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.
Understanding Huntington's disease

Huntington's disease (HD) is a neurological, hereditary disease. HD has physical, emotional, behavioral, and cognitive effects, and symptoms that can be disruptive to relationships, jobs, and everyday activities. Some symptoms can make performing daily tasks challenging, and may eventually prevent some tasks altogether, such as driving or managing a job or a household.

There are 3 main categories of HD symptoms:

- **Memory** (cognition, thinking)
- **Mood** (emotions, behavior)
- **Movement** (motor symptoms, including chorea)

AUSTEDO® (deutetrabenazine) tablets is a medicine to treat HD chorea. It does not treat other symptoms of HD, such as problems with thinking or emotions.

90% of people with HD will develop chorea

The impact of HD chorea

Chorea is the most visible symptom of HD and can affect the ability to do everyday activities. With chorea, you may experience involuntary, random movements of various parts of your body. In a survey published in 2016, caregivers reported chorea as the most impactful symptom of HD.

How much does chorea affect your daily activities?

- Do you have difficulty pouring a beverage? Drinking?
- Do you have a hard time brushing your teeth?
- Do you have trouble bathing or getting dressed?
- Do you sometimes struggle to form words or speak clearly, due to chorea?
- Do you have a hard time swallowing or eating?
- If you're still working, do you have difficulty controlling your movements while at work?
- Has the furniture in your home been rearranged to accommodate changes in your ability to move around?

If you’ve answered “yes” to one or more of these questions...

Talk to your doctor about how you can help manage your HD chorea

Please read Important Safety Information on pages 10-11 and the accompanying Medication Guide.
How AUSTEDO® (deutetrabenazine) tablets may help

AUSTEDO® treats the involuntary movements (chorea) of HD

- 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.

A clinical study evaluated the effects of AUSTEDO® in participants with HD chorea

- 90 participants with HD chorea were studied for 12 weeks.
- 45 participants were randomly selected to take AUSTEDO®, and 45 participants were randomly selected to take placebo (inactive tablets).

Primary goal

The study used the Total Maximal Chorea (TMC) score to measure the effectiveness of AUSTEDO® on HD chorea.

- On this scale, chorea is rated from 0 to 4 (with 0 representing no chorea) across 7 parts of the body. The total score ranges from 0 to 28.

Secondary goals

To evaluate the effects of AUSTEDO® on:

- Overall HD symptoms, as reported by participants and their doctors.
- Participants’ limitations in performing daily activities.

AUSTEDO® significantly reduced HD chorea vs placebo

Change in Total Maximal Chorea (TMC) score

The TMC score was assessed before, during, and at the end of the 12-week study.

TMC score at end of study

- The TMC score improved by 4.4 points in participants taking AUSTEDO® vs 1.9 points with placebo.
- This represents a 2.5-point improvement in TMC score with AUSTEDO® over placebo.
- The TMC score improved by at least 6 points for 33% of participants taking AUSTEDO® vs 2% taking placebo.

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.

Please read Important Safety Information on pages 10-11 and the accompanying Medication Guide.
Secondary goals demonstrating the effects of AUSTEDO® (deutetrabenazine) tablets

Overall HD symptoms were rated as “much improved” or “very much improved” with AUSTEDO® vs placebo

51% of participants taking AUSTEDO® reported that their overall HD symptoms were “much improved” or “very much improved” at the end of treatment, compared with 20% of those taking placebo.

42% of doctors treating participants taking AUSTEDO® reported that overall HD symptoms observed were “much improved” or “very much improved” at the end of treatment, compared with 13% treating participants taking placebo.

AUSTEDO® is a medicine to treat HD chorea. It does not treat other symptoms of HD, such as problems with thinking or emotions.

Participants taking AUSTEDO® also reported being less limited in performing daily activities.*

*Based on Short Form-36 (SF-36) Physical Functioning Scale vs placebo, at 12 weeks.

Common side effects of AUSTEDO®

In a clinical study for chorea associated with Huntington’s disease (HD)

The most common side effects of AUSTEDO® included:

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

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 healthcare provider if you have any side effects that bother you or that do not go away.

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

Do not take AUSTEDO® if you:

- 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®) or valbenazine (Ingrezza®).
Starting AUSTEDO® (deutetabenazine) tablets treatment

Reaching your appropriate dose

AUSTEDO® dosing is individualized. It’s important to take AUSTEDO® exactly as your doctor tells you to take it.

Your doctor may adjust your dose of AUSTEDO® each week for several weeks, to find the dose that is appropriate for you. This process is known as titration.

AUSTEDO® tablets are available in 3 strengths:

- 6 mg
- 9 mg
- 12 mg

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.

Switching from tetrabenazine

In another AUSTEDO® clinical study, 37 participants with HD chorea switched overnight from tetrabenazine to AUSTEDO®. Participants received AUSTEDO® at approximately half the milligram dose of tetrabenazine.

Do not take AUSTEDO® if you 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®).

Your doctor will tell you the dose of AUSTEDO® that is appropriate for you.
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.
Support from Teva’s Shared Solutions®

Your partner, here to support you

Through financial assistance programs, training and educational resources, Teva’s Shared Solutions® will partner with you throughout your AUSTEDO® (deutetrabenazine) tablets treatment.

Financial assistance programs

Shared Solutions® is committed to helping you find affordable access to AUSTEDO® so you can start and stay on treatment. We offer:

- Financial assistance eligibility determination
- $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

Call Teva’s Shared Solutions® at 1-800-887-8100 or visit SharedSolutions.com

*Terms and Conditions 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 when 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.

Training and nurse support

Shared Solutions® is dedicated to providing training and education to help support you during your AUSTEDO® treatment.

- Teva’s Shared Solutions® nurse phone support
  - Our trained nurses are available by phone from 8:00 AM to 8:00 PM Central Time, so you will have someone to talk to about your AUSTEDO® treatment. Phone calls received after 8:00 PM will be returned after 8:00 AM the next morning

Our nurses will help answer questions you may have about your AUSTEDO® treatment.

Educational resources

Shared Solutions® cares about supporting you throughout your AUSTEDO® treatment. We can help keep you informed, educated, and connected.

- You can receive personalized, ongoing contact from the team at Shared Solutions® via email, mail, or phone, so you can feel supported every step of the way
Ask your doctor if AUSTEDO® (deutetrabenazine) tablets is right for you

How to get started

When you and your doctor decide that AUSTEDO® is right for you, here’s what to expect next.

1. Your doctor’s office will send your paperwork to either Teva’s Shared Solutions® or your filling pharmacy.

2. You may receive a call from Shared Solutions or your filling pharmacy to verify your contact and insurance information. It’s important that you answer this call so they can process your prescription.

3. Your paperwork will be processed.

4. Your prescription will be filled by your pharmacy.

**Talk to your doctor today about AUSTEDO®**

Please read Important Safety Information on pages 10-11 and the accompanying Medication Guide.
**MEDICATION GUIDE**

*AUSTEDO® (aw-STED-oh)*

(deutetrabenazine)

tablets, for oral use

---

### 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.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: August 2017