

YOUR GUIDE TO STARTING ON INGREZZA

Actor portrayals

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**



Important Information

Approved Uses

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.

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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.



Welcome

You or your loved one have taken an important step toward Huntington's disease (HD) chorea control with one-capsule, once-daily INGREZZA® (valbenazine) capsules.

Use this guide to help you track how treatment is helping your or your loved one's 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.

MY TREATMENT GUIDE

Use this guide to track your treatment with INGREZZA® (valbenazine) capsules and bring it to every in-person, phone, or online appointment with a healthcare provider.

Your info
Healthcare provider:
Healthcare provider's address:
Healthcare provider's phone number:
Social worker's name and phone number:
Insurance provider:
Pharmacy:
INGREZZA start date:
Upcoming appointments:



YOU ARE NOT ALONE ON YOUR TREATMENT JOURNEY

If you have questions or concerns, talk to your healthcare provider. You can also call 1-84-INGREZZA (1-844-647-3992) 8 AM to 8 PM ET, Monday through Friday, or visit INGREZZA.com/resources to learn more

Here are some frequently asked questions patients have about INGREZZA and HD chorea:

What is INGREZZA?

INGREZZA® (valbenazine) capsules is an FDA-approved treatment for adults with the involuntary movements (chorea) of Huntington's disease (HD).

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

Do not take INGREZZA if you are allergic to valbenazine or any of the ingredients in INGREZZA.

What should I know about taking INGREZZA?

INGREZZA makes dosing simple from the start:

- Starts at an effective dose
- Also available in sprinkle formulation
- Always one capsule, once daily
- Taken any time

• With or without food

• Can be added to most stable mental health regimens

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

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



Additional frequently asked questions patients have about INGREZZA and HD chorea:

How does INGREZZA work?

INGREZZA® (valbenazine) capsules selectively and specifically targets a protein called VMAT2.* VMAT2 is responsible for 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.

Does INGREZZA improve uncontrollable body movements?

In a 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 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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• 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.



Additional frequently asked questions patients have about INGREZZA and HD chorea:

I have trouble swallowing due to my uncontrollable movements. Are there other ways to take INGREZZA?

If you have trouble swallowing, or prefer not to swallow pills, ask your doctor about INGREZZA® SPRINKLE (valbenazine) capsules.

In addition to the same simple dosing benefits of INGREZZA, INGREZZA SPRINKLE:

• Is easy to open • May be sprinkled on soft food

How do I know INGREZZA is working?

Ask your healthcare provider to explain how INGREZZA works, when to expect results, and to clarify the goals of your treatment, including what you should look for to know if it's working.

What are some common side effects of INGREZZA?

The most common side effects of INGREZZA 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 the possible side effects of INGREZZA.



Actor portrayal

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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.



Additional frequently asked questions patients have about INGREZZA and HD chorea:

Will I see continued results with INGREZZA?

53% of people reported their overall HD chorea was "very much improved" or "much improved" at 12 weeks with the help of INGREZZA® (valbenazine) capsules.*

*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.

I didn't understand what my healthcare provider said to me. What can I do?

Call or email your healthcare provider (if it's an option) and ask them to repeat any information you didn't understand at your appointment or to explain it differently.

Also, consider including a family member, caregiver, or friend to join you at your next appointment. They can help you better understand and remember your healthcare provider's advice and instructions.

Learn more at INGREZZA.com/huntingtons-chorea

Select Important Safety Information

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.



CARING FOR SOMEONE WITH HD CHOREA

HD chorea doesn't just affect people with HD—it affects those who live with and care for them as well.

As you do this important work, it's important to remember to take time for yourself, too. Taking care of yourself will help you better care for your loved one.

Caring for a loved one with HD chorea

As your loved one's HD chorea progresses, it will become more and more difficult for him or her to complete activities of daily living unassisted. At each stage, you, other family members, and your healthcare providers should have active discussions about how much supervision is necessary, and what modifications are most appropriate and helpful.





Some ways that you can help your loved one include:

- Following a consistent daily routine—this can help with memory difficulties and reduce stress
- Helping your loved one dress and bathe and helping with meal preparation as he or she may begin to struggle with balance and muscle control problems
- Assisting your loved one with his or her medication regimen, including supervising and recording any changes in his or her prescription and managing prescription refills and pickups
- Joining your loved one at his or her appointment for emotional and practical support, such as documenting instructions and information discussed during the appointment
- Using this guide to keep track of changes in their movements

Looking for support and community?

