

Huntington's disease (HD) in adults



seize the everyday



Models are not actual patients

Patient Treatment Tracking Guide

Helping you set goals and track HD chorea treatment progress with AUSTEDO (deutetrabenazine) tablets

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 Important Safety Information on pages 12-13 and the accompanying Medication Guide.

Patient Treatment Tracking Guide

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Model is not



actual patients

Welcome

This resource is designed to address questions, provide support, and guide conversations with your doctor in order to help you or the person you care for set goals and track HD chorea treatment progress with AUSTEDO® (deutetrabenazine) tablets.

How to use this resource:

- Define your personal HD chorea treatment goals.
- 2. Determine the steps you'll take to achieve those goals.
- **3.** Track progress during treatment with AUSTEDO.
- **4.** Bring this guide with you to each doctor appointment to help assess progress and discuss treatment.

Huntington's disease chorea treatment goals

You and your healthcare team have worked together to develop a plan to treat your/your loved one's HD chorea that includes AUSTEDO® (deutetrabenazine) tablets. To help ensure that you or the person you care for stay on track with the plan, it's important to define HD chorea treatment goals.

Here are a few questions to get you started.

Write answers in the spaces provided, and share them with your healthcare team:

1.	What involuntary movements are you hoping that treatment will help?
2.	What HD chorea treatment goals have you/your loved one set with your healthcare team?
3.	What steps have you/your loved one and your healthcare team identified to help you achieve those HD chorea treatment goals?
4.	How will achieving HD chorea treatment goals help you and/or the person you care for?

What to expect once your doctor prescribes AUSTEDO® (deutetrabenazine) tablets

AUSTEDO tablets are available in three strengths. Your/your loved one's prescribed dose may require a combination of tablet strengths.







tablets not actual size

Filling your prescription:

- Your doctor may write your/your loved one's prescription on paper and have you bring it to your pharmacy, or may send it electronically to your pharmacy.
- A pharmacy will process your/your loved one's prescription using the information provided.
- Your/your loved one's prescription will be filled by your pharmacy.
- After you receive your/your loved one's prescription, discuss any additional questions you have about how to take AUSTEDO with the pharmacist or your doctor.

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®).





Reaching your appropriate dose

AUSTEDO® (deutetrabenazine) tablets is a titrated medication, meaning that your/your loved one's dose may be adjusted throughout the first few weeks of treatment until your doctor identifies the appropriate dose. Each dosing schedule is *personalized* to an *individual's needs*, ensuring your doctor will prescribe the *dose that works best for you/your loved one*.

It's important to take
AUSTEDO exactly as
prescribed by your doctor.
Be sure to ask your doctor
or pharmacist if you
have any questions about
prescription instructions
or the titration process.



Models are not actual patients

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.





The importance of taking AUSTEDO® (deutetrabenazine) tablets as prescribed

Life can get busy and sometimes it's not always easy to remember all of your doctor's instructions. However, it is important that you/your loved one continue to take AUSTEDO exactly as prescribed by your doctor.



Exactly as prescribed



By mouth



Whole (do not chew, crush, or break tablets)*



With food

*If you cannot swallow AUSTEDO tablets whole, tell your healthcare provider. You may need a different medicine.

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.



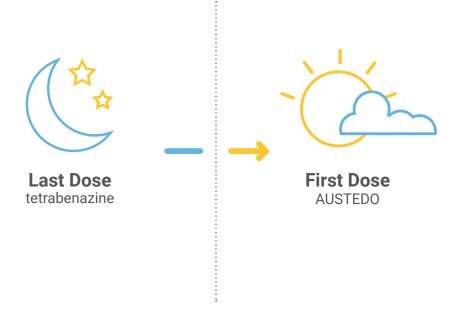


Switching from tetrabenazine

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®).





Staying on track

Whether they see progress as expected or not, it's important that people on AUSTEDO® (deutetrabenazine) tablets take it exactly as prescribed. If you have concerns, talk to your doctor so he or she can make adjustments to your/your loved one's dose as necessary.



