INGREZZA™ (valbenazine) capsules is the first and only FDA-approved product indicated for the treatment of adults with tardive dyskinesia (TD).

WHAT IS TARDIVE DYSKINESIA?

TD is characterized by **uncontrollable, abnormal and repetitive movements** of the trunk, extremities and/or face, which can include hand or foot movements, rocking of the trunk, lip smacking, grimacing, tongue protrusion, facial movements or blinking, as well as puckering and pursing of the lips.¹⁻³

These symptoms may be **severe, persistent and often irreversible.**¹ TD is associated with treatments that block dopamine receptors in the brain, such as antipsychotics and other medications. In patients with TD, these treatments are thought to result in irregular dopamine signalling in one of the regions of the brain that controls movement.¹⁻⁴

TD is thought to affect at least **500,000** people in the U.S.,⁵⁻⁶ and although many physicians are aware of the condition¹, TD is often misdiagnosed or underdiagnosed.†

TD often has a disruptive impact and may increase the stigma of mental illness on patients, leaving them feeling marginalized and creating **barriers between them and the outside world.**²⁻⁷

Select Important Safety Information

ADVERSE REACTIONS

The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >Placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

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* Based on an online survey with psychiatrists (n=101) and neurologists (n=100). Physicians represented solo, group, and hospital/mental health center practice settings across each specialty. Physicians were asked whether they hesitate before diagnosing TD and if they prefer to observe patients over several visits before diagnosing TD.
† Based on online surveys with psychiatrists (n=101) and neurologists (n=100). Physicians represented solo, group, and hospital/mental health center practice settings across each specialty. Physicians were asked to select the statement that best described why they do not formally code TD.
ABOUT INGREZZA (valbenazine) CAPSULES

- INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor. VMAT2 is a protein in the brain that packages transmitters, such as dopamine, for transport and release, and helps to control brain signalling. As with many neurologic treatments, although the exact mechanism of INGREZZA is unknown, it is thought to be mediated through the reversible inhibition of vesicular monoamine transporter 2 (VMAT2), a transporter that regulates monoamine uptake from the cytoplasm to the synaptic vesicle of storage and release.\(^8\)
  - INGREZZA is indicated for the treatment of adults with TD and is administered in once-daily doses without titration.\(^8\)
  - INGREZZA may be taken together with psychiatric medications such as antipsychotics or antidepressants.\(^8\)

- A randomized, double-blind, placebo-controlled trial of INGREZZA was conducted in patients with moderate to severe tardive dyskinesia as determined by clinical observation. The primary efficacy endpoint was the mean change from baseline in the Abnormal Involuntary Movement Scale (AIMS) dyskinesia total score at the end of Week 6. The change from baseline for two fixed doses of INGREZZA (40 mg or 80 mg) was compared to placebo.\(^9\)

- In the KINECT 3 study, after six weeks of treatment, patients taking 80mg per day of INGREZZA demonstrated a statistically significant reduction in AIMS total dyskinesia score of -3.2 points versus -0.1 points for placebo (p<0.0001). Further, at Week 6, 40% of patients in the 80mg treatment group, compared to 9% of patients in the placebo group, demonstrated an AIMS reduction of at least 50% from baseline (nominal, p<0.001). Patients taking 40mg per day of INGREZZA demonstrated a reduction in AIMS total dyskinesia score of -1.9 points versus -0.1 points for placebo (nominal, p=0.002), with 23.8% of participants demonstrating an AIMS reduction of at least 50% from baseline (nominal, p=0.02).\(^9\)

SAFETY PROFILE

In clinical studies, INGREZZA was generally well tolerated through 48 weeks of treatment. Patients were allowed to stay on stable psychiatric treatment regimens throughout the course of the study.\(^8\)

In clinical studies, an impact on schizophrenia and mood disorder safety measures was not observed.\(^8\)

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IMPORTANT SAFETY INFORMATION

WARNINGS & PRECAUTIONS

Somnolence

INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation

INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

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You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.com/medwatch or call 1-800-FDA-1088.

Please see attached INGREZZA full Prescribing Information or visit www.INGREZZA.com

REFERENCES


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CP-TD-US-0069 04/17