(p) 877-641-3461 6027 Edgewood Bend Court, San Diego, CA 92130
(f) 913.451.6409 http://www.neurocrinemedical.com/

Recommended Dosing of INGREZZA® (valbenazine) Capsules and INGREZZA® SPRINKLE (valbenazine) Capsules in Patients with Tardive Dyskinesia

Thank you for contacting Neurocrine Biosciences with your unsolicited Medical Information request regarding the recommended dosing of INGREZZA and INGREZZA SPRINKLE.

INGREZZA and INGREZZA SPRINKLE are vesicular monoamine transporter 2 (VMAT2) inhibitors indicated for the treatment of adults with tardive dyskinesia (TD).[1]

The FDA-approved full Prescribing Information states the following regarding dosage and administration[1]:

> Administer INGREZZA and INGREZZA SPRINKLE orally with or without food.
>
> Tardive Dyskinesia
>
> The initial dosage 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.
>
> Administration Information for INGREZZA SPRINKLE
>
> Open INGREZZA SPRINKLE and sprinkle the entire contents of the capsule over a bowl containing a small amount (1 tablespoonful) of soft food such as applesauce, yogurt, or pudding.
>
> Do not sprinkle the contents of the capsule into milk or drinking water.
>
> Stir the contents of the capsule into the soft food with the tablespoon and swallow the drug/food mixture immediately. If necessary, the mixture can be stored for up to 2 hours at room temperature. Discard of any unused portion after 2 hours. Following administration of the drug/food mixture, drink a glass (e.g., 240 mL) of water.
>
> Do not administer INGREZZA SPRINKLE via nasogastric, gastrostomy, or other enteral tubes because it may cause obstruction of enteral tubes.
>
> INGREZZA SPRINKLE may be swallowed whole with water. Do not crush or chew INGREZZA SPRINKLE.

The FDA-approved full Prescribing Information does not restrict the timing of when INGREZZA or INGREZZA SPRINKLE may be administered. In the clinical trials assessing efficacy and safety of valbenazine use in adults with TD, both morning and evening doses were permitted - morning dosing in the double blind, placebo controlled studies, and morning and evening dosing in the open-label rollover study.[2]

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.
2. Data on file (VBZ-TD-0008).

Enclosure:

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A. INGREZZA [package insert]. San Diego, CA: Neurocrine Biosciences, Inc.
B. INGREZZA [Important Safety Information]. San Diego, CA: Neurocrine Biosciences, Inc.