Important Information

Approved Use

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).

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

IMPORTANT SAFETY INFORMATION

Do not take INGREZZA if you:

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

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.

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
What is tardive dyskinesia (TD)?

TD means having movements you can’t control.

Where are TD movements seen?

While it can occur anywhere in the body, TD is often seen in the

- Lips
- Tongue
- Jaw
- Eyes

TD can also affect the

- Upper body
- Torso
- Arms/hands
- Legs/feet

Why do I have TD?

TD is associated with taking certain kinds of prescription medications, such as antipsychotics, for a long time.

These medications may create abnormal dopamine signaling in the brain, which is associated with TD. You may have been prescribed one of these medications to treat conditions such as:

- Depression
- Bipolar disorder
- Schizophrenia
- Anxiety

TD can result from the use of certain other medications that treat upset stomach, nausea, and vomiting.

Living with TD

Sometimes it can feel like you are the only one with uncontrollable movements. But remember, you are not alone.

TD can be disruptive for many people

“When I speak to people it’s distracting … I’m afraid they are focusing on it …”

- Eleanor, history of anxiety disorder

“At work … they say, ‘Oh, why are you [moving like that], are you okay?’”

- Katherine, history of bipolar disorder

“This lip-smacking, the eyebrow twitching, the jerky movements—my kids don’t understand … I make up stories. It’s very tough, actually, to explain them.”

- Colin, history of schizophrenia

Surrounding yourself with people who understand your condition can help you with your needs, such as staying on track with your treatment.

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
What is INGREZZA?

INGREZZA® (valbenazine) capsules is a prescription medicine FDA-approved to treat adults with movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia [TD]).

• It is not known whether INGREZZA is safe and effective in children

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

INGREZZA may cause serious side effects, including:

- Sleepiness (somnolence)
  Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREZZA affects you.

- Heart rhythm problems (QT prolongation) with symptoms that include:
  • Fast, slow, or irregular heartbeat
  • Shortness of breath
  • Dizziness or fainting

- Parkinson-like symptoms that include:
  • Shaking
  • Body stiffness
  • Trouble moving or walking, or keeping your balance

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

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
INGREZZA reduced uncontrollable movements of TD at 6 weeks

- INGREZZA® (valbenazine) capsules was studied in a 6-week clinical trial
- The study measured the difference in people’s uncontrollable movements from the beginning of the study and at 6 weeks, while observing the effect at certain times throughout the study

- People in the study had moderate to severe TD and a physician’s diagnosis of one of the following:
  - Schizophrenia
  - Schizoaffective disorder
  - Mood disorder

-30% reduction in TD movements at 6 weeks with INGREZZA 80 mg

INGREZZA reduced the uncontrollable movements of TD through almost 1 year

- After completing the 6-week trial, participants were allowed to enroll in a 42-week extension study
- The change in people’s uncontrollable movements with INGREZZA was studied for a total of 48 weeks

-39% reduction in TD movements at 48 weeks with INGREZZA 80 mg

What is the most common side effect of INGREZZA?

The most common side effect of INGREZZA is sleepiness (somnolence). Other side effects include changes in balance (balance problems, dizziness) or an increased risk of falls, headache, feelings of restlessness, dry mouth, constipation, and blurred vision.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
Side effects while taking INGREZZA

The most common side effect was sleepiness

It is common to experience some side effects while taking a new medication. In clinical trials, people did experience some side effects while taking INGREZZA® (valbenazine) capsules.

INGREZZA may cause serious side effects, including:

- Sleepiness
- Heart rhythm problems
- Parkinson-like symptoms including shaking, body stiffness, trouble moving or walking, or keeping your balance

Other side effects included:

- Changes in balance (balance problems, dizziness) or an increased risk of falls
- Headache
- Feelings of restlessness
- Dry mouth
- Constipation
- Blurred vision

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

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

What should I do if I experience side effects?

