ONCE-DAILY

Austedo® XR

(deutetrabenazine) extended-release

6 mg, 12 mg, 18 mg, 24 mg, 30 mg, 36 mg, 42 mg, and 48 mg tablets

PointClickCare®

PointClickCare order instructions manual: AUSTEDO XR

Table of contents

INDICATIONS AND USAGE

AUSTEDO XR and AUSTEDO are indicated in adults for the treatment of chorea associated with Huntington's disease and for the treatment of tardive dyskinesia.

IMPORTANT SAFETY INFORMATION

Depression and Suicidality in Patients with Huntington's Disease: AUSTEDO XR and AUSTEDO can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Balance the risks of depression and suicidality with the clinical need for treatment of chorea. Closely monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior. Inform patients, their caregivers, and families of the risk of depression and suicidality and instruct them to report behaviors of concern promptly to the treating physician. Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation. AUSTEDO XR and AUSTEDO are contraindicated in patients who are suicidal, and in patients with untreated or inadequately treated depression.

Please see additional Important Safety Information throughout and click here to visit www.AUSTEDOhcp.com to read/print the full Prescribing Information, including Boxed Warning, for AUSTEDO XR.

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Overview of AUSTEDO XR Pharmacy Order Template: full template example

To access and manage the AUSTEDO XR Pharmacy Order Template, the default template must be published at the corporate level. Once published, it will be active and available to facilities.

In the default AUSTEDO XR Pharmacy Order Template shown on page 2, certain fields will be prefilled to support efficient pharmacy order entry and medication administration. Throughout this manual, any field that requires an entry by the facility user will be noted.

Please note that names mentioned in this manual are not real residents or providers.

Please see the PointClickCare (PCC) Trail Guide for in-depth instructions on using the AUSTEDO Pharmacy Order Template.

Please reference the ICD-10 codes for tardive dyskinesia (TD) and Huntington's disease (HD) chorea below, as well as the NDC billing codes chart for one pill, once-daily AUSTEDO XR dosage strengths.

Billing Codes

ICD-10 CM Diagnosis Code:

G24.01 Tardive Dyskinesia (TD) and G10 Huntington's Chorea (HD)

AUSTEDO XR Dosage	10-digit NDC	11-digit NDC
4-week Titration Kit	68546-477-29	68546-0477-29
12 mg	68546-471-56	68546-0471-56
18 mg	68546-479-56	68546-0479-56
24 mg	68546-472-56	68546-0472-56

AUSTEDO XR Dosage	10-digit NDC	11-digit NDC
30 mg	68546-473-56	68546-0473-56
36 mg	68546-474-56	68546-0474-56
42 mg	68546-475-56	68546-0475-56
48 mg	68546-476-56	68546-0476-56

Please note that for some prior authorization submissions, an Abnormal Involuntary Movement Scale (AIMS) score may be required.

IMPORTANT SAFETY INFORMATION (Continued)

Contraindications: AUSTEDO XR and AUSTEDO are contraindicated in patients with Huntington's disease who are suicidal, or have untreated or inadequately treated depression. AUSTEDO XR and AUSTEDO are also contraindicated in: patients with hepatic impairment; patients taking reserpine or within 20 days of discontinuing reserpine; patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of discontinuing MAOI therapy; and patients taking tetrabenazine or valbenazine.

AUSTEDO XR Pharmacy Order Template Default

Order Details

Order Date: 8/24/2023 12 03 *
Order Category: Pharmacy *
Communication Method: Phone Verbal Prescriber written Prescriber entered *
Ordered By: * Last prescribed by: Nicole Barilla
(Current Primary Physician: Harold Bassett)
Medication: Austedo XR Oral Tablet Extended Release 24 Hour clear *
Order Template: * Austedo XR (deutetrabenazine) Titration for Involuntary Movements re: TD or HD
Generic: Deutetrabenazine
Medication Class: PSYCHOTHERAPEUTIC AND NEUROLOGICAL AGENTS - MISC.
Dispense as Written (DAW):
Order Type: Medication - [MAR] *
Route of Administration: by mouth show all *

