Approved Uses

AUSTEDO® (deutetrabenazine) tablets 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 10-12 and the accompanying Medication Guide.
Welcome

This resource is designed to provide support and help guide conversations with your doctor during your treatment with AUSTEDO® (deutetrabenazine) tablets. AUSTEDO® is a prescription medicine that is used to treat the uncontrolled movements of tardive dyskinesia (TD) in adults.

How to use this resource:
1. Keep track of when you take AUSTEDO®.
2. Track the uncontrolled movements of TD that you experience.
3. Write down questions for your doctor.

Using this resource may help your healthcare team determine a dose of AUSTEDO® that is appropriate for you. Make sure to bring this resource to each doctor’s appointment.

Teva’s Shared Solutions® is committed to providing you with support. Remember, if you ever have questions about AUSTEDO®, our trained nurses are available by phone.

Best regards,

Your Shared Solutions® Team

Call Teva’s Shared Solutions® at 1-800-887-8100
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Health information

Primary care doctor .................................................................
Phone number........................................................................
Address ................................................................................

Psychiatrist ...........................................................................
Phone number........................................................................
Address ................................................................................

Hospital ..................................................................................
Phone number........................................................................
Address ................................................................................

Pharmacy .................................................................................
Phone number........................................................................
Address ................................................................................

Insurance carrier ...................................................................
Phone number........................................................................
Health insurance member number ............................................

AUSTEDO® (deutetrabenzamine) tablets start date ______

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Support from Teva’s Shared Solutions®

Through financial assistance programs for eligible patients, and nurse support, Teva’s Shared Solutions® will partner with you throughout your AUSTEDO® (deutetabenazine) tablets treatment.

Financial assistance programs
Teva’s Shared Solutions® is committed to helping you find affordable access to AUSTEDO® so you can start and stay on treatment as prescribed by your doctor.

Nurse support
Our professional nurses can help you by offering:
- Shared Solutions® nurse phone support
- Communications through email, mail, or phone to help support you throughout your AUSTEDO® treatment

For more information, call Teva’s Shared Solutions® at 1-800-887-8100

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Treatment tips for taking AUSTEDO® (deutetrabenazine) tablets

Set a routine
• Create and follow a dosing routine. Remember that AUSTEDO® must be taken exactly as prescribed
• You may want to set an alarm as a treatment reminder
• Keep your AUSTEDO® tablets in the same place so you know where they are

Record your treatment
• Use this tracker to record when AUSTEDO® is taken
• Keep track of your uncontrolled movements, daily activities, and questions you may have for your doctor and the healthcare team

Take AUSTEDO® as prescribed
• Before starting AUSTEDO®, you should talk to your doctor about what to do if you miss a dose
• Tell your doctor if you stop taking AUSTEDO® for more than 1 week. Do not take another dose until you talk to your doctor

It’s important to take AUSTEDO® exactly as your doctor tells you to take it

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Approved Uses

AUSTEDO® (deutetrabenazine) tablets 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.

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.

Do not take AUSTEDO® if you:

- 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. Symptoms include: slight shaking, body stiffness, trouble moving, trouble keeping your balance, or falls.

Please read Important Safety Information on the following pages and the accompanying Medication Guide.
Important Safety Information (continued)

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

Online resources

Below are several websites you may find helpful.

Caregiver Action Network (CAN)
www.caregiveraction.org

Depression and Bipolar Support Alliance (DBSA)
www.dbsalliance.org

MedlinePlus
https://medlineplus.gov/ency/article/000685.htm

Mental Health America (MHA)
www.mentalhealthamerica.net

National Alliance on Mental Illness (NAMI)
www.nami.org
DAILY TREATMENT
AND ACTIVITY LOG

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
How to use this resource

Recording treatment

“Did I take my medication this morning?” Or, “Do I need to take another dose?” Avoid these questions by using the treatment tracker daily. Simply record with a check mark when AUSTEDO® (deutetrabenazine) tablets is taken in the morning and evening (sun and moon symbols).

Using the activity log

Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week. Mark your answers in the boxes below.

Write down any questions you’d like to discuss with your doctor during your next visit. Remember to bring this log with you to all upcoming doctor appointments.