Connect with HD caregivers and families at INGREZZA.com/caregiver-resources

Find helpful resources and organizations for patients at INGREZZA.com/resources

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.



THE INBRACE® SUPPORT PROGRAM IS DEDICATED TO HELPING YOU ON YOUR TREATMENT JOURNEY

There are a variety of financial assistance programs that may be available to help you fill your prescription for INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules.



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

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





If you are eligible, a Savings Card may be applied automatically at the pharmacy, which may help you save money on your INGREZZA prescription.

Call the INGREZZA Call Center at 1-84-INGREZZA (1-844-647-3992) to learn about \$0 copay eligibility.



For patients with no prescription coverage:

If you do not have prescription coverage for INGREZZA® (valbenazine) capsules 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.¹ Your healthcare provider can help you apply for the program or call 1-84-INGREZZA to learn more.

[†]Additional terms and conditions apply.

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.



INGREZZA START PROGRAM

The INGREZZA Start Program is a free trial (one-month supply) of INGREZZA[®] (valbenazine) capsules 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.

*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.

Getting your prescription

INGREZZA is available through a select network of specialty and local affiliated pharmacies. A specialty pharmacy provides medicines that aren't typically available at your local retail pharmacy. Once coverage has been authorized, INGREZZA will be shipped directly to you via overnight mail.

In some cases, your healthcare provider may send your prescription to a local affiliated pharmacy. This pharmacy will work with you and your provider to fill your INGREZZA prescription.

To learn more about INGREZZA, the Copay Savings Card, or the INBRACE[®] Support Program, visit <u>INGREZZA.com/save</u>

Select Important Safety Information

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

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.



WHAT TO EXPECT ON INGREZZA FOR HD CHOREA

DOSAGE

INGREZZA® (valbenazine) capsules or INGREZZA® SPRINKLE (valbenazine) capsules is available in 3 effective dosages.



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

Select Important Safety Information

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 <u>1-800-FDA-1088</u>.

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





2 WEEKS

12 WEEKS

In a clinical study, 80% of people taking INGREZZA[®] (valbenazine) capsules began experiencing improvement in HD chorea in just 2 weeks.*

*In a post-clinical study evaluation, 51 of 64 patients (80%) taking INGREZZA 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. In the clinical study, significant improvement was shown at 12 weeks vs placebo.¹ Do not stop taking INGREZZA

without talking to your healthcare provider first.

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



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 **www.fda.gov/medwatch** 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.

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HELPFUL TIPS FOR STAYING ON TRACK WITH YOUR TREATMENT

- Keep INGREZZA[®] (valbenazine) capsules or INGREZZA[®] SPRINKLE (valbenazine) capsules in the same place so you know where it is
- Record your or your loved one's HD chorea movements each week using the pages provided in this guide
- Talk to your healthcare provider about any concerns and questions you have
- Remember to take INGREZZA as instructed by your healthcare provider—for some people, INGREZZA may work more gradually
- When it's time to refill your INGREZZA prescription, call your specialty pharmacy if they haven't contacted you

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Evaluate your HD chorea movements and pay close attention to where they occur. Then, answer some questions about how they impact you. **Bring your guide to every appointment to discuss with your healthcare provider.**

Indicate where you had uncontrollable body movements.



Compared to last week, were they better, worse, or the same?

How did your movements impact you physically? (For example, are you falling or dropping items more frequently, having difficulty speaking, eating, or swallowing, or requiring more assistance with daily tasks?)

How did your movements impact you emotionally and/or socially?

(For example, have you felt isolated or embarrassed in public, work, or social settings? Have the movements caused you frustration or worry?)

What did you talk about at your appointment? Write down any important notes.



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Notes



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IMPORTANT SAFETY INFORMATION (CONTINUED)

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- **Parkinson-like symptoms.** Symptoms include: body stiffness, drooling, trouble moving or walking, trouble keeping your balance, shaking (tremors), or falls.

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.

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

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 <u>1-800-FDA-1088</u>.

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





HAVE QUESTIONS ABOUT HD CHOREA AND INGREZZA?

Find answers at INGREZZA.com/HDC-FAQs

Please see Important Safety Information on pages 31–32 and accompanying full <u>Prescribing Information</u>, including Boxed Warning, and <u>Medication Guide</u>.



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