Scheduling Details

Add Schedule: Routine PRN One Time Only Next Titration STAT

Titration 1 | Titration 2 | Titration 3 | Titration 4 | Titration 5 | Titration 6 | Titration 7

Dose or Admin Quantity: 12 mg show all *
Frequency: one time a day *
Schedule Type: Everyday *
Facility Time Code: *
Start Date: 8/24/2023 12 03 *
End Date: Duration 7 Day 08/31/2023 12 02 *
Requires Reassessment
Admin Notes
Supplementary Documentation: SEs, SXs

Related Diagnoses: clear
For (Indications for Use): Involuntary Movements clear
Additional Directions: Do Not Crush, Chew, or Break Tablet.
Administered By: Clinician Assisted Non-Clinical Staff Supervised Self-Administration Unsupervised Self-Administration *

Source Details

Permanent Medication Source: Pharmacy * Inventory on Hand
Pharmacy: ACME Pharmacy *
Pharmacy Notes:

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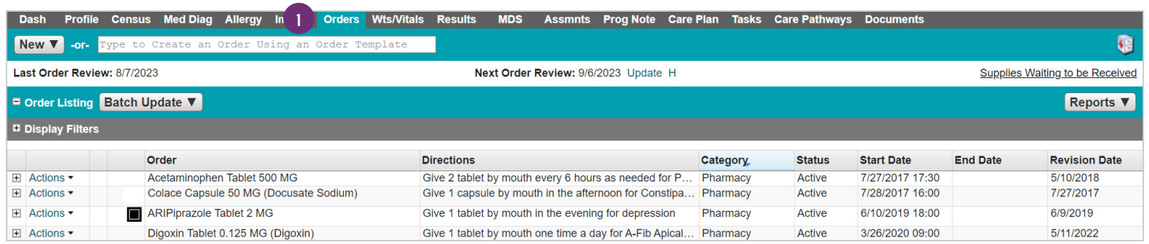
Accessing the AUSTEDO XR Pharmacy Order Template

There are two options available for users to access the AUSTEDO XR Pharmacy Order Template and order AUSTEDO XR for residents.

Option 1: New Order Entry—medication search

1 Select "Clinical" > "Residents" > select the specified resident > "Orders" to access a resident's record and "Order Listing" view.



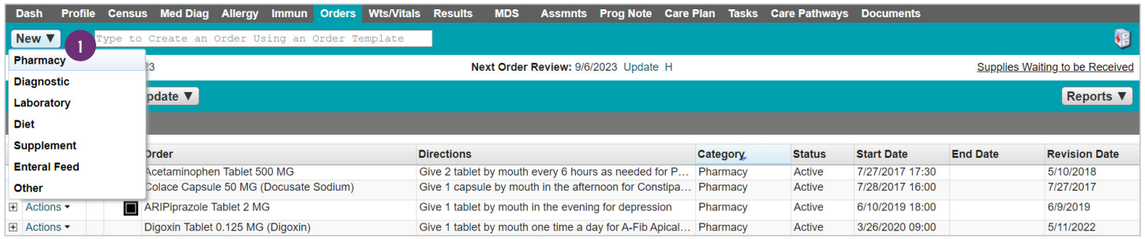
2 Add a new order for the resident using the "Type to Create an Order Using an Order Template" search bar. Search for "Austedo XR (deutetrabenazine) Titration for Involuntary Movements" and the appropriate diagnosis to populate the correct PCC Pharmacy Order Template.

