INGREZZA TAKES HD CHOREA CONTROL A STEP FORWARD, SO HD CHOREA WON'T CONTROL ME

Find out today how INGREZZA could be the optimal approach to treating Huntington's disease (HD) chorea for you



Actor portrayals

Important Information

Approved Uses

ONCE-DAILY

INGREZZA®

(valbenazine) capsules

INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules are prescription medicines 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 or INGREZZA SPRINKLE do not cure the cause of involuntary movements, and do not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

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

SELECT IMPORTANT SAFETY INFORMATION

INGREZZA or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE 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.

HD AND UNCONTROLLABLE Body movements

Huntington's disease (HD) is a hereditary disorder that causes nerve cells in the brain to gradually break down.

Over time, this damage causes symptoms that can disrupt everyday life physically, mentally, and emotionally.



CHOREA (UNCONTROLLABLE MOVEMENTS) IS THE DEFINING SYMPTOM OF HD, AND CAN BE ONE OF THE MOST IMPACTFUL*

*In an HDSA survey, HD patients and caregivers were asked to identify HD symptoms that had the biggest impact on daily life. Of 2591 respondents, 30% of caregivers and 17% of HD patients reported chorea as the most impactful.

STAGES OF HD CHOREA

>	EARLY	A gradual increase in uncontrollable movements may impact daily function
>	MIDDLE	Chorea may become worse, leading to increased difficulty with muscle control
>	LATE	Chorea may become severe or stabilize; people may also experience muscle stiffness and the inability to walk or speak



HD chorea is progressive and some of the areas it affects can include:



Finger and hand coordination: loss of muscle control can lead to problems with manual dexterity



Walking: balance issues can lead to falls



Mouth movements: uncontrollable movements can cause difficulty with talking and chewing



swallowing: swallowing difficulties may lead to choking



If you notice these symptoms in yourself or a loved one, you should start a conversation with your healthcare provider—even if the symptoms are mild.



WHAT'S THE IMPACT OF CHOREA ON PEOPLE WITH HD AND THEIR FAMILIES?

Over time, HD chorea may worsen, which could make daily life more difficult for those living with HD and their caregivers.





Bathing



Eating or swallowing



Dressing



Speaking

Δ





THERE IS NOT YET A CURE OR TREATMENT TO DELAY HD PROGRESSION, BUT **THERE ARE MEDICATIONS THAT CAN HELP CONTROL HD CHOREA**



Don't wait until your or your loved one's movements have started affecting daily living to begin a conversation with your healthcare provider about appropriately managing HD chorea.

Select Important Safety Information Do not take INGREZZA or INGREZZA SPRINKLE if you:

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



ASK YOUR HEALTHCARE PROVIDER ABOUT INGREZZA **FDA APPROVED FOR HD CHOREA**



The only treatment proven to reduce HD chorea that's available in a sprinkle formulation for those with trouble swallowing, and always one capsule, once daily.

FDA approved for over 7 years with more than 1 million prescriptions filled across indications.

INGREZZA® (valbenazine) capsules was studied in a clinical trial as a treatment for HD chorea:

128 PEOPLE ENROLLED

64 PEOPLE randomly selected to take INGREZZA 64 PEOPLE randomly selected to take a placebo

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• Allergic reactions. Allergic reactions, including an allergic reaction that causes sudden swelling called angioedema, can happen after taking the first dose or after many doses of INGREZZA or INGREZZA SPRINKLE. Signs and symptoms of allergic reactions and angioedema include: trouble breathing or shortness of breath, swelling of your face, lips, eyelids, tongue, or throat, or other areas of your skin, trouble with swallowing, or rash, including raised, itchy red areas on your skin (hives). Swelling in the throat can be life-threatening and can lead to death. Stop taking INGREZZA or INGREZZA SPRINKLE and go to the nearest emergency room right away if you develop these signs and symptoms of allergic reactions and angioedema.



