Lip smacking, eye blinking, dancing hands and fingers, hip jerking...

Could your uncontrollable movements be **tardive dyskinesia (TD)**?

There’s a treatment with **INGREZZA**.

Approved for adults with TD

TD can occur in a variety of places in your body. INGREZZA is the first FDA-approved treatment specifically designed to reduce these uncontrollable movements.

**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.

Please see Important Safety Information on pages 14 & 15 and Patient Prescribing Information at the end of this brochure.
What is tardive dyskinesia (TD)?

TD means having movements you can’t control

Have you experienced any of the following movements in your body?
- Trunk and hip rocking, jerking, or thrusting
- Twisting or dancing fingers and toes
- Lip smacking, puckering, or pursing
- Tongue darting or protrusion
- Blinking
- Jaw swinging, chewing, or grimacing

Any of these uncontrollable movements may be symptoms of TD.
While it can occur anywhere in the body, TD is often seen in the lips, jaw, tongue, and eyes. It can also affect the upper body, arms, hands, torso, legs, and feet. TD affects everyone differently. It may look or feel different to you from day to day.

Why do I have TD?

TD is associated with taking certain kinds of drugs, such as antipsychotics, that help control dopamine, a chemical in the brain.

You may have been prescribed one of these drugs to treat a condition such as depression, bipolar disorder, schizophrenia, or anxiety. TD can also be caused by other medications used to treat upset stomach, nausea, and vomiting.

Living with TD

It’s important to know that you are not alone

It is estimated that over 500,000 people in the United States are affected by TD.

For many people, living with TD may be disruptive. It’s important to know that you are not alone and there is support available to you.

It may be helpful to create your own network of support, too.
Surrounding yourself with people who understand your condition can help you with your needs, such as staying on track with your treatment.

Having movements that you can’t control may present a variety of challenges. Don’t be afraid to ask for the help you need.
INGREZZA was specifically designed to treat TD

How INGREGZA works in your body

INGREZZA® (valbenazine) capsules is thought to work directly in the region of the brain that causes the uncontrollable movements of TD.

TD is associated with taking certain medications, such as antipsychotics, that create irregular dopamine signaling in the brain.

INGREZZA is believed to reduce this irregular dopamine signaling.

What is INGREGZA?

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 INGREGZA is safe and effective in children.

INGREGZA may cause serious side effects, including:

Sleepiness (somnolence).

Do not drive, operate heavy machinery, or do other dangerous activities until you know how INGREGZA affects you.

Heart rhythm problems (QT prolongation).

INGREGZA 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

Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint.
INGREZZA reduced the uncontrollable movements of TD within 6 weeks

Uncontrollable movements were improved by ~30% in 6 weeks

INGREZZA® (valbenazine) capsules was studied in a 6-week clinical trial. The main objective was to measure the difference in people’s uncontrollable movements at the beginning of the study and at the end of the study.

In 79 people taking the recommended INGREZZA dose of 80 mg

Reduction in uncontrollable movements at 6 weeks

~30%

Reductions were seen in as early as 2 weeks

Who participated in the trial?

• 234 people with moderate to severe tardive dyskinesia
• People who had a clinical diagnosis of schizophrenia, schizoaffective disorder, or a mood disorder. Most were allowed to stay on their regular medications during the study

INGREZZA reduced the uncontrollable movements of TD through almost 1 year

Reductions in uncontrollable movements were maintained through 48 weeks

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

In 63 people taking the recommended INGREZZA dose of 80 mg

Reduction in uncontrollable movements at 48 weeks

~39%

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.
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.

Other side effects included:

- Changes in balance (balance problems, dizziness) or an increased risk of falls
- Headache
- Feelings of restlessness

These are not all of the possible side effects of 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

INGREZZA is taken once a day

- INGREZZA is a capsule
- INGREZZA can be taken with or without food

Your doctor will likely start you on a 40-mg dose

After 1 week, your doctor may increase your dose to 80 mg.