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<th>UNCONTROLLED MOVEMENTS</th>
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<td>(Face and mouth)</td>
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<td><img src="image" alt="Worse" /> <img src="image" alt="Same" /> <img src="image" alt="Better" /></td>
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<th>ABILITY TO DO DAILY ACTIVITIES</th>
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<td>(eg, eating and drinking, bathing and grooming, household chores, etc)</td>
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<td><img src="image" alt="Worse" /> <img src="image" alt="Better" /> <img src="image" alt="Same" /></td>
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<th>QUESTIONS TO DISCUSS WITH YOUR DOCTOR</th>
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Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Assess your activity
Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

**UNCONTROLLED MOVEMENTS**
(Face and mouth)
- Better
- Same
- Worse

(Arms, legs, trunk)
- Worse
- Same
- Better

**ABILITY TO DO DAILY ACTIVITIES**
(eg, eating and drinking, bathing and grooming, household chores, etc)
- Worse
- Same
- Better

**QUESTIONS TO DISCUSS WITH YOUR DOCTOR**

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Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
**Week 2**

**Record each dose**

After the morning and evening dose of AUSTEDO® (deutetrabenazine) tablets has been taken, place a check mark in the corresponding box.

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**Assess your activity**

Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

**UNCONTROLLED MOVEMENTS**

(Face and mouth)

- Worse
- Same
- Better

(Arms, legs, trunk)

- Worse
- Same
- Better

**ABILITY TO DO DAILY ACTIVITIES**

(eg, eating and drinking, bathing and grooming, household chores, etc)

- Worse
- Same
- Better

**QUESTIONS TO DISCUSS WITH YOUR DOCTOR**

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Questions about your treatment? Teva’s Shared Solutions® can help. Call 1-800-887-8100

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Week 3  month/day-month/day

Assess your activity
Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

UNCONTROLLED MOVEMENTS
(Face and mouth)

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(Arms, legs, trunk)

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ABILITY TO DO DAILY ACTIVITIES
(eg, eating and drinking, bathing and grooming, household chores, etc)

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Questions about your treatment?
Teva’s Shared Solutions® can help. Call 1-800-887-8100

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Week 4 month/day-month/day

Record each dose
After the morning and evening dose of AUSTEDO® (deutetabenazine) tablets has been taken, place a check mark in the corresponding box.

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Questions about your treatment?
Teva’s Shared Solutions® can help. Call 1-800-887-8100

Assess your activity
Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

UNCONTROLLED MOVEMENTS
(Face and mouth)
- Worse
- Same
- Better

(Arms, legs, trunk)
- Worse
- Same
- Better

ABILITY TO DO DAILY ACTIVITIES
(eg, eating and drinking, bathing and grooming, household chores, etc)
- Worse
- Same
- Better

QUESTIONS TO DISCUSS WITH YOUR DOCTOR

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Week 5  

Record each dose

After the morning and evening dose of AUSTEDO® (deutetrabenazine) tablets has been taken, place a check mark in the corresponding box.

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Questions about your treatment?
Teva’s Shared Solutions® can help. Call 1-800-887-8100

Assess your activity
Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

UNCONTROLLED MOVEMENTS
(Face and mouth)

- Worse  
- Same  
- Better

(Arms, legs, trunk)

- Worse  
- Same  
- Better

ABILITY TO DO DAILY ACTIVITIES
(eg, eating and drinking, bathing and grooming, household chores, etc)

- Worse  
- Same  
- Better

QUESTIONS TO DISCUSS WITH YOUR DOCTOR


Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Week 6  month/day-month/day

Record each dose
After the morning and evening dose of AUSTEDO® (deutetrabenazine) tablets has been taken, place a check mark in the corresponding box.

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Assess your activity
Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

UNCONTROLLED MOVEMENTS
(Face and mouth)

- Worse
- Same
- Better

(Arms, legs, trunk)

- Worse
- Same
- Better

ABILITY TO DO DAILY ACTIVITIES
(eg, eating and drinking, bathing and grooming, household chores, etc)

- Worse
- Same
- Better

QUESTIONS TO DISCUSS WITH YOUR DOCTOR

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Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.

Questions about your treatment? Teva’s Shared Solutions® can help. Call 1-800-887-8100
Week 7  month/day-month/day

Record each dose
After the morning and evening dose of AUSTEDO® (deutetrabenazine) tablets has been taken, place a check mark in the corresponding box.

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Assess your activity
Each week, evaluate your uncontrolled movements of TD and the impact they’ve had on daily activities as compared to the previous week.

UNCONTROLLED MOVEMENTS
(Face and mouth)

- Worse
- Same
- Better

(Arms, legs, trunk)

- Worse
- Same
- Better

ABILITY TO DO DAILY ACTIVITIES
(eg, eating and drinking, bathing and grooming, household chores, etc)

- Worse
- Same
- Better

QUESTIONS TO DISCUSS WITH YOUR DOCTOR

Questions about your treatment? Teva’s Shared Solutions® can help. Call 1-800-887-8100

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
Shared Solutions®

Your partner, here to support you

Call Teva’s Shared Solutions® at 1-800-887-8100

Please read Important Safety Information on pages 10-12 and the accompanying Medication Guide.
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 breastfeeding. 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. 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)
• 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.

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, 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.

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