IMPORTANT SAFETY INFORMATION (Continued)

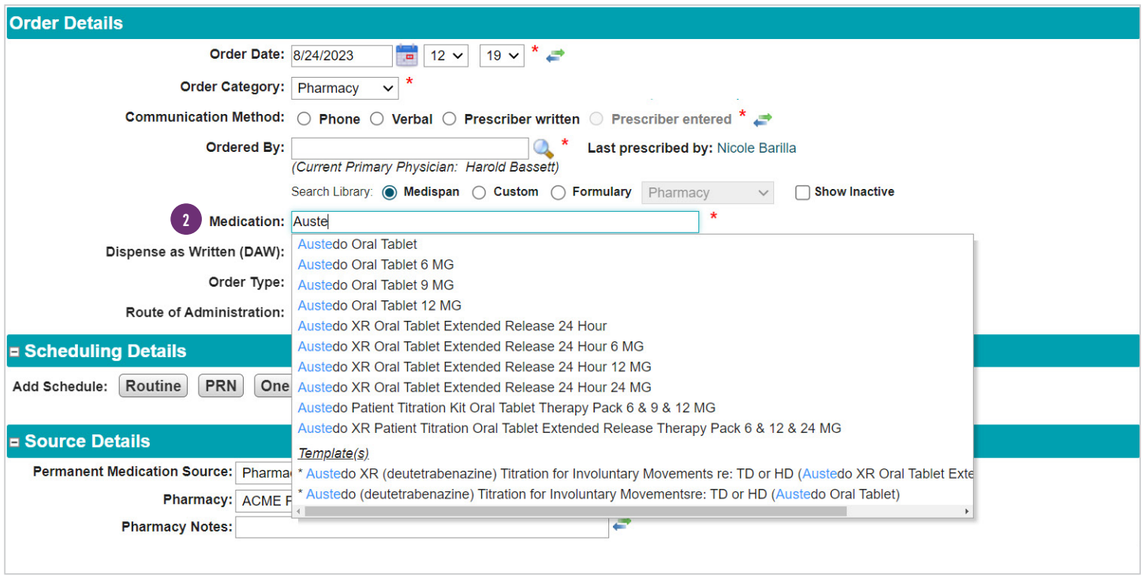
Clinical Worsening and Adverse Events in Patients with Huntington's Disease: AUSTEDO XR and AUSTEDO may cause a worsening in mood, cognition, rigidity, and functional capacity. Prescribers should periodically re-evaluate the need for AUSTEDO XR or AUSTEDO in their patients by assessing the effect on chorea and possible adverse effects.

Option 2: New Order Entry–pharmacy search

1 Under the "Orders" tab in a resident's record, click on "New" and then select "Pharmacy" to open a blank PCC Pharmacy Order Template.



2 Navigate toward the "Order Details" section of the blank PCC Pharmacy Order Template and search for "Austedo Oral Tablet" and the appropriate dose in the "Medication" field.



Either new order entry method will take users to the same AUSTEDO XR Pharmacy Order Template. It is important to remember that certain template details will be prefilled and will need to be reviewed by the user.

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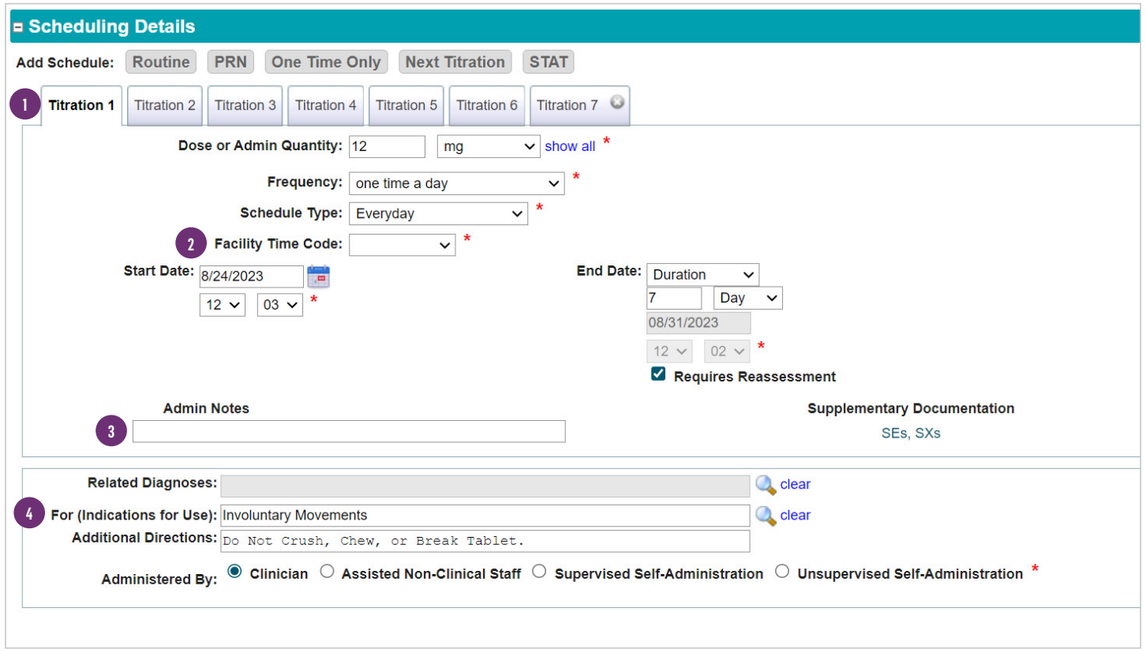
Completing the AUSTEDO XR Pharmacy Order Template

