

## INGREZZA<sup>®</sup> (valbenazine) capsules and Hypersensitivity

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the potential for hypersensitivity with the use of INGREZZA for adults with tardive dyskinesia (TD).

INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of adults with tardive dyskinesia.<sup>1</sup>

### FDA-approved Full Prescribing Information<sup>1</sup>

#### CONTRAINDICATIONS

INGREZZA is contraindicated in patients with a history of hypersensitivity to valbenazine or any components of INGREZZA. Rash, urticaria, and reactions consistent with angioedema (e.g., swelling of the face, lips, and mouth) have been reported.

#### ADVERSE REACTIONS

Hypersensitivity [see *Contraindications*]

#### Post Marketing Experience

The following adverse reactions have been identified during post-approval use of INGREZZA that are not included in other sections of the labeling. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

*Immune System Disorders:* hypersensitivity reactions (including allergic dermatitis, angioedema, pruritis, and urticaria)

*Skin and Subcutaneous Tissue disorders:* rash

### Clinical Trial Data<sup>2</sup>

Safety data were pooled from three 6-week, randomized, double-blind, placebo-controlled trials (2 Phase 2 and 1 Phase 3: KINECT [NCT01688037], KINECT 2 [NCT01733121], and KINECT 3 [NCT02274558], respectively) to further evaluate incidence of hypersensitivity in clinical trials. The pooled analysis population composed of 432 subjects with 254 (58.8%) subjects treated with valbenazine (all doses) and 178 (41.2%) subjects treated with placebo. The incidence of hypersensitivity reactions was approximately 1.2% (n=3) for valbenazine (all dose levels) compared to 1.7% (n=3) for placebo.

**This letter and the enclosed material are provided in response to your unsolicited medical information inquiry. Please feel free to contact Neurocrine Medical Information at (877) 641-3461 or [medinfo@neurocrine.com](mailto:medinfo@neurocrine.com) if you would like to request additional information.**

#### References:

1. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
2. Data on File (VBZ-TD-0006). Neurocrine Biosciences, Inc.

#### Enclosure:

- A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.