

Ingrezza[™] (valbenazine) – New drug approval

- On April 11, 2017, the [FDA announced](#) the approval of [Neurocrine Biosciences' Ingrezza \(valbenazine\)](#), for the treatment of adults with tardive dyskinesia (TD).
 - Ingrezza is the first FDA approved drug to treat TD.
- TD is a neurological disorder characterized by repetitive involuntary movements, usually of the jaw, lips, and tongue. Some affected individuals may also experience involuntary movement of the extremities or difficulty breathing.
 - TD is estimated to affect at least 500,000 Americans.
 - TD is sometimes seen in patients who have been treated with antipsychotic medications for long periods of time.
 - The symptoms of TD can be severe and are often persistent and irreversible.
- Ingrezza is a selective inhibitor of vesicular monoamine transporter 2 (VMAT2), a transporter that regulates monoamine uptake from the cytoplasm to the synaptic vesicle for storage and release.
- The safety and efficacy of Ingrezza were based on a placebo-controlled trial in 234 patients with moderate to severe TD. The primary endpoint was change from baseline in the Abnormal Involuntary Movement Scale (AIMS), a 12-item assessment of TD severity.
 - At the end of week 6, greater improvement in mean AIMS score occurred with Ingrezza vs. placebo. However, statistical significance was achieved only with the 80 mg dose.
- Warnings and precautions of Ingrezza include somnolence and QT prolongation.
- The most common adverse reaction (≥ 5% and twice the rate of placebo) with Ingrezza use was somnolence.
- The initial dose of Ingrezza is 40 mg orally once daily.
 - After one week, the recommended dose is 80 mg (2 capsules) once daily.
 - Continuation of 40 mg once daily may be considered in some patients.
- To assist TD patients with access to Ingrezza, Neurocrine Biosciences has created the INBRACE[™] patient support program, which is designed to provide personalized product assistance and services.
- Ingrezza will be in the distribution channel next week and will be available through a select pharmacy network. Ingrezza will be available as 40 mg capsules.