

MEDICATION GUIDE

**INGREZZA® (in greh zah)
(valbenazine)
capsules**

**INGREZZA® SPRINKLE (in greh zah spring kuhl)
(valbenazine)
capsules**

What is the most important information I should know about INGREZZA or INGREZZA SPRINKLE?

- INGREZZA or INGREZZA SPRINKLE can cause serious side effects in people with Huntington's disease, including:
 - depression
 - suicidal thoughts
 - 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 or have any of the following symptoms, especially if they are new, worse, or worry you:

- feel sad or have crying spells
- lose interest in seeing your friends or doing things you used to enjoy
- sleep a lot more or a lot less than usual
- feel unimportant
- feel guilty
- feel hopeless or helpless
- feel more irritable, angry or aggressive than usual
- feel more or less hungry than usual or notice a big change in your body weight
- have trouble paying attention
- feel tired or sleepy all the time
- have thoughts about hurting yourself or ending your life

What is INGREZZA or INGREZZA SPRINKLE?

INGREZZA or INGREZZA SPRINKLE are prescription medicines used to treat adults with:

- movements in the face, tongue, or other body parts that cannot be controlled (tardive dyskinesia).
- the involuntary movements (chorea) of Huntington's disease. INGREZZA or INGREZZA SPRINKLE do not cure the cause of the 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.

Who should not take INGREZZA or INGREZZA SPRINKLE?

Do not take INGREZZA or INGREZZA SPRINKLE if you are allergic to valbenazine, or any of the ingredients in INGREZZA or INGREZZA SPRINKLE. See the end of this Medication Guide for a complete list of ingredients in INGREZZA or INGREZZA SPRINKLE.

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

- have emotional or mental problems (for example, depression, nervousness, anxiety, anger, agitation, psychosis, previous suicidal thoughts or suicide attempts)
- 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 or INGREZZA SPRINKLE may harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if INGREZZA or INGREZZA SPRINKLE passes into your breast milk. **Do not** breastfeed during treatment with INGREZZA or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE.

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 and may affect the way that INGREZZA or INGREZZA SPRINKLE works. **Especially tell your healthcare provider if you:**

- 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. Ask your healthcare provider if you are not sure if you take a MAOI.
- take digoxin

Do not start any new medicines during treatment with INGREZZA or INGREZZA SPRINKLE without talking to your healthcare provider first.

How should I take INGREZZA or INGREZZA SPRINKLE?

- Take INGREZZA or INGREZZA SPRINKLE exactly as your healthcare provider tells you to.
- Your healthcare provider may change your dose of INGREZZA or INGREZZA SPRINKLE during treatment.
- Take INGREZZA or INGREZZA SPRINKLE 1 time each day.
- Take INGREZZA or INGREZZA SPRINKLE with or without food.
- **If you take INGREZZA**, swallow the capsule
- **If you take INGREZZA SPRINKLE:**
 - You may open the capsule and sprinkle the contents (granules) over a small amount (1 tablespoonful) of soft food such as applesauce, yogurt, or pudding before taking INGREZZA SPRINKLE.
 - You may also swallow the capsule whole with water.
 - **Do not** add the granules to milk or water.
 - **Do not** crush or chew INGREZZA SPRINKLE.
 - **See the detailed Instructions for Use on how to take a dose of INGREZZA SPRINKLE.**
- If you take too much INGREZZA or INGREZZA SPRINKLE, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What should I avoid while taking INGREZZA or INGREZZA SPRINKLE?

Do not drive a car or operate dangerous machinery until you know how INGREZZA or INGREZZA SPRINKLE affects you because INGREZZA or INGREZZA SPRINKLE can cause sleepiness and tiredness that could cause slow reaction times. Drinking alcohol and taking other medicines that may also cause sleepiness during treatment with INGREZZA or INGREZZA SPRINKLE may increase any sleepