

Austedo[®] XR (deutetrabenazine) – New formulation approval

- On February 17, 2023, [Teva Pharmaceuticals announced](#) the FDA approval of [Austedo XR \(deutetrabenazine\)](#), in adults for the treatment of chorea associated with Huntington's disease and tardive dyskinesia.
- Austedo XR is a once-daily, extended-release formulation of deutetrabenazine. Deutetrabenazine is also available as a twice-daily formulation (Austedo) approved for the same indications.
- The efficacy of Austedo XR is based on a relative bioavailability study comparing Austedo XR tablets administered once daily and Austedo tablets administered twice daily.
- Austedo and Austedo XR carry boxed warnings for depression and suicidality in patients with Huntington's disease.
- Austedo and Austedo XR are contraindicated in patients:
 - With Huntington's disease who are suicidal, or have untreated or inadequately treated depression
 - With hepatic impairment
 - Taking reserpine
 - Taking monoamine oxidase inhibitors
 - Taking tetrabenazine or valbenazine.
- Additional warnings and precautions for Austedo and Austedo XR include clinical worsening and adverse events in patients with Huntington's disease; QTc prolongation; neuroleptic malignant syndrome; akathisia, agitation, and restlessness; parkinsonism; sedation and somnolence; hyperprolactinemia; and binding to melanin-containing tissues.
- The most common adverse reactions (> 8% of Austedo-treated patients with Huntington's disease and greater than placebo) were somnolence, diarrhea, dry mouth, and fatigue.
- The most common adverse reactions (4% of Austedo-treated patients with tardive dyskinesia and greater than placebo) were nasopharyngitis and insomnia.
- The recommended starting dose of Austedo XR is 12 mg once daily. The dosage may be increased at weekly intervals in increments of 6 mg per day based on reduction of chorea or tardive dyskinesia, and tolerability, up to a maximum recommended daily dosage of 48 mg.
 - When switching between Austedo and Austedo XR, switch to the same total daily dosage.
- Teva Pharmaceuticals plans to launch Austedo XR later this year. Austedo XR will be available as 6 mg, 12 mg, and 24 mg extended-release tablets.