ABOUT THE INGREZZA CLINICAL STUDY

Participants started taking INGREZZA® (valbenazine) capsules 40 mg for the first 2 weeks of the study. For those who could tolerate it, dosage was increased at weeks 2, 4, and 6 until the maximum dose of 80 mg per day was reached.

The goal of the study was to see if people taking INGREZZA experienced improvements in their HD chorea as measured by changes in TMC score.



WHAT IS TMC?

TMC, or Total Maximal Chorea score, measures the severity of HD chorea in several areas of the body.



Approximately **120 people** who completed the study were then **enrolled in a 3-year extension** to evaluate the long-term safety and effectiveness of INGREZZA in the treatment of HD chorea.

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PEOPLE TAKING INGREZZA CAN STAY ON MOST OF THEIR STABLE MENTAL HEALTH MEDICATIONS

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INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

• Sleepiness and tiredness that could cause slow reaction times (somnolence and sedation). Do not drive a car or operate dangerous machinery until you know how INGREZZA or INGREZZA SPRINKLE affects you. Drinking alcohol and taking other medicines may also cause sleepiness during treatment with INGREZZA or INGREZZA SPRINKLE.



INGREZZA TAKES **HD CHOREA CONTROL A STEP FORWARD**



In the clinical study, most people began to experience improvement at 2 weeks.* Significant improvement was shown at 12 weeks vs placebo.[†]

*In a post-clinical study evaluation, 51 of 64 patients (80%) taking INGREZZA® (valbenazine) capsules 40 mg had at least a 1-point reduction in TMC score at 2 weeks vs before treatment, vs 43 of 60 (72%) for those taking placebo.

INGREZZA was studied in a 12-week clinical trial. A total of 128 patients participated in the study. Results were based on 64 patients taking INGREZZA 40 mg, 60 mg, or 80 mg. The primary efficacy endpoint was change in TMC from the baseline to maintenance periods.

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INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

• Heart rhythm problems (QT prolongation). INGREZZA or INGREZZA SPRINKLE may cause a heart rhythm problem known as QT prolongation. You have a higher chance of getting QT prolongation if you also take certain other medicines during treatment with INGREZZA or INGREZZA SPRINKLE. Tell your healthcare provider right away if you develop any signs or symptoms of QT prolongation, including: fast, slow, or irregular heartbeat (heart palpitations), shortness of breath, dizziness or lightheadedness, or fainting or feeling like you are going to faint.







INGREZZA **SIGNIFICANTLY IMPROVED** HD CHOREA

People taking INGREZZA® (valbenazine) capsules experienced greater HD chorea improvement vs placebo as measured by TMC score*

Most people taking INGREZZA experienced clinically meaningful improvement at 12 weeks[†]

4.6-POINT IMPROVEMENT*

VS PLACEBO **1.4**-POINT IMPROVEMENT*

*4.6-point improvement seen with INGREZZA (n=58) vs 1.4 with placebo (n=54) in TMC score from the start to the end of the 12-week clinical study.

Most patients (57%) experienced clinically meaningful improvements, defined as a 4-point or greater change in TMC score.

Select Important Safety Information

INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

- 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, irregular pulse or blood pressure, increased sweating, or very fast or uneven heartbeat.
- **Parkinson-like symptoms.** Symptoms include: body stiffness, drooling, trouble moving or walking, trouble keeping your balance, shaking (tremors), or falls.



SIGNIFICANTLY MORE PATIENTS AND HEALTHCARE PROVIDERS **REPORTED IMPROVEMENT WITH INGREZZA**

53% OF PEOPLE

in the clinical study reported their overall HD chorea as "very much improved" or "much improved" with the help of INGREZZA® (valbenazine) capsules vs 26% for placebo at 12 weeks.*

53%

VERY MUCH IMPROVED OR MUCH IMPROVED

VS PLACEBO* 26%

*53% of patients (29/55) taking INGREZZA vs 26% of those taking placebo (14/53), based on patient-reported chorea severity scale (PGI-C scale) at 12 weeks vs before treatment.

