Now Approved for Tardive Dyskinesia: INGREZZA™ (valbenazine) capsules

2 minutes ago at 1:23 PM

From Info from Neurocrine

To Dr. Smith

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NOW APPROVED

INGREZZA™
(valbenazine) capsules

The first and only FDA-approved treatment indicated for tardive dyskinesia

View the press release

Visit the INBRACE™ Support Program website to get INGREZZA treatment resources

Important Information

Indication and Usage

INGREZZA is a selective vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of tardive dyskinesia.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

INGREZZA is contraindicated in patients:

- Taking a VMAT inhibitor (eg, reserpine or tetrabenazine)
- Taking a monoamine oxidase inhibitor (MAOI)
- With known hypersensitivity to INGREZZA (including any of the excipients)

WARNINGS & PRECAUTIONS

Somnolence

Somnolence has been reported with INGREZZA treatment. 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.

QTc Prolongation

INGREZZA may cause an increase in the corrected QT interval. INGREZZA should be avoided in patients with congenital long QT syndrome and in patients with a history of cardiac arrhythmias. In INGREZZA clinical studies, patients taking concomitant medications with the potential to prolong the QT interval did not show an increased risk of cardiac safety events or prolongation of QTcF.

Alcohol

Concomitant use of alcohol and INGREZZA has not been evaluated. Concomitant use of alcohol and INGREZZA may increase somnolence.

VMAT Inhibitors

INGREZZA should not be used in combination with VMAT inhibitors, or within 20 days of discontinuing therapy with reserpine.

MAOIs

INGREZZA should not be used in combination with an MAOI, or within 14 days of discontinuing therapy with an MAOI.

ADVERSE REACTIONS

Common Adverse Reactions (incidence ≥5% and at least twice the rate of placebo): somnolence.

OR

The most common adverse reactions reported (≥2% for INGREZZA and >placebo) were somnolence (5.5% vs 2.2%), headache (3.9% vs 2.2%), akathisia (2.4% vs 0.6%), fatigue (3.9% vs 1.7%), dry mouth (3.1% vs 1.7%), vomiting (2.4% vs 0.6%), arthralgia (2.4% vs 0.6%).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

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

REFERENCE: INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc; 2017.

Neurocrine BIOSCIENCES

Advancing the science of hyperkinetic movement disorders

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