AUSTEDO® is a prescription medicine that is used to treat the involuntary movements (chorea) of Huntington's disease in adults.

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.

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 complete Important Safety Information on pages 20-21 and the accompanying Medication Guide.
WHAT IS HD CHOREA?

Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
Understanding Huntington’s Disease

Huntington’s disease (HD) is a hereditary disorder that affects nerve cells in the brain.

HD causes physical, emotional, behavioral, and cognitive issues, and has 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)

- **Movement**
  (motor symptoms, including chorea)

- **Mood**
  (emotions/behavior)

Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
Chorea is the most visible symptom of HD

It may appear as unexpected and uncontrolled jerking and twisting body movements. These movements can be large or small, and may worsen with stress.

Signs of chorea may include:

- Flicking the fingers
- Flailing of the arms or legs
- Shrugging the shoulders
- Having a grimacing look
- Irregular eye movements or blinking
The impact of HD chorea

People with HD chorea may find it difficult to do everyday things like going to the bathroom, taking a walk, or dressing themselves without help.

HD chorea may also make it difficult to talk, chew, and swallow.

In a survey, care partners reported chorea as the most impactful symptom of HD. As HD progresses, people experiencing movements may have pain, and may become increasingly dependent on their care partners for help. They often find they can no longer drive a car or work outside the home.

Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
If you’ve answered yes to one or more of these questions, talk to your doctor about the impact of HD chorea and how you can manage it.
How AUSTEDO® may help

In a clinical study, AUSTEDO® (deutetrabenazine) tablets was effective for the treatment of Huntington's disease chorea.

AUSTEDO® is thought to work by inhibiting the release of dopamine, which is related to the involuntary movements associated with HD chorea.

AUSTEDO® dosing is personalized. Your doctor will work with you to find the dose that's right for you.

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

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®).

Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
Clinical study details

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

90 people with HD chorea were studied for 12 weeks.

45 people randomly selected to take AUSTEDO®

45 people randomly selected to take placebo (inactive tablets)

People’s involuntary movements were measured at the beginning and end of the study, with movements also being observed at intervals throughout the 12-week period.
first goal of the study:

To measure the effectiveness of AUSTEDO® (deutetrabenazine) tablets on HD chorea using the Total Maximal Chorea (TMC) score.

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.

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
Clinical study results

AUSTEDO® (deutetrabenazine) tablets significantly reduced Huntington’s disease chorea vs. placebo

Change in Total Maximal Chorea (TMC) score at the end of the 12-week study*

The TMC score improved by **4.4 points** in people 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 people taking AUSTEDO® vs 2% of people taking placebo.

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

**IMPORTANT SAFETY INFORMATION**

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.

Please read **Important Safety Information** on pages 20-21 and the accompanying **Medication Guide**.
Self-reported symptom improvement

Overall HD symptoms were rated as “much improved” or “very much improved” with AUSTEDO® (deutetrabenazine) tablets vs placebo.

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

51% of people 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 people taking AUSTEDO® reported that overall HD symptoms observed were “much improved” or “very much improved” at the end of treatment, compared with 13% treating people 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.

IMPORTANT SAFETY INFORMATION

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.
- 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.
Common side effects

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

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

2% of people taking AUSTEDO® dropped out of the study due to side effects.

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.

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.

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.

In the clinical study, AUSTEDO® provided significant and meaningful control of HD chorea with demonstrated safety and tolerability. 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

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 tardive dyskinesia include inflammation of the nose and throat (nasopharyngitis) and problems sleeping (insomnia).
STARTING TREATMENT

Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
Personalized dosing

AUSTEDO® (deutetrabenazine) tablets dosing is personalized, meaning you can work with your doctor to find the dose that’s right for you.

Available in three strengths

- 6 mg
- 9 mg
- 12 mg

Your prescribed dose may require a combination of AUSTEDO® tablet strengths.

Your doctor may increase your dose of AUSTEDO® each week for several weeks to find the dose that is appropriate for you. This process is known as titration. It is important to follow your doctor’s instructions during this process. While many people experience treatment benefits sooner, it may take up to 12 weeks to reach the full benefits of AUSTEDO®.

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

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

Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
Switching from tetrabenazine

When switching to AUSTEDO® (deutetrabenazine) tablets from tetrabenazine, you can start AUSTEDO® the day after you stop tetrabenazine.

This means you can continue treating your HD chorea without missing a dose.

In a clinical study, 37 people with HD chorea switched overnight from tetrabenazine to AUSTEDO®. People in the study received AUSTEDO® at approximately half the dose of tetrabenazine.

IMPORTANT SAFETY INFORMATION

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®).
Please read Important Safety Information on pages 20-21 and the accompanying Medication Guide.
Financial support from Teva’s Shared Solutions®

Our team of dedicated Benefits Specialists are committed to helping you gain access to AUSTEDO® (deutetrabenazine) tablets as soon as possible.

- Financial assistance eligibility determination
- Assistance with navigating Medicare Part D
- Additional financial assistance programs may exist, depending on your insurance coverage and certain eligibility requirements

* 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 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 (ie 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.
Our commitment to you

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

- Nurse phone support. Our trained nurses are available by phone, so you will have someone to talk to about your AUSTEDO® treatment
- Communication through email, mail, or phone to help support you throughout your AUSTEDO® treatment

For financial assistance and nurse support, call Teva’s Shared Solutions® at 1-800-887-8100
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.

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®).
IMPORTANT SAFETY INFORMATION (CONTINUED)

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.

**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.
Now is the time

Talk to your doctor about how AUSTEDO® (deutetrabenazine) tablets may help manage HD chorea

Treats the involuntary movements of HD chorea.

Dosing is personalized, allowing you and your doctor to work together to determine the dose that’s appropriate for you.

In a clinical study, the most common side effects of AUSTEDO® included sleepiness (sedation), diarrhea, dry mouth, and tiredness.

Teva’s Shared Solutions® is committed to supporting you throughout your AUSTEDO® treatment.

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 complete Important Safety Information on pages 20-21 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 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. 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.
- 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.

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