

Chorea is involuntary body movements associated with Huntington's disease (HD), a hereditary disorder that affects nerve cells in the brain. These uncontrolled jerking and twisting movements are the most visible symptoms of HD.



If you are considering treatment for HD chorea for yourself or your loved one, begin by having an informed discussion with your healthcare provider. Answer the questions below with your care partner or loved one and bring this guide with you to your next doctor's appointment.

1 Which of the following involuntary movements are you experiencing?

SELECT ALL THAT APPLY:

Flicking the fingers

Flailing arms and/or legs

Shrugging the shoulders

Grimacing

Jerking and/or twisting

Irregular eye movements or blinking

2 How often do you experience these involuntary movements?

PLEASE SELECT ONE:

Multiple times per minute

Multiple times per hour

Multiple times per day

Other

3 Do you have trouble with any of these daily activities?

SELECT ALL THAT APPLY:

Getting dressed

Drinking beverages

Brushing your teeth

Bathing

Speaking clearly

Swallowing and/or eating

Other

None

4 Does someone help assist you with everyday tasks?

PLEASE SELECT ONE:

Yes

No

5 Has a loved one or care partner noticed your unintentional movements?

PLEASE SELECT ONE:

Yes

No

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.

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[®]).

Please read Important Safety Information continued on the following page and the accompanying Medication Guide.

In a clinical study, AUSTEDO was effective for the treatment of HD chorea. AUSTEDO dosing is personalized, meaning you can work with your doctor to find the dose that's right for you.

Ask your doctor about managing HD chorea with AUSTEDO.

These questions will help you learn more about AUSTEDO treatment. When discussing the following, be sure to:

i Use the space provided to note your doctor's responses and any additional concerns you may have.

i Ask your doctor to carefully review any topic you are not clear about.

1. Will my HD chorea get worse over time?
2. How may AUSTEDO help me?
3. What is the Total Maximal Chorea (TMC) score? How is it used to determine the effectiveness of HD chorea treatment?
4. How does personalized dosing work with AUSTEDO and how will it impact my HD chorea treatment?
5. How do I take AUSTEDO?
6. Can you tell me about possible side effects of AUSTEDO?
7. What patient and care partner support will be available during AUSTEDO treatment?

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.
- **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 are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please read 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.
- **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.

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