUSTEDO®, do not drive a car or operate dangerous machinery until you know how AUSTEDO® affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking AUSTEDO® may increase any sleepiness caused by 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).

These are not all the possible side effects of AUSTEDO®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please read the accompanying Medication Guide.
Support from Teva’s Shared Solutions®

Your partner, here to support you

Teva’s Shared Solutions® understands how your condition can affect you. Through financial assistance programs and nurse support, Shared Solutions® will partner with you throughout your AUSTEDO® (deutetrabenazine) tablets treatment.

Financial assistance programs

Our team of dedicated Benefits Specialists are committed to helping you gain access to AUSTEDO® as soon as possible. We offer:

- Financial assistance eligibility determination
- AUSTEDO® Copay Program
  - $0 copay per month, for eligible commercially insured patients* (please visit www.AUSTEDO.com to review the full Terms and Conditions)
- Assistance with navigating Medicare Part D
- Additional financial assistance programs may exist, depending on your insurance coverage and if you meet certain eligibility requirements

Teva’s Shared Solutions® is dedicated to providing support throughout your AUSTEDO® treatment by offering:

- Teva’s Shared Solutions® nurse phone support
  - Our trained nurses are available by phone, so you will have someone to talk to about your AUSTEDO® treatment
- Communications through email, mail, or phone to help support you throughout your AUSTEDO® treatment as prescribed by your doctor

Our team is just one call away. Call Shared Solutions® at 1-800-887-8100.

*t&c for the AUSTEDO® Copay Program: The AUSTEDO® Copay Program is available to eligible individuals who have been prescribed AUSTEDO® and have commercial insurance. Maximum annual benefits apply and out-of-pocket expenses may vary. Patient is responsible for costs above maximum benefit amounts. This Program is available to eligible individuals who reside in the United States, including Puerto Rico. Cash-paying individuals are NOT eligible for this Program nor are individuals with commercial insurance that does not provide coverage for AUSTEDO® (except in certain limited situations while a prior authorization is pending). Individuals whose prescriptions are paid for in part or full by any state or federally funded programs, including but not limited to Medicare or Medicaid, Medigap, VA, DOD, TRICARE, or by private health benefit programs, which reimburse for the entire cost of the prescription drug are NOT eligible for this Program. Patients who are Medicare eligible and are enrolled in an employer-sponsored health plan or prescription drug benefit program for retirees (i.e. patients who are eligible for Medicare Part D but receive a prescription drug benefit through a former employer) are NOT eligible for this Program. Please see complete Terms and Conditions at www.AUSTEDO.com.
Ask your doctor about AUSTEDO® (deutetrabenazine) tablets

- In clinical studies, AUSTEDO® was proven to effectively reduce the uncontrolled movements of TD in adults
- Most study participants taking AUSTEDO® were able to continue taking their antipsychotics and/or antidepressants
- The most common side effects of study participants taking AUSTEDO® were inflammation of the nose and throat (nasopharyngitis) and problems sleeping (insomnia)
- Dosing is individualized, so you and your doctor can find the dose that is right for you
- With AUSTEDO®, you can receive support from Teva’s Shared Solutions® throughout your treatment

Visit www.AUSTEDO.com to learn more
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<th>MEDICATION GUIDE</th>
<th>AUSTEDO® (aw-STED-oh) (deutetrabenazine) tablets, for oral use</th>
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**What is the most important information I should know about AUSTEDO?**
- AUSTEDO can cause serious side effects in people with Huntington’s disease, including:
  - depression
  - suicidal thoughts
  - suicidal actions
- Do not start taking 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 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 is AUSTEDO?**
AUSTEDO is a prescription medicine that is used to treat:
- the involuntary movements (chorea) of Huntington’s disease. AUSTEDO does 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 is safe and effective in children.

**Who should not take AUSTEDO?**
Do not take 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?”
- have liver problems.
- are taking a monoamine oxidase inhibitor (MAOI) medicine. **Do not** take an MAOI within 14 days after you stop taking AUSTEDO. **Do not** start 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 reserpine. **Do not** take medicines that contain reserpine (such as Serpalan and Renese-R) with AUSTEDO. If your healthcare provider plans to switch you from taking reserpine to AUSTEDO, you must wait at least 20 days after your last dose of reserpine before you start taking AUSTEDO.
- are taking tetrabenazine (Xenazine). If your healthcare provider plans to switch you from tetrabenazine (Xenazine) to AUSTEDO, take your first dose of AUSTEDO on the day after your last dose of tetrabenazine (Xenazine).
- are taking valbenazine (Ingrezza).

Before taking 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.
- are pregnant or plan to become pregnant. It is not known if AUSTEDO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if 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 with certain other medicines may cause side effects. Do not start any new medicines while taking AUSTEDO without talking to your healthcare provider first.
How should I take AUSTEDO?

- Take AUSTEDO exactly as your healthcare provider tells you to take it.
- Take AUSTEDO by mouth and with food.
- Swallow AUSTEDO tablets whole with water. Do not chew, crush, or break AUSTEDO tablets before swallowing. If you cannot swallow AUSTEDO tablets whole, tell your healthcare provider. You may need a different medicine.
- If your dose of AUSTEDO is 12 mg or more each day, take AUSTEDO tablets 2 times a day in equal doses with food.
- Your healthcare provider will increase your dose of 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 for more than 1 week. Do not take another dose until you talk to your healthcare provider.

What should I avoid while taking AUSTEDO?

Sleepiness (sedation) is a common side effect of AUSTEDO. While taking AUSTEDO, do not drive a car or operate dangerous machinery until you know how AUSTEDO affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking AUSTEDO may increase any sleepiness caused by AUSTEDO.

What are the possible side effects of AUSTEDO?

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?”
- Irregular heartbeat (QT prolongation). 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 with certain medicines may increase this chance.
  - If you are at risk of QT prolongation, your healthcare provider should check your heart before and after increasing your AUSTEDO dose above 24 mg a day.
- 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
  - problems thinking
  - increased sweating
  - stiff muscles
  - very fast or uneven heartbeat
- Restlessness. You may get a condition where you feel a strong urge to move. This is called akathisia.
- Parkinsonism in people with Huntington’s disease. Symptoms of parkinsonism include: slight shaking, body stiffness, trouble moving, or keeping your balance.

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

These are not all the possible side effects of 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?

- Store AUSTEDO tablets at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed to protect AUSTEDO from light and moisture.

Keep AUSTEDO tablets and all medications out of reach of children.

General information about the safe and effective use of AUSTEDO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AUSTEDO for a condition for which it was not prescribed. Do not give 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 that is written for health professionals.

What are the ingredients in 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, talc, 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.

Distributed by:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454
AUSMG-002
For more information, go to www.AUSTEDO.com or call 1-888-483-8279.