

MEDICATION GUIDE
AUSTEDO[®] XR (*aw-STED-oh XR*)
(deutetrabenazine) extended-release tablets, for oral use
AUSTEDO[®] (*aw-STED-oh*)
(deutetrabenazine) tablets, for oral use

What is the most important information I should know about AUSTEDO XR and AUSTEDO?

- AUSTEDO XR and AUSTEDO can cause serious side effects in people with Huntington's disease, including:
 - depression
 - suicidal thoughts
 - suicidal actions
- Do not start taking AUSTEDO XR or 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 XR or 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 are AUSTEDO XR and AUSTEDO?

AUSTEDO XR and AUSTEDO are prescription medicines that are used to treat:

- the involuntary movements (chorea) of Huntington's disease. AUSTEDO XR and AUSTEDO do 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 XR and AUSTEDO are safe and effective in children.

Who should not take AUSTEDO XR or AUSTEDO?

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

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

How should I take AUSTEDO XR or AUSTEDO?

- Take AUSTEDO XR or AUSTEDO exactly as your healthcare provider tells you to take it.
- If you take AUSTEDO XR, take your dose by mouth one time each day, with or without food.
- If you take AUSTEDO, take your dose by mouth and with food. If your dose of AUSTEDO is 12 mg or more each day, take AUSTEDO tablets 2 times a day in equal doses.
- Swallow AUSTEDO XR or AUSTEDO tablets whole with water. Do not chew, crush, or break AUSTEDO XR or AUSTEDO tablets before swallowing. If you cannot swallow AUSTEDO XR or AUSTEDO tablets whole, tell your healthcare provider. You may need a different medicine.
- The AUSTEDO XR tablet shell does not dissolve completely in the body after all the medicine has been released. Sometimes the tablet shell may be seen in your stool. This is normal.
- Your healthcare provider may increase your dose of AUSTEDO XR or 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 XR or 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 XR or AUSTEDO?

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

What are the possible side effects of AUSTEDO XR and AUSTEDO?

AUSTEDO XR and 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 XR and AUSTEDO?"
- **Irregular heartbeat (QT prolongation).** AUSTEDO XR and 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 XR or 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
 - stiff muscles
 - problems thinking
 - very fast or uneven heartbeat
 - increased sweating
- **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)
- tiredness
- diarrhea
- 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)

The most common side effects of AUSTEDO XR are expected to be similar to AUSTEDO in people with Huntington's disease or tardive dyskinesia.

These are not all the possible side effects of AUSTEDO XR or 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 XR and AUSTEDO?

- Store AUSTEDO XR and AUSTEDO tablets at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed to protect AUSTEDO XR and AUSTEDO from light and moisture.
- Do not throw away the desiccant canister in the bottle until the last dose of AUSTEDO XR or AUSTEDO is taken.

Keep AUSTEDO XR and AUSTEDO and all medicines out of the reach of children.

General information about the safe and effective use of AUSTEDO XR and AUSTEDO.

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

What are the ingredients in AUSTEDO XR and AUSTEDO?**AUSTEDO XR:**

Active ingredient: deutetrabenazine

Inactive ingredients: ammonium hydroxide, black iron oxide, butyl alcohol, butylated hydroxyanisole, butylated hydroxytoluene, cellulose acetate, hydroxypropyl cellulose, hypromellose, isopropyl alcohol, magnesium stearate, polyethylene glycol, polyethylene glycol 3350, polyethylene oxide, polyvinyl alcohol, propylene glycol, shellac, sodium chloride, talc, titanium dioxide, and FD&C red #40 lake. The 6 mg, 12 mg, 18 mg, 30 mg, 36 mg, and 42 mg extended-release tablets also contain FD&C yellow #6 lake. The 6 mg, 12 mg, 24 mg, and 36 mg extended-release tablets also contain FD&C blue #2 lake. The 18 mg extended-release tablets also contain carmine.

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.

Manufactured for:

Teva Neuroscience, Inc.

Parsippany, NJ 07054

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AUSMG-010

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: July 2024

AUS-47099