- Create and follow a dosing routine. Remember that AUSTEDO must be taken exactly as prescribed
- You can set an alarm as a treatment reminder
- Set a routine
- Keep your/your loved one's AUSTEDO tablets in the same place so you know where they are



Record treatment

Use the Progress Tracker and Activity Log included in this guide to record when AUSTEDO is taken, and any questions you have for your doctor



Have a plan

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- Before starting AUSTEDO, talk to your doctor about what to do if you/your loved one miss(es) a dose
- Attach your/your loved one's dosing schedule to other daily routines so you are less likely to miss a dose
- Tell your doctor if you/your loved one stop(s) taking AUSTEDO for more than 1 week. Do not take another dose until you talk to your doctor

IMPORTANT SAFETY INFORMATION

Other possible serious side effects include:

- 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.







Answering your concerns

It's completely normal to have concerns when starting a new medication. Here are some common questions from patients and care partners, with answers provided by a healthcare professional:

Q: Why did my doctor prescribe AUSTEDO® (deutetrabenazine) tablets for me/the person I care for?

A: After discussing your/your loved one's HD chorea with you, your doctor likely considered the impact uncontrolled movements were having on your/your love one's life and how AUSTEDO may help before making the decision to prescribe it.

In a clinical study, AUSTEDO was effective for the treatment of HD chorea.

Q: How long does it take for AUSTEDO to start working?

A: HD chorea affects everyone differently, so treatment results may vary from person to person. While some people may start to experience treatment benefits sooner, it may take up to 12 weeks to reach the full benefits of AUSTEDO.

At your next appointment, your doctor will assess your/your loved one's progress and together, the two of you can decide if your treatment plan should be adjusted or not.

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.





Q: What does titration mean?

A: Titration is the process of the doctor adjusting the dose of a medication to determine the appropriate dose based on how well the medication is helping and any side effects. When you/your loved one start(s) taking AUSTEDO® (deutetrabenazine) tablets, your doctor will work with you/your loved one to adjust the daily dose up or down for a period of time until he or she finds the right dose based on reduction of uncontrolled movements and how well the medicine is tolerated. This titration period is different for everyone. This is one of the reasons AUSTEDO dosing is personalized. It's important to take AUSTEDO exactly as your doctor tells you/your loved one to take it.

Q: What happens after titration?

A: Once your doctor determines the dose of AUSTEDO that's right for you/your loved one, then that amount would become the ongoing maintenance dose. It's important to track treatment progress (using the Progress Tracker included in this guide) both during the titration period and with the maintenance dose, so your/your loved one's treatment plan can be adjusted if something changes.

Q: What about side effects?

A: Read the Important Safety Information on the following pages and the accompanying Medication Guide to learn about possible side effects of AUSTEDO. As with any medication, it's always important to discuss any and all possible side effects with your doctor before you/your loved one start(s) taking AUSTEDO. It's also important to keep your doctor informed as to how you or your loved one is feeling throughout treatment. If something doesn't feel right, discuss it with your doctor first so he or she can adjust your/your loved one's treatment plan as necessary.

Q: What happens if I/the person I'm caring for forget(s) and miss(es) a dose?

A: As cognitive function declines, people with Huntington's disease may find it difficult to remember to take their medications as prescribed. Before starting AUSTEDO, talk to your doctor about what to do if you/your loved one forget(s) a dose. Also, be sure to tell your doctor if you/your loved one stop(s) taking AUSTEDO for more than 1 week. Do not take another dose until you talk to your doctor. Using the Progress Tracker and Activity Log included later in this guide will help you/your loved one remember to take daily medication as prescribed.

IMPORTANT SAFETY INFORMATION

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).







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.
- 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.



Huntington's Disease Online Resources

Below are several online resources you may find helpful if you have questions about Huntington's disease.

Huntington's Disease Society of America (HDSA) hdsa.org

Honestly HD facebook.com/HonestlyHD

National Institutes of Health (NIH) ghr.nlm.nih.gov/condition/huntington-disease

MedlinePlus medlineplus.gov/huntingtonsdisease.html

Family Caregiver Alliance (FCA) caregiver.org

National Alliance for Caregiving (NAC) caregiving.org

Caregiver Action Network (CAN)
caregiveraction.org

Help for HD International help4hd.org

Huntington's Disease Lighthouse Families hdlf.org

> HD Buzz en.hdbuzz.net

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Please read **Important Safety Information** on pages 12-13 and the accompanying **Medication Guide**.



Progress tracker and activity log

A guide to help you when talking to your doctor during your/your loved one's treatment with AUSTEDO® (deutetrabenazine) tablets

How to use this tool

1. Recording treatment

"Did I take my medication this morning?" Or, "Do I need to take another dose?" Avoid these questions by using the progress tracker daily.

Write the Week # (eg, Week 1) and the month/day/year you/your loved one start(s) treatment.

Note your prescribed dose for that week from the dosing instructions provided by your doctor. Be sure to indicate whether you are in the titration period or taking the ongoing maintenance dose. It's important to track progress both during the titration period and with the maintenance dose, so your/your loved one's treatment plan can be adjusted if something changes.

Each day, *indicate with a check mark* when AUSTEDO is taken in the morning and in the evening (sun and moon symbols).

☐ Titration (T):

The process of adjusting the dose to find the dose that's right for you/your loved one.

Maintenance Dose (M):
Your/your loved one's ongoing
daily dose after your doctor has
determined the right amount
of medicine for you/your loved
one (after titration ends).

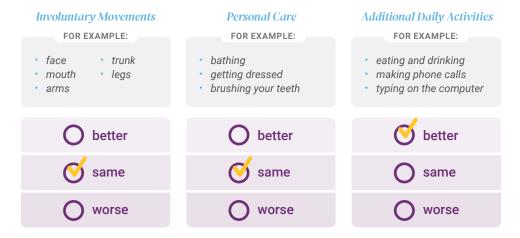
SUN	MON	TUES	WED	THURS	FRI	SAT
-MA	-MA	- AM	- AM	- AM	- AM	- AM
S PM	€ PM	€ PM	€ PM	€ PM	S PM	€ PM
	/	V				





2. Using the activity log

Do you or the person you care for have involuntary body movements that make doing some of the everyday activities listed below more difficult? At the end of each week, take a few minutes to **evaluate your/your loved one's involuntary movements** and the impact they may have on daily activities compared to last week. In the space provided, **write down any questions** that you'd like to discuss with your doctor during your next conversation. You should also **bring this log with you** to any doctor's appointments you may have within the next few weeks.



3. Notes

Use this space to *write down any questions you'd like to discuss* with your doctor during your next visit, take any notes about your/your loved one's daily dose, and also record accomplishments you'd like to celebrate during the week.

QUESTIONS TO DISCUSS WITH MY DOCTOR	THIS WEEK I ACCOMPLISHED

If you need additional Progress Tracker and Activity Log sheets, go to www.austedo.com/huntingtons-chorea/resources.

Remember to bring this log with you to all upcoming doctor appointments.







	(deutetrabenazine) 6 mg, 9 mg, and 12 mg tablets		
Week #		/	
PRESCRIBED DOSE	CHECK ONE		
mg times a day	Titration	Maintenance dose	

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	AM AM	₽Ď: AM	AM	AM	AM	AM AM
S PM	€ PM	Ç PM	S PM	S PM	S PM	€ PM

Rate ability to do daily activities as compared to last week

At the end of each week, take a few minutes to evaluate your involuntary movements and rate the impact of HD chorea on the ability to perform certain activities compared to last week.