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
- If you take too much INGREZZA, call your poison control center at 1-800-222-1222

Please see Important Safety Information on pages 14 & 15 and Patient Prescribing 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.

**There were no observed significant changes in safety measures for:**
- Bipolar disorder
- Schizophrenia
- Schizoaffective disorder
- Major depression

**Make sure your doctor knows about all your medical conditions and 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.**

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**Before taking INGREZZA, tell your doctor about all 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 doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking INGREZZA with certain medicines may cause serious side effects. **Do not start any new medicines while taking INGREZZA without talking to your doctor first.**

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

See page 12 for more tips on how to stay on track with INGREZZA.
Staying on track with INGREZZA

Proactively address questions about your treatment

After you’ve been prescribed INGREZZA® (valbenazine) capsules, questions or concerns may arise that you didn’t think about before. The following chart outlines potential questions you might have, along with actionable answers, to help your treatment journey run as smoothly as possible.

<table>
<thead>
<tr>
<th>I have questions about</th>
<th>What you can do</th>
</tr>
</thead>
</table>
| Understanding what my doctor says to me | • Take someone in your network of support to appointments with you, such as a family member, caregiver, or friend. They can help you understand and remember your doctor’s advice  
• Ask your doctor to repeat information or to explain it differently |
| If my medicine is really helping my symptoms | • Ask your doctor to explain how the medicine works and to clarify the goals of your treatment, and what you should look for to know if it’s working  
• Your doctor may adjust the dose of your medicine to help meet these treatment goals |
| Feeling overwhelmed with all of the medicines I take | • Go over a list of all your medicines with your doctor. They may be able to help you with a plan, such as creating a medicine calendar |
| Paying for my medicine | • The INBRACE™ Support Program can help you with financial assistance for INGREZZA. Ask your doctor to enroll you today |
| What to do if I think I’m having side effects | • Report all potential side effects to your doctor right away. Your doctor may be able to suggest ways to help manage your side effects |

The INBRACE™ Support Program

With INGREZZA, getting your medication is simple

Once you and your doctor have decided that INGREZZA is right for you, the INBRACE™ Support Program is here to help. Support includes:

- **Verifying insurance coverage**
  The INBRACE™ Support Program will verify your insurance coverage, and your case manager will call you and your healthcare provider with the results.

- **Connecting with a specialty pharmacy**
  You can get INGREZZA only from a specialty pharmacy. Once your insurance has authorized coverage, a specialty pharmacy will call you to arrange shipment.

- **Arranging INGREZZA deliveries directly to your home**
  Your specialty pharmacy will ship INGREZZA directly to you at a location of your choosing via overnight delivery.

The INBRACE™ Support Program and your specialty pharmacy will call you with important information about your medication. These calls may come from an unidentified toll-free number, so be sure to answer your phone.

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

Please see Important Safety Information on pages 14 & 15 and Patient Prescribing Information at the end of this brochure.
**Important Safety 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**

**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.

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

**IMPORTANT SAFETY INFORMATION (continued)**

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 Patient Prescribing Information at the end of this brochure or visit www.INGREZZA.com.

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INGREZZA®
(valbenazine) capsules

The tardive dyskinesia (TD) treatment you’ve been waiting for

INGREZZA is the first FDA-approved treatment for adults with the involuntary movements of tardive dyskinesia

Once-a-day capsule
INGREZZA was specifically designed to treat TD

In clinical trials, INGREZZA reduced the uncontrollable movements of TD in most people

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

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 pages 14 & 15 and Patient Prescribing Information at the end of this brochure.

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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.

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.

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.

What are the possible side effects of 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:
  o fast, slow, or irregular heartbeat
  o shortness of breath
  o dizziness or fainting

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
• dry mouth
• headache
• feelings of restlessness
• constipation
• 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.

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.

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: mannitol, partially pregelatinized starch, fumed silica, and magnesium stearate. The capsule shell contains gelatin, candurin silver fine, FD&C Red#40, and FD&C Blue#1.

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

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

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

Approved: 4/2017

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