ONCE-DAILY
INGREZZA®
(valbenazine) capsules

FOR ADULTS WITH
TARDIVE DYSKINESIA (TD)

The VMAT2 inhibitor with the MOST CLINICALLY INFORMED DOSING RECOMMENDATIONS[1] for drug interactions

	INGREZZA[1]		Deutetrabenazine[2]	
	STUDIED?		STUDIED?	
Strong CYP2D6 inhibitors *(eg, paroxetine, fluoxetine, quinidine, tetrahydrocannabinol, cannabidiol)*	✓	**90%** **increase** in exposure to active metabolite Recommended dosage is 40 mg/day	✓	**550%** **increase** in exposure to active metabolite Max dosage of 36 mg/day
Poor CYP2D6 metabolizers	✓	**90%** **increase** in exposure to active metabolite Recommended dosage is 40 mg/day	?	NO DATA DISCLOSED* Max dosage of 36 mg/day
Strong CYP3A4 inhibitors *(eg, itraconazole, ketoconazole, clarithromycin, cannabidiol)*	✓	**110%** **increase** in exposure to active metabolite Recommended dosage is 40 mg/day	?	NO DATA DISCLOSED
Strong CYP3A4 inducers *(eg, rifampin, phenytoin, carbamazepine, St. John's wort)*	✓ NO ADDED SAFETY CONCERNS	**80%** **decrease** in exposure to active metabolite Not recommended due to subtherapeutic exposure	?	NO DATA DISCLOSED

CYP2D6 >6x greater exposure with deutetrabenazine[2]

+β-HTBZ is the primary active metabolite for deutetrabenazine vs +α-HTBZ for INGREZZA[1,2]

*Deutetrabenazine was not systemically evaluated in patients with poor CYP2D6 metabolizers. Exposure likely similar to taking a strong CYP2D6 inhibitor.[2]

EXPLORE INGREZZA DOSING

Dosing considerations do not imply differences in safety, efficacy, or clinical outcomes.

Important Information

INDICATION & USAGE

INGREZZA® (valbenazine) capsules and INGREZZA® SPRINKLE (valbenazine) capsules are indicated in adults for the treatment of tardive dyskinesia and for the treatment of chorea associated with Huntington's disease.

IMPORTANT SAFETY INFORMATION

Depression and Suicidality in Patients with Huntington's Disease: VMAT2 inhibitors, including INGREZZA and INGREZZA SPRINKLE, 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, suicidal ideation, or unusual changes in behavior. Inform patients, their caregivers, and families of the risk of depression and suicidal ideation and behavior 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, which are increased in frequency in patients with Huntington's disease.

CONTRAINDICATIONS

INGREZZA and INGREZZA SPRINKLE are contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA or INGREZZA SPRINKLE.

WARNINGS & PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions, including cases of angioedema involving the larynx, glottis, lips, and eyelids, have been reported in patients after taking the first or subsequent doses of INGREZZA. Angioedema associated with laryngeal edema can be fatal. If any of these reactions occur, discontinue INGREZZA or INGREZZA SPRINKLE.

Somnolence and Sedation

INGREZZA and INGREZZA SPRINKLE can cause somnolence and sedation. 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 or INGREZZA SPRINKLE.

QT Prolongation

INGREZZA and INGREZZA SPRINKLE may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA and INGREZZA SPRINKLE 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.

Please see additional Important Safety Information on reverse side and accompanying full Prescribing Information, including Boxed Warning.

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FOR ADULTS WITH
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INGREZZA was proven **ACROSS THE WIDEST RANGE OF PATIENTS**[1,2]

	INGREZZA[1,3]		Deutetrabenazine[2]	
	STUDIED?		STUDIED?	
Hepatic impairment	✓	**NO ADJUSTMENT REQUIRED** for **MILD** impairment **40 MG RECOMMENDED** for **MODERATE/SEVERE** impairment	✗	CONTRAINDICATED*
Renal impairment	✓	**NO ADJUSTMENT REQUIRED**	✗	NOT STUDIED†
Elderly patients (age 65+)	✓	**NO ADJUSTMENT REQUIRED**		Dose selection should be cautious INSUFFICIENT DATA‡
Risk for hyperprolactinemia	✓ Prolactin levels	**NO RESTRICTIONS OR RECOMMENDATIONS** **DOSE-RELATED INCREASE** in prolactin observed	✗	WARNING & PRECAUTION§
Concomitant anticholinergics (*eg, benztropine*)	✓ 31% patients	**INCLUDED** in pivotal studies	✗	**EXCLUDED** from pivotal studies
Swallowing issues/ pill aversion	**SPRINKLE FORMULATION**		No option available	

Dosing considerations do not imply differences in safety, efficacy, or clinical outcomes.

*See deutetrabenazine prescribing information section 8.6.
†See deutetrabenazine prescribing information section 12.3.
‡See deutetrabenazine prescribing information section 8.5.
§See deutetrabenazine prescribing information section 5.8.

IMPORTANT SAFETY INFORMATION (continued)

Neuroleptic Malignant Syndrome

A potentially fatal symptom complex referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with drugs that reduce dopaminergic transmission, including INGREZZA. The management of NMS should include immediate discontinuation of INGREZZA or INGREZZA SPRINKLE, intensive symptomatic treatment and medical monitoring, and treatment of any concomitant serious medical problems. If treatment with INGREZZA or INGREZZA SPRINKLE is needed after recovery from NMS, patients should be monitored for signs of recurrence.

Parkinsonism

INGREZZA and INGREZZA SPRINKLE may cause parkinsonism. Parkinsonism has also been observed with other VMAT2 inhibitors. Reduce the dose or discontinue INGREZZA or INGREZZA SPRINKLE treatment in patients who develop clinically significant parkinson-like signs or symptoms.

ADVERSE REACTIONS

The most common adverse reaction in patients with tardive dyskinesia (≥5% and twice the rate of placebo) is somnolence.

The most common adverse reactions in patients with chorea associated with Huntington's disease (≥5% and twice the rate of placebo) are somnolence/lethargy/sedation, urticaria, rash, and insomnia.

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

Dosage Forms and Strengths: INGREZZA and INGREZZA SPRINKLE are available in 40 mg, 60 mg, and 80 mg capsules.

Please see full Prescribing Information, including Boxed Warning.

REFERENCES: 1. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc. **2.** Deutetrabenazine [package insert]. Parsippany, NJ: Teva Neuroscience, Inc. **3.** Data on file. Neurocrine Biosciences, Inc.

NEUROCRINE® BIOSCIENCES