

INGREZZA[®] (valbenazine) capsules is approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults with Huntington's disease (HD) chorea.

Who is appropriate for treatment with INGREZZA?

INGREZZA is a prescription medicine used to treat adults with HD chorea.¹ INGREZZA is a vesicular monoamine transporter 2 (VMAT2) inhibitor that selectively and specifically targets a protein called VMAT2 to inhibit the release of dopamine, a chemical in the brain that helps control movement.^{1,*} Current research suggests that INGREZZA reduces abnormal dopamine signaling that causes HD chorea. However, how INGREZZA works to treat HD chorea is not fully understood.¹

INGREZZA is the only treatment option that always offers a one-capsule, once-daily treatment, with no complex dose adjustments. In the clinical study, 80 percent began experiencing improvement in just 2 weeks.⁺ Significant improvement was shown at 12 weeks versus placebo.^{1,‡}

*Based on laboratory tests. This does not imply a treatment advantage. *Patients had at least a 1-point reduction in TMC score at 2 weeks vs before treatment. This post-clinical study evaluation included 64 patients taking INGREZZA 40 mg, measuring HD chorea before starting treatment and at Patients had at least a 1-point reduction in TMC score at 2 weeks vs before treatment. This post-clinical study evaluation included 64 patients taking INGREZZA 40 mg, measuring HD chorea before starting treatment and at 2 weeks of treatment. 2 weeks of treatment. 4INGREZZA was studied in a 12-week clinical trial. A total of 128 people participated in the study. Results were based on 58 people taking INGREZZA 40 mg, 60 mg or 80 mg. The primary efficacy endpoint was change in TMC from baseline to maintenance periods.

What are the possible side effects of INGREZZA for the treatment of HD chorea?

In clinical studies in HD, treatment-emergent adverse events included somnolence and sedation, urticaria, rash and insomnia.²

See below for Important Safety Information.

Can INGREZZA be taken at the same time as other medications?

INGREZZA can be added to most stable mental health regimens.² It's important for each person to speak with their healthcare provider to determine the optimal treatment plan.

When and where is INGREZZA available?

INGREZZA is currently available through a carefully selected network of specialty and local affiliated pharmacies. These include Amber Specialty Pharmacy, CVS Specialty Pharmacy, Orsini Specialty, PANTHERx Rare, AllianceRx Walgreens Pharmacy, Genoa Healthcare Pharmacy and select local pharmacies. INGREZZA is currently only approved for use in the United States. To learn more, visit the INBRACE® Support Program website.

Are there financial assistance programs for INGREZZA?

The INBRACE Support Program helps patients who are prescribed INGREZZA by assisting with product support and prescription fulfillment through a dedicated network of carefully selected specialty and local affiliated pharmacies. Patients with commercial insurance may be eligible for copay assistance and patients with no prescription coverage who also lack the financial resources to pay for their medicine may be eligible for participation in the patient assistance program.[§]

To learn more about INGREZZA, the Copay Savings Card or the INBRACE Support Program, call 1-84-INGREZZA (1-844-647-**3992**) 8 AM to 8 PM ET, Monday through Friday, or visit the **INBRACE Support Program website**.

[§]Additional terms and conditions apply.

Select Important Safety Information

INGREZZA can cause serious side effects in people with Huntington's disease, including: depression, suicidal thoughts, or suicidal actions. Tell your healthcare provider before you start taking INGREZZA if you have Huntington's disease and are depressed (have untreated depression or depression that is not well controlled by medicine) or have suicidal thoughts. Pay close attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings. This is especially important when INGREZZA is started and when the dose is changed. Call your healthcare provider right away if you become depressed, have unusual changes in mood or behavior, or have thoughts of hurting yourself.

For more information, visit INGREZZA.com or call 1-84-INGREZZA (1-844-647-3992). See full Important Safety Information, including Boxed Warning, on the following page.

Important Information

Approved Uses

INGREZZA® (valbenazine) capsules is a prescription medicine used to treat adults with:

- movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).
- involuntary movements (chorea) of Huntington's disease. INGREZZA does not cure the cause of involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

It is not known if INGREZZA is safe and effective in children.

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Do not take INGREZZA if you:

• are allergic to valbenazine, or any of the ingredients in INGREZZA.

INGREZZA may cause serious side effects, including:

- Sudden swelling from an allergic reaction (angioedema). Sudden swelling has happened after the first dose or after many doses of INGREZZA. Signs and symptoms of angioedema include: swelling of your face, lips, throat, and other areas of your skin, difficulty swallowing or breathing, and raised, red areas on your skin (hives). Swelling in the throat can be life-threatening and can lead to death. Go to the nearest emergency room right away if you develop these signs and symptoms. Your healthcare provider should stop your treatment with INGREZZA.
- Heart rhythm problems (QT prolongation). INGREZZA may cause a heart problem known as QT prolongation. Symptoms of QT prolongation may include: fast, slow, or irregular heartbeat, dizziness or fainting, or shortness of breath.

Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.

- Neuroleptic Malignant Syndrome (NMS): NMS is a serious condition that can lead to death. Call a healthcare provider right away or go to the nearest emergency room if you develop these symptoms and they do not have another obvious cause: high fever, stiff muscles, problems thinking, very fast or uneven heartbeat, or increased sweating.
- Abnormal movements (Parkinson-like). Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

Before taking INGREZZA, tell your healthcare provider about all of your medical conditions including if you: have liver or heart problems, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Sleepiness (sedation) is a common side effect with INGREZZA. While taking INGREZZA, do not drive a car or operate dangerous machinery until you know how INGREZZA affects you. Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking INGREZZA may increase any sleepiness caused by INGREZZA.

The most common side effect of INGREZZA in people with tardive dyskinesia is sleepiness (somnolence).

The most common side effects of INGREZZA in people with Huntington's disease are sleepiness (somnolence), allergic itching, rash, and trouble getting to sleep or staying asleep.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at <u>www.fda.gov/medwatch</u> or call **1-800-FDA-1088**.

Please see INGREZZA full Prescribing Information, including Boxed Warning.

REFERENCES:

1. INGREZZA capsules (package insert). San Diego, CA; Neurocrine Biosciences. 2023 2. Stimming EF, Claassen DO, Kayson E, et al. Safety and efficacy of valbenazine for the treatment of chorea associated with Huntington disease (KINECT-HD): a phase 3, randomised, double-blind, placebo-controlled trial. Lancet Neurol. 2023;22(6):494-504. doi:10.1016/S1474-4422(23)00127-8