Select Important Safety Information

Before taking INGREZZA or INGREZZA SPRINKLE, 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. Make sure you tell all of your healthcare providers that you are taking INGREZZA or INGREZZA SPRINKLE. Taking INGREZZA or INGREZZA SPRINKLE with certain other medicines may cause serious side effects. Especially tell your healthcare provider if you: take digoxin or take or have taken a monoamine oxidase inhibitor (MAOI) medicine. You should not take INGREZZA or INGREZZA SPRINKLE if you are taking, or have stopped taking, a MAOI within the last 14 days.



SIGNIFICANTLY MORE PATIENTS AND HEALTHCARE PROVIDERS **REPORTED IMPROVEMENT WITH INGREZZA**

43% OF HEALTHCARE PROFESSIONALS

in the clinical study reported HD chorea as "very much improved" or "much improved" with the help of INGREZZA® (valbenazine) capsules vs 13% for placebo at 12 weeks.*



*43% of patients (24/56) taking INGREZZA vs 13% of those taking placebo (7/53), based on clinician-reported chorea severity (CGI-C scale) at 12 weeks vs before treatment.

Select Important Safety Information

13%

VS PLACEBO*

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with tardive dyskinesia are sleepiness and tiredness.



INGREZZA **SAFETY PROFILE**

In the clinical study, INGREZZA® (valbenazine) capsules was shown to be generally well tolerated.

INGREZZA or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE 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.

INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

- Allergic reactions, including an allergic reaction that causes sudden swelling (angioedema)
- Sleepiness and tiredness that could cause slow reaction times (somnolence and sedation)
- Heart rhythm problems (QT prolongation)
- Neuroleptic Malignant Syndrome (NMS)
- **Parkinson-like symptoms** including body stiffness, drooling, trouble moving or walking, trouble keeping your balance, shaking (tremors), or falls

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with chorea associated with Huntington's disease include

sleepiness and tiredness, raised itchy red areas on your skin (hives), rash, and trouble getting to sleep or staying asleep.

These are not all of the possible side effects of INGREZZA or INGREZZA SPRINKLE. 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**.

People with Huntington's disease have a higher risk of depression and suicidal thoughts or actions. INGREZZA is a VMAT2 inhibitor. VMAT2 inhibitors are a group of medicines that all include the warning that they could increase this risk.





9/10 PEOPLE COMPLETED THE STUDY

Nearly all people (9 out of 10) taking INGREZZA completed the full 12-week clinical study, with 4 out of 5 able to tolerate the highest dose.

Select Important Safety Information

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with chorea associated with Huntington's disease include sleepiness and tiredness, raised itchy red areas on your skin (hives), rash, and trouble getting to sleep or staying asleep.



ONLY INGREZZA OFFERS SIMPLE DOSING

Remembering when and how to take medication can be challenging for anyone, but even more so if you're living with HD.

INGREZZA® (VALBENAZINE) CAPSULES MAKES DOSING SIMPLE FROM THE START:



Starts at an effective dose



Taken any time



Also available in sprinkle formulation



With or without food



Always one capsule, once daily



Can be added to most stable mental health regimens

Select Important Safety Information

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Dosage Forms and Strengths: INGREZZA and INGREZZA SPRINKLE are available in 40 mg, 60 mg, and 80 mg capsules.

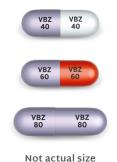




INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules is the only HD chorea treatment with **3 effective strengths** for simple dosing with **no complex dose adjustments**.

Finding the right dosage of INGREZZA for you

Your healthcare provider will start you on 40 mg for 2 weeks and may increase your dosage every 2 weeks to 60 mg or 80 mg, depending on your treatment needs. The recommended dose of INGREZZA is 80 mg.



Select Important Safety Information

Do not take INGREZZA or INGREZZA SPRINKLE if you:

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



WHAT MAKES INGREZZA **DIFFERENT?**

Unlike other medications approved to treat HD chorea, INGREZZA® (valbenazine) capsules selectively and specifically targets a protein called VMAT2.* VMAT2 aids in the release of dopamine.