Scheduling Details

The "Scheduling Details" section allows users to verify a resident's titration schedule. Titration doses are automatically prefilled for each titration week based on the Prescribing Information for one pill, once-daily AUSTEDO XR. The titration schedule on the following page outlines the default doses for each titration week—increasing in increments of 6 mg up to a maximum total daily dose of 48 mg.[1] Duration will be prefilled to 7 days per the titration schedule. Users should confirm the preselected fields for each resident's order before moving to the next section in the order template.



1. Navigate through each titration tier and confirm the correct start and end date based on the start and end date for Titration 1. Please note the end date for Titration 7 will be indefinite. Users can use the titration schedule for one pill, once-daily AUSTEDO XR as a reference.

2. Depending on each facility, the "Facility Time Code" field may be predefined and available for the user to select using the drop-down menu. If a Facility Time Code is not predefined, the user will need to enter it into the field.

3. The "Admin Notes" field is used to provide staff with additional information. Users can enter additional notes requested by the provider into this field.

4. Users can adjust the "For (Indications for Use)" field to give more details about a resident's formal diagnosis.

IMPORTANT SAFETY INFORMATION (Continued)

QTc Prolongation: AUSTEDO XR and AUSTEDO may prolong the QT interval, but the degree of QT prolongation is not clinically significant when AUSTEDO XR or AUSTEDO is administered within the recommended dosage range. AUSTEDO XR and AUSTEDO should be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias.

Neuroleptic Malignant Syndrome (NMS), a potentially fatal symptom complex reported in association with drugs that reduce dopaminergic transmission, has been observed in patients receiving tetrabenazine. The risk may be increased by concomitant use of dopamine antagonists or antipsychotics. The management of NMS should include immediate discontinuation of AUSTEDO XR and AUSTEDO; intensive symptomatic treatment and medical monitoring; and treatment of any concomitant serious medical problems.

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Completing the AUSTEDO XR Pharmacy Order Template (Continued)

For reference: titration schedule for AUSTEDO and one pill, once-daily AUSTEDO XR

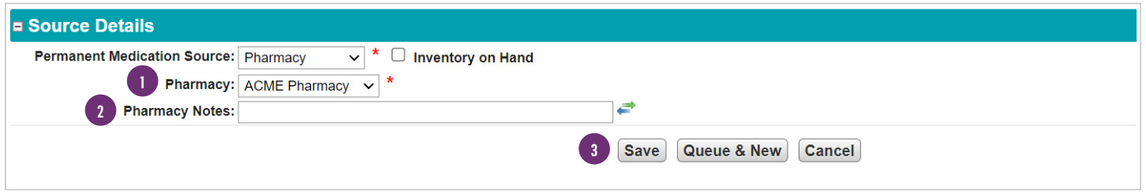
Increase dose of AUSTEDO and AUSTEDO XR toward effective and tolerable symptom control.[1]

