

INGREZZA®

YOUR GUIDE TO STARTING ON INGREZZA



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

Important Information

ONCE-DAILY

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.

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 38 and accompanying INGREZZA full <u>Prescribing Information</u>, including Boxed Warning.



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 if you:

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

MY INGREZZA TREATMENT GUIDE

Be sure to bring this guide 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 <u>1-84-INGREZZA</u>

(1-844-647-3992) 8 AM to 8 PM ET, Monday through Friday, or visit <u>INGREZZA.com/resources</u> to learn more

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

What is INGREZZA® (valbenazine) capsules?

INGREZZA 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.

How does INGREZZA work?

INGREZZA 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.

What should I know about taking INGREZZA?

INGREZZA makes dosing simple from the start:

- No complex dose adjustments
- · Always one capsule, once daily

• Taken any time

- With or without food
- Can be added to most stable mental health regimens

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

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.

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.

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.

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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, diffculty 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.



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

How do I know INGREZZA® (valbenazine) capsules 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 Huntington's disease are sleepiness (somnolence), allergic itching, rash, and trouble getting to sleep or staying asleep. These are not all the possible side effects of INGREZZA.

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.*

*Based on patient-reported chorea severity (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



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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.



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:

- If possible, modifying your home as needed to reduce fall risks and increase independence—for instance, by installing grab bars in the shower and next to the toilet, and handrails in hallways
- 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

Get more tips for caregivers at INGREZZA.com/resources

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.



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.

\$0

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 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.

[†]Additional terms and conditions apply.

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.



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.



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 in people with Huntington's disease are sleepiness (somnolence), allergic itching, rash, and trouble getting to sleep or staying asleep.



WHAT TO EXPECT ON INGREZZA FOR HD CHOREA



DOSAGE

START

2 WEEKS

12 WEEKS

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



Not actual size

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.

In a clinical study, 80% of people taking INGREZZA began experiencing improvement in HD chorea in just 2 weeks.*

*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. In the clinical study, significant improvement was shown at 12 weeks vs placebo.†
Do not stop taking INGREZZA without talking to your HCP first.

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 baseline to maintenance periods.

Select Important Safety Information

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.

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.

Please see Important Safety Information on page 38 and accompanying INGREZZA full Prescribing Information, including Boxed Warning.



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.

MY INGREZZA TREATMENT GUIDE

HELPFUL TIPS FOR STAYING ON TRACK WITH YOUR TREATMENT

- Keep INGREZZA® (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
- Look for drowsiness, which is the most common side effect of INGREZZA
- When it's time to refill your INGREZZA prescription, call your specialty pharmacy if they haven't contacted you

Select Important Safety Information Do not take INGREZZA if you:

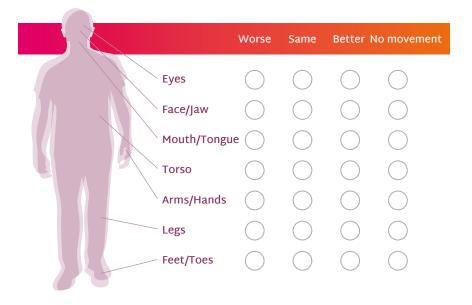
• are allergic to valbenazine, or any of the ingredients in INGREZZA.



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 or eating, 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.

Notes		

LOOKING FOR SUPPORT AND COMMUNITY?

Find groups near you at **INGREZZA.com/resources**



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CAREGIVER TIP:

If possible, modify your home as needed to reduce fall risks and increase independence—for instance, by installing grab bars in the shower and next to the toilet, and handrails in hallways



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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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Eyes				
Face/Jaw				
Mouth/Tongue				
Torso				
Arms/Hands				
Legs				
Feet/Toes				

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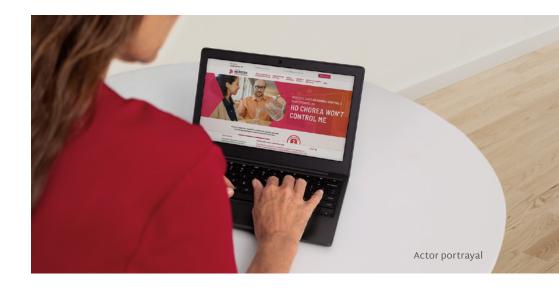
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Notes		

Visit INGREZZA.com/huntingtons-chorea for more information about HD chorea and INGREZZA



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• 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.



CAREGIVER TIP:

Help your loved one follow a consistent daily routine—this can help with memory difficulties and reduce stress



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

• Abnormal movements (Parkinson-like). Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

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INGREZZA MAKES DOSING SIMPLE FROM THE START:





No complex dose adjustments

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Can be added to most stable mental health regimens

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



CAREGIVER TIP:

Assist 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



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.

Please see Important Safety Information on page 38 and accompanying INGREZZA full <u>Prescribing Information</u>, including Boxed Warning.



TRACK. REFLECT. DISCUSS.

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HAVE QUESTIONS ABOUT HD CHOREA AND INGREZZA?

Find answers at INGREZZA.com/huntingtons-chorea-FAQs



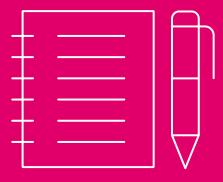
Select Important Safety Information

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.



CAREGIVER TIP:

Join your loved one at his or her appointment for emotional and practical support, such as documenting instructions and information discussed during the appointment



Select Important Safety Information

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.

Please see Important Safety Information on page 38 and accompanying INGREZZA full <u>Prescribing Information</u>, including Boxed Warning.



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IMPORTANT SAFETY INFORMATION

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.

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.

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

Please see accompanying INGREZZA full <u>Prescribing Information</u>, including Boxed Warning.



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