

Important Information

Actor portrayals

Approved Uses

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

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- 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.

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.

Please see Important Safety Information on page 11 and accompanying INGREZZA full Prescribing Information, including Boxed Warning.

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 ALSO 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.

HD chorea is progressive and some of the areas it can affect 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.

STAGES	
OF I	HD
CHOREA	

FARIY

A gradual increase in uncontrollable movements may impact daily function

MIDDI F

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

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.



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

HD CHORFA CAN MAKE DAILY ACTIVITIES **MORE CHALLENGING, SUCH AS:**



Bathing



Eating



Dressing



Speaking



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 if you:

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



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



The only treatment proven to reduce HD chorea that's always one capsule, once daily.

FDA approved for over 5 years and prescribed to over 57,000 patients with tardive dyskinesia

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

128 PEOPLE ENROLLED FOR 12 WEEKS



64 PEOPLE

randomly selected to take INGREZZA

64 PEOPLE

randomly selected to take a **placebo**

Select Important Safety Information

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.

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4 INGREZZA full <u>Prescribing Information</u>, including Boxed Warning.

WHAT WAS **STUDIED**

Participants started taking INGREZZA 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.



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

NEXT: INGREZZA STUDY RESULTS



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.†

*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.

†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.

Select Important Safety Information INGREZZA may cause serious side effects, including:

• 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.

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INGRE77A SIGNIFICANTLY **IMPROVED** HD CHOREA

People taking INGREZZA 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

VS PLACEBO

1.4-POINT IMPROVEMENT*

4.6-point improvement seen with INGREZZA vs 1.4 with placebo 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 may 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, 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.



INGREZZA TAKES HD CHOREA CONTROL A STEP FORWARD

53% OF PFOPLE

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.*

VERY MUCH IMPROVED OR MUCH IMPROVED

53%

VS PLACEBO* 26%

Select Important Safety Information

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.

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43% OF HEALTHCARE PROFESSIONALS

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

VERY MUCH IMPROVED
OR MUCH IMPROVED

43%

13% VS PLACEBO

[†]Based on clinician-reported chorea severity (CGI-C scale) at 12 weeks vs before treatment.

Select Important Safety Information

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.

^{*}Based on patient-reported chorea severity (PGI-C scale) at 12 weeks vs before treatment.



INGREZZA **SAFETY PROFILE**

In the clinical study, INGREZZA was shown to be generally well tolerated.

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

INGREZZA may cause serious side effects, including:

- · Depression and suicidal thoughts
- Sudden swelling from an allergic reaction (angioedema)
- Heart rhythm problems
- Neuroleptic Malignant Syndrome (NMS)
- Abnormal movements, including shaking, body stiffness, trouble moving or walking or keeping your balance

These are not all of the possible side effects of INGREZZA.

If you experience side effects, call your healthcare provider for medical advice. To report side effects to the FDA, call <u>1-800-FDA-1088</u>.

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 a warning that they could increase this risk.

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.

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PEOPLE COMPLETED THE STUDY

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



ONLY INGREZZA OFFERS SIMPLE DOSING THAT'S ALWAYS ONE CAPSULE, ONCE DAILY

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

INGREZZA MAKES DOSING SIMPLE FROM THE START: No complex dose adjustments Always one capsule, once daily With or without food Can be added to most stable mental health regimens

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INGREZZA® (valbenazine) capsules is the only HD chorea treatment with **3 effective dosing options and no required complex adjustments** to get to an effective dose.

Finding the right dosage of INGREZZA for you

40 40

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.



Not actual size

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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 www.fda.gov/medwatch or call 1-800-FDA-1088.



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.

OUESTIONS ABOUT INGREZZA? Visit **INGREZZA.com** today

Dopamine is a **chemical** in the brain that helps control movement.



HD chorea may be caused by too much dopamine signaling in the brain.



INGREZZA selectively and specifically targets **VMAT2,*** a protein that aids in the release of dopamine...

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...which is believed to reduce this abnormal dopamine signaling.

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INBRACE® SUPPORT PROGRAM

Dedicated to helping you on your treatment journey.

The INBRACE® Support Program is designed to help patients who are prescribed INGREZZA® (valbenazine) capsules 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. Your healthcare provider can help you apply for the program or call 1-84-INGREZZA to learn more.

'This 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.

*Additional terms and conditions apply.

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Actor portrayals



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



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TAKE HD CHOREA CONTROL A STEP FORWARD TODAY WITH INGREZZA:



Simple from the start—INGREZZA® (valbenazine) capsules is the only treatment proven to reduce HD chorea that's always one capsule, once daily

IMPROVEMENT STARTING AS EARLY AS 2 WEEKS*

MORE THAN 3X GREATER HD CHOREA IMPROVEMENT VS PLACEBO AT 12 WEEKS[†]

ASK YOUR HEALTHCARE PROVIDER

if INGREZZA could be the optimal approach to treating HD chorea for you

Visit INGREZZA.com today



'4.6-point improvement seen with INGREZZA vs 1.4 with placebo in TMC score from the start to the end of the 12-week clinical study.

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