What is INGREZZA?

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

Here’s a list of questions that you may want to address with your doctor during your next visit:

1. Are you currently taking or have you ever taken antipsychotic medication(s)?
   - Yes
   - No

2. Have you recently changed any of your antipsychotic medications?
   - Yes
   - No

3. Have you ever been prescribed antipsychotic medication(s) to treat any of the following conditions? (Select all that apply)
   - Depression
   - Bipolar disorder
   - Schizophrenia
   - Anxiety
   - Other: ________________________________

4. Have you experienced uncontrollable movements such as pursing, puckering, squinting, jerking, rocking, or twisting in the: (Select all that apply)
   - Lips
   - Tongue
   - Jaw
   - Eyes
   - Upper body
   - Torso
   - Arms/hands
   - Legs/feet
   - Other: ________________________________

5. How bothersome are these movements to your daily routine?
   - Barely noticeable
   - Mildly bothersome
   - Moderately bothersome
   - Extremely bothersome

6. Who first noticed your movements?
   - Me
   - Spouse
   - Family member
   - Friend/coworker
   - Healthcare provider
   - Other: ________________________________

Select Important Safety Information

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.

Please see full Important Safety Information on the following page.

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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.

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.

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 attached INGREZZA Patient Information or visit www.INGREZZA.com
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.

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.

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  • 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.

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: 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 84-INGREZZA (844-647-3992).

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

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