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How to take INGREZZA

One capsule, once daily

Your doctor will start you on a 40-mg dose of INGREZZA. After 1 week, your doctor may increase your dose to 80 mg.

Your doctor may keep you on the 40-mg dose based on your needs.

Take INGREZZA exactly as your doctor tells you

Your doctor will tell you how much INGREZZA to take and when to take it.

- INGREZZA can be taken with or without food
- Do not stop taking INGREZZA without talking to your doctor first
- If you take too much INGREZZA, call your poison control center at 1-800-222-1222

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
INGREZZA and your other medications

In clinical trials, people were generally allowed to stay on their stable medications, including antipsychotics.

No overall changes in safety measures were observed for:
- Bipolar disorder
- Schizoaffective disorder
- Schizophrenia
- Major depression

Make sure your doctor knows about all the medicines you take

Before you start treatment with INGREZZA® (valbenazine) capsules, your doctor needs to know about all the medicines you currently take. It may be helpful to keep a list of these medicines, so you can show your list to your doctor each time you are prescribed a new one.

Write down any medications you take. Show the list to your doctor and nurse.

Do not start any new medicines while taking INGREZZA without talking to your doctor first

Before taking INGREZZA, tell your doctor about all of your medical conditions, including if you:
- Have liver problems
- Have heart issues
- Have an irregular heart rhythm or heartbeat
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed

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

Tell your doctor about all the medicines you take, including:
- Prescription medicines
- Over-the-counter medicines
- Herbal supplements

Taking INGREZZA with certain other medicines may cause serious side effects.

Are you concerned about keeping track of INGREZZA on top of your other medications?

Turn the page for more tips on how to stay on track with INGREZZA.
Staying on track with INGREZZA

Proactively address questions about your TD treatment

After you’ve been prescribed INGREZZA® (valbenazine) capsules, questions or concerns may arise. To help make your treatment as smooth as possible, review the chart below on questions you may have and actionable answers that may help you on your journey.

<table>
<thead>
<tr>
<th>QUESTIONS</th>
<th>WHAT YOU CAN DO</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I can’t understand what my doctor says to me. What can I do?”</td>
<td>• Take a family member, caregiver, or friend with you to appointments. They can help you understand and remember your doctor’s advice</td>
</tr>
<tr>
<td></td>
<td>• Ask your doctor to repeat information or to explain it differently</td>
</tr>
<tr>
<td>“Is my medicine really helping my symptoms?”</td>
<td>• Ask your doctor to explain how the medicine works and to clarify the goals of your treatment, including what to look for to know if it’s working</td>
</tr>
</tbody>
</table>

Visit www.INGREZZA.com/FAQ for additional answers and support

INBRACE® Support Program

Once you and your doctor have decided that INGREZZA is right for you, the INBRACE® Support Program is here to help. This program assists you and your caregivers—so that you can make the most out of your treatment.

The program includes:

• Financial assistance
• Prescription fulfillment
• Reimbursement assistance
  - Benefits investigation
  - Prior authorization
  - Appeals process

Can I still get INGREZZA without prescription insurance?

• If you do not have insurance and are unable to pay for your medicine, you may be eligible to receive your prescription at no cost through the INGREZZA Patient Assistance Program

Learn more about INBRACE®

For additional information, visit www.inbracesupportprogram.com or call 844-INGREZZA (844-647-3992), 8 am–8 pm, Monday–Friday

INGREZZA SAVINGS PROGRAM

You may qualify for a $0 copay on your INGREZZA prescription*

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

Caring for someone with tardive dyskinesia may be challenging

As a caregiver of someone living with tardive dyskinesia (TD), you may be taking on the responsibility of identifying and managing their uncontrollable movements.