	AUSTEDO				ONE PILL, ONCE-DAILY AUSTEDO XR			
	Schedule	Dose to Admin.	Frequency	End Date Duration	Schedule	Dose to Admin.	Frequency	End Date Duration
Week 1	Titration 1	6 mg	Two times a day	7 Days	Titration 1	12 mg	Every day	7 Days
Week 2	Titration 2	9 mg	Two times a day	7 Days	Titration 2	18 mg	Every day	7 Days
Week 3	Titration 3	12 mg	Two times a day	7 Days	Titration 3	24 mg	Every day	7 Days
Week 4	Titration 4	15 mg	Two times a day	7 Days	Titration 4	30 mg	Every day	7 Days
Week 5	Titration 5	18 mg	Two times a day	7 Days	Titration 5	36 mg	Every day	7 Days
Week 6	Titration 6	21 mg	Two times a day	7 Days	Titration 6	42 mg	Every day	7 Days
Week 7	Titration 7	24 mg	Two times a day	Indefinite	Titration 7	48 mg	Every day	Indefinite

Source Details

The “Source Details” section defines how AUSTEDO XR will be administered to the resident. The “Permanent Medication Source” will be the pharmacy, but this may be changed by the user if the resident requires a different administration source.

1. Users can select a specific pharmacy for an individual resident.
2. Pharmacy notes may be entered if additional information is required for the pharmacy.
3. Users must “Save” the template to have it transmitted to the pharmacy, “Queue & New” the template if they would like to revisit the template before saving and submitting, or “Cancel” the template to discard.



IMPORTANT SAFETY INFORMATION (Continued)

Akathisia, Agitation, and Restlessness: AUSTEDO XR and AUSTEDO may increase the risk of akathisia, agitation, and restlessness. The risk of akathisia may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops akathisia, the AUSTEDO XR or AUSTEDO dose should be reduced; some patients may require discontinuation of therapy.

Parkinsonism: AUSTEDO XR and AUSTEDO may cause parkinsonism in patients with Huntington’s disease or tardive dyskinesia. Parkinsonism has also been observed with other VMAT2 inhibitors. The risk of parkinsonism may be increased by concomitant use of dopamine antagonists or antipsychotics. If a patient develops parkinsonism, the AUSTEDO XR or AUSTEDO dose should be reduced; some patients may require discontinuation of therapy.

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Order Summary

An Order Summary is generated once the user completes and submits the order template. It summarizes a resident's full titration schedule for a complete 7-week titration series as discussed in the "Scheduling Details" section.

Please note that names mentioned in this manual are not real residents or providers.