Involuntary Movements	Personal Care	Additional Daily Activities
FOR EXAMPLE:	FOR EXAMPLE:	FOR EXAMPLE:
facetrunkmouthlegsarms	bathinggetting dressedbrushing your teeth	eating and drinkingmaking phone callstyping on the computer
O better	O better	O better
o same	o same	O same
O worse	O worse	O worse
QUESTIONS TO DISCUSS WITH	MY DOCTOR 1	THIS WEEK I ACCOMPLISHED
1		

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Please read Important Safety Information on pages

12-13 and the accompanying Medication Guide.



		leutetrabenazine) 6 mg, 9 mg, and 12 mg tablets		
Week #	_	_	//	
PRESCRIBED DOSE		CHECK ONE		
mg	times a day	Titration	Maintenance dose	

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	AM	AM AM	AM	AM	AM	AM
S PM	S PM	€ PM	S PM	C PM	S PM	C PM

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Week #		/
PRESCRIBED DOSE	CHECK ONE	
mg times a	a day Titration	Maintenance dose

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	₽Ď: AM	₽Ď: AM	AM	AM	AM	AM
S PM	Ç PM	Ç PM	C PM	S PM	S PM	€ PM

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Week #	_		//	
PRESCRIBED DOSE		CHECK ONE		
mg	times a day	Titration	Maintenance dose	

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	AM AM	AM AM	AM	AM	AM	AM
S PM	S PM	€ PM	S PM	C PM	S PM	C PM

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QUESTIONS TO DISCUSS WITH		THIS WEEK I ACCOMPLISHED

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			(deutetrabenazine) 6 mg. 9 mg. and 12 mg tablets		
We	eek #			/	
PRE	ESCRIBED DOS	Е	CHECK ONE		
	mg	times a day	Titration	Maintenance dose	

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	AM AM	AM	AM	AM	AM	AM
S PM	S PM	Ç PM	S PM	C PM	S PM	€ PM

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1		

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		(deutetrabenazine) 6 mg, 9 mg, and 12 mg tablets		
Week #			//	
PRESCRIBED DOSE		CHECK ONE		
mg	times a day	+ Titration	Maintenance dose	

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	AM	₽ĎĘ AM	AM	AM	AM	AM
S PM	€ PM	Ç PM	€ PM	S PM	S PM	S PM

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		deutetrabenazine) 6mg, 9 mg, and 12 mg tablets		
Week #	_	_	//	
PRESCRIBED DOSE		CHECK ONE		
mg	times a day	Titration	Maintenance dose	

23

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

SUN	MON	TUES	WED	THURS	FRI	SAT
AM	AM AM	₽Ď: AM	AM	AM	AM	AM AM
S PM	€ PM	Ç PM	S PM	S PM	S PM	€ PM

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O better	O better	O better	
o same	Same	Same	
O worse	O worse	O worse	
QUESTIONS TO DISCUSS WITH MY DOCTOR		THIS WEEK I ACCOMPLISHED	
Please read Important Sa	afety Information on pages	EAustedo: Long	

12-13 and the accompanying Medication Guide.

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Health information

AUSTEDO® (deutetrabenazine) tablets start date: Primary care doctor _____ Phone number _____ Address _____ Neurologist _____ Phone number _____ Address Hospital _____ Phone number Address _____ Pharmacy _____ Phone number Address Insurance carrier _____ Phone number _____





Health insurance member

Appointment record

Record your next appointment date in the space provided.

My next appointment is:	My next appointment is:
MONTH:	MONTH:
DAY: TIME: AM / PM	DAY: TIME: AM/P
NOTES:	NOTES:
My next appointment is:	My next appointment is:
WONTH.	MONTH.
DAY: TIME: AM / PM	DAY: TIME: AM/P
NOTES:	NOTES:
My next appointment is:	My next appointment is:
MONTH:	MONTH:
DAY: TIME: AM / PM	DAY: TIME: AM/P





For those with HD chorea, life in the moment can't wait.

Now is the time.



Models are not actual patients

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

Visit www.austedo.com to learn more.

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 12-13 and the accompanying **Medication Guide**.

The brands listed are the registered trademarks of their respective owners.

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AUS-42856 January 2021



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 quilty
- · 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.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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