*Based on laboratory tests. This does not imply a treatment advantage.

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.

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QUESTIONS ABOUT INGREZZA? Visit INGREZZA.com today

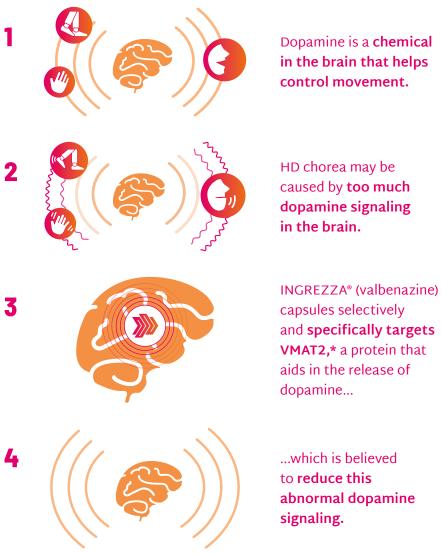
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HOW INGREZZA WORKS



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INBRACE® SUPPORT PROGRAM

Dedicated to helping you on your treatment journey through a range of financial assistance programs



COPAY SAVINGS CARD

\$0 copay program can make INGREZZA out-of-pocket costs for eligible patients less expensive than generics.*

*This offer is valid only for patients who have commercial (nongovernment-funded) insurance. Additional terms and conditions apply.

INGREZZA START PROGRAM

The INGREZZA Start Program is a free trial (one-month supply) of INGREZZA available for new patients.[†] Your healthcare provider can enroll you in the INGREZZA Start Program by downloading the enrollment form from the INBRACE[®] website and submitting the completed form on your behalf.

INGREZZA PATIENT ASSISTANCE PROGRAM

If you do not have prescription coverage for INGREZZA and lack the financial resources to pay for the medicine, you may be able to receive your prescription at no cost through the INGREZZA Patient Assistance Program.⁴ Your healthcare provider can help you apply for the program or call 1-84-INGREZZA to learn more.

¹This program is not contingent on a purchase of any kind. Product dispensed under this free trial program may not be submitted for reimbursement to any third-party payer. We reserve the right to modify or cancel the program at any time. ⁴Additional terms and conditions apply.

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INBRACE[®] SUPPORT PROGRAM

Actor portrayals

TO LEARN MORE ABOUT THE INBRACE[®] SUPPORT PROGRAM, CALL **1-84-INGREZZA (<u>1-844-647-3992</u>)** 8 AM TO 8 PM ET, MONDAY THROUGH FRIDAY, OR VISIT **INGREZZA.COM/SAVINGS**



IMPORTANT SAFETY INFORMATION

Important Information

Approved Uses

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IMPORTANT SAFETY INFORMATION (CONTINUED)

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Dosage Forms and Strengths: INGREZZA and INGREZZA SPRINKLE are available in 40 mg, 60 mg, and 80 mg capsules.

Please see additional Important Safety Information on previous page and accompanying full <u>Prescribing Information</u>, including





TAKE HD CHOREA CONTROL A STEP FORWARD TODAY **WITH INGREZZA:**

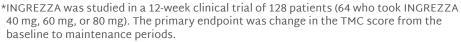
IMPROVEMENT STARTING AS EARLY AS 2 WEEKS* MORE THAN 3X GREATER HD CHOREA IMPROVEMENT VS PLACEBO AT 12 WEEKS[†]



When choosing treatment, start with INGREZZA[®] (valbenazine) capsules—an HD chorea treatment that offers simple dosing options throughout your treatment journey. Only INGREZZA is available in a sprinkle formulation for those with trouble swallowing and is always one capsule, once daily.

ASK YOUR HEALTHCARE PROVIDER

if INGREZZA could be the optimal approach to treating HD chorea for you Visit INGREZZA.com today



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