

INGREZZA[®] (valbenazine) Capsules and INGREZZA[®] SPRINKLE (valbenazine) Capsules at Doses Greater than 80 mg

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the use of INGREZZA and INGREZZA SPRINKLE at doses greater than 80 mg.

INGREZZA and INGREZZA SPRINKLE are indicated in adults for the treatment of tardive dyskinesia (TD) and for the treatment of chorea associated with Huntington's disease (HD).¹

The FDA-approved full Prescribing Information states the following regarding dosage and administration¹:

Administer INGREZZA and INGREZZA SPRINKLE orally with or without food.

Tardive Dyskinesia

The initial dosage for INGREZZA and INGREZZA SPRINKLE is 40 mg once daily. After one week, increase the dose to the recommended dosage of 80 mg once daily. A dosage of 40 mg or 60 mg once daily may be considered depending on response and tolerability.

Chorea Associated with Huntington's Disease

The initial dosage for INGREZZA and INGREZZA SPRINKLE is 40 mg once daily. Increase the dose in 20 mg increments every two weeks to the recommended dosage of 80 mg once daily. A dosage of 40 mg or 60 mg once daily may be considered depending on response and tolerability.

An exposure-response (E-R) model indicated that exposures at doses greater than 80 mg valbenazine would confer a minimal increase in benefit. There exists an increased risk of safety burden at doses higher than 80 mg.²

There have been no studies conducted to evaluate the safety and efficacy of valbenazine in doses greater than 80 mg in adult patients with TD or chorea associated with HD.

However, in a Phase 2 study in patients with TD (KINECT[®]), valbenazine 100 mg once daily was used for 2 weeks followed by 50 mg daily for 4 weeks in one of the study arms (n=27).²⁻⁴ A total of 109 participants entered the 6-week double-blind study and 93 participants completed the 6-week study.^{3,4} For more information on the KINECT study, please contact Neurocrine Medical Information at (877) 641-3461 or medinfo@neurocrine.com.

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 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-0005). Neurocrine Biosciences, Inc.
3. Jimenez, R., Shiwach, R., Bari, M., O'Brien, C.F.; Twelve-week treatment of tardive dyskinesia with NBI-98854 [abstract]. *Mov Disord* 2014;29 Suppl 1 :826.
4. Jimenez R. et al. Kinect Extension: 12-week Treatment of Tardive Dyskinesia with NBI-98854. Poster presented at 18th International Congress of Parkinson's Disease and Movement Disorders; June 8-12, 2014; Stockholm, Sweden.

Enclosures:

- A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
- B. INGREZZA [Important Safety Information]. San Diego, CA: Neurocrine Biosciences, Inc.
- C. Jimenez R. et al. Kinect Extension: 12-week Treatment of Tardive Dyskinesia with NBI-98854. Poster presented at 18th International Congress of Parkinson's Disease and Movement Disorders; June 8-12, 2014; Stockholm, Sweden.