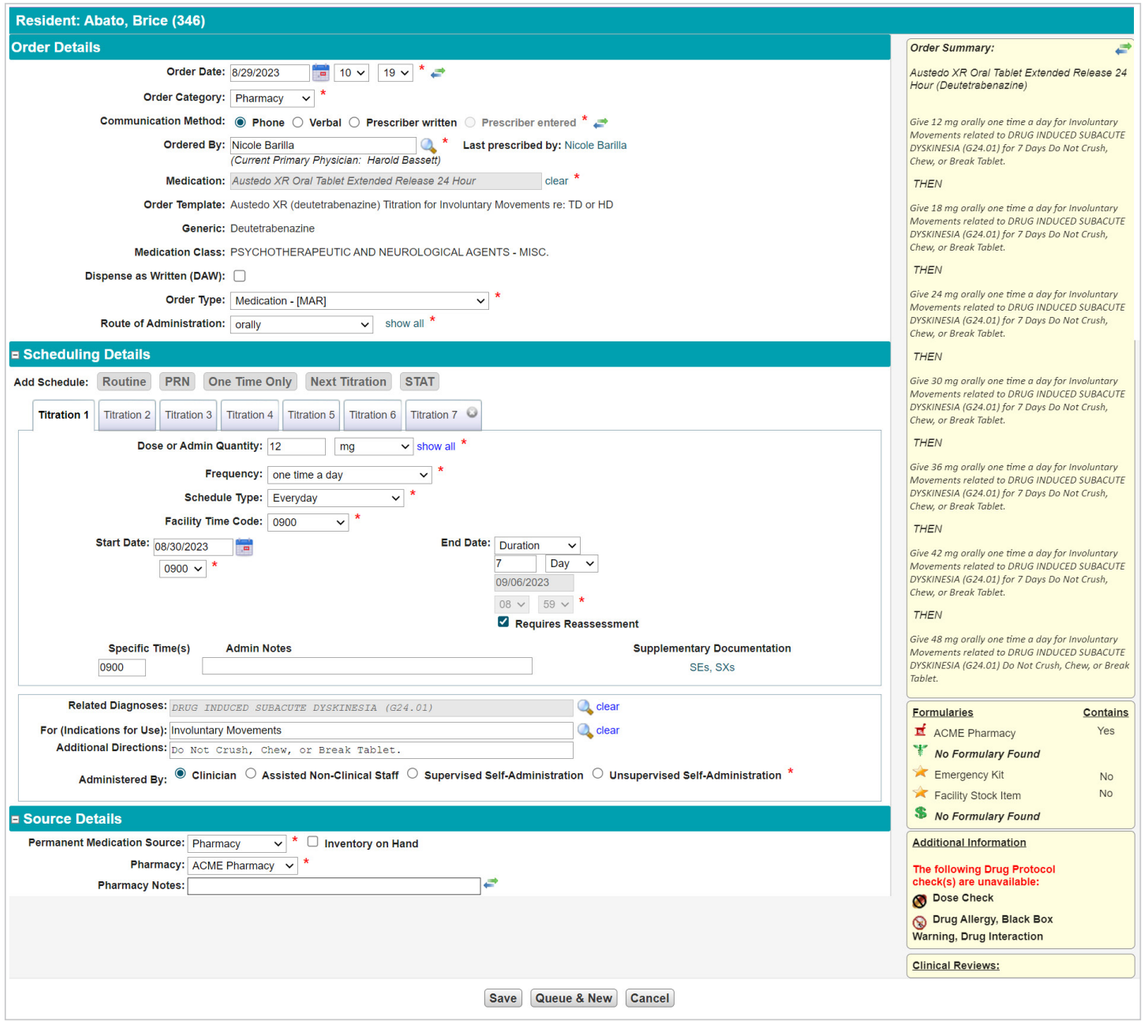
IMPORTANT SAFETY INFORMATION (Continued)

Sedation and Somnolence: Sedation is a common dose-limiting adverse reaction of AUSTEDO XR and AUSTEDO. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or hazardous machinery, until they are on a maintenance dose of AUSTEDO XR or AUSTEDO and know how the drug affects them. Concomitant use of alcohol or other sedating drugs may have additive effects and worsen sedation and somnolence.

Hyperprolactinemia: Tetrabenazine elevates serum prolactin concentrations in humans. If there is a clinical suspicion of symptomatic hyperprolactinemia, appropriate laboratory testing should be done and consideration should be given to discontinuation of AUSTEDO XR and AUSTEDO.

Binding to Melanin-Containing Tissues: Deutetrabenazine or its metabolites bind to melanin-containing tissues and could accumulate in these tissues over time. Prescribers should be aware of the possibility of long-term ophthalmologic effects.

AUSTEDO XR Order Template–Order Summary



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Additional resources for managing your residents' treatment

Click here to contact a Teva sales representative for more information on AUSTEDO XR

Click here to learn more about new dosing and administration information for AUSTEDO XR

IMPORTANT SAFETY INFORMATION (Continued)

Common Adverse Reactions: The most common adverse reactions for AUSTEDO (>8% and greater than placebo) in a controlled clinical study in patients with Huntington's disease were somnolence, diarrhea, dry mouth, and fatigue. The most common adverse reactions for AUSTEDO (4% and greater than placebo) in controlled clinical studies in patients with tardive dyskinesia were nasopharyngitis and insomnia. Adverse reactions with AUSTEDO XR extended-release tablets are expected to be similar to AUSTEDO tablets.

REFERENCE: 1. AUSTEDO® XR (deutetrabenazine) extended-release tablets and AUSTEDO® current Prescribing Information. Parsippany, NJ: Teva Neuroscience, Inc.

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