

Recommended Dosing of INGREZZA® (valbenazine) Capsules

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the recommended dosing of INGREZZA® (valbenazine) capsules.

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

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

The FDA-approved prescribing information does not restrict the timing of when INGREZZA may be administered. While in previous clinical studies, valbenazine had been administered in the mornings, both morning and evening dosing were permitted during the open label (up to 72 weeks or until valbenazine became commercially available) rollover study of valbenazine in adults with tardive dyskinesia (TD) (patients who completed Phase 3 valbenazine trials).

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.

Reference:

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

Enclosure:

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