It’s helpful to try to remember that your loved one:

- May not know if the uncontrollable movements they are exhibiting are TD
- May reject seeking help because they can’t understand their condition

Start an open discussion with their doctor and healthcare team:

- They can provide answers to questions on identifying and managing TD
- You can help them stay up to date on your loved one’s changes in movement and progress

Remember that there is a community to help support you

Visit www.INGREZZA.com for support and resources that can help you as you care for someone with TD

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IMPORTANT SAFETY INFORMATION

Do not take INGREZZA if you:

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

INGREZZA may cause serious side effects, including:

- **Sleepiness (somnolence).** Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREZZA affects you.
- **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, shortness of breath, dizziness or fainting.
- **Parkinson-like symptoms.** Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

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

**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 most common side effect of INGREZZA is sleepiness (somnolence). Other side effects include changes in balance (balance problems, dizziness) or an increased risk of falls, headache, feelings of restlessness, dry mouth, constipation, and blurred vision.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
What is the most common side effect of INGREZZA?

The most common side effect of INGREZZA is sleepiness (somnolence). Other side effects include changes in balance (balance problems, dizziness) or an increased risk of falls, headache, feelings of restlessness, dry mouth, constipation, and blurred vision.

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see Important Safety Information on page 15 and Patient Information at the end of this brochure.
**What is INGREZZA?**

INGREZZA is a prescription medicine used to treat adults with movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).

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. See the end of this Patient Information leaflet for a complete list of ingredients in INGREZZA.

**Before taking INGREZZA, tell your healthcare provider about all of your medical conditions including if you:**

- have liver problems
- have heart disease that is not stable, have heart failure or recently had a heart attack
- have an irregular heart rhythm or heartbeat (QT prolongation, heart arrhythmia)
- are pregnant or plan to become pregnant. INGREZZA may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if INGREZZA passes into your breast milk. Do not breastfeed during treatment with INGREZZA and for 5 days after the final dose. Talk to your healthcare provider about the best way to feed your baby during treatment with INGREZZA.

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

Taking INGREZZA with certain other medicines may cause serious side effects. **Do not start any new medicines while taking INGREZZA without talking to your healthcare provider first.**

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**How should I take INGREZZA?**

- Take INGREZZA exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much INGREZZA to take and when to take it.
- Do not stop taking INGREZZA without talking to your healthcare provider first.
- INGREZZA can be taken with or without food.
- If you take too much INGREZZA, call your poison control center at 1-800-222-1222.

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**What are the possible side effects of INGREZZA?**

INGREZZA may cause serious side effects, including:

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- **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
  - shortness of breath
  - dizziness or fainting
- **Parkinson-like symptoms.** Symptoms include: shaking, body stiffness, trouble moving or walking, or keeping your balance.

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

**The most common side effect of INGREZZA is sleepiness (somnolence).**

**Other common side effects include:**

- changes in balance (balance problems, dizziness) or an increased risk of falls
- headache
- constipation
- feelings of restlessness
- dry mouth
- blurred vision

These are not all of the possible side effects of INGREZZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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**How should I store INGREZZA?**

- Store INGREZZA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep INGREZZA and all medicines out of the reach of children.

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**General information about the safe and effective use of INGREZZA**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INGREZZA for a condition for which it was not prescribed. Do not give INGREZZA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about INGREZZA that is written for healthcare professionals.
What are the ingredients in INGREZZA?

**Active ingredient:** valbenazine

**Inactive ingredients:**
- 40 mg Size 1 capsule: colloidal silicon dioxide, magnesium stearate, mannitol, and pregelatinized starch;
- 40 mg Size 2 capsule, 80 mg capsule: hypromellose, isomalt, magnesium stearate, pregelatinized starch, and silicified microcrystalline cellulose.

The capsule shells contain candurin silver fine, FD&C Blue#1, FD&C Red#40, and gelatin.

Distributed by: Neurocrine Biosciences, Inc., San Diego, CA 92130, U.S.A

For more information, go to www.INGREZZA.com or call 844-INGREZZA (844-647-3992).

This Patient Information has been approved by the U.S. Food and Drug Administration

Revised 07/2019

CP-VBZ-US-0834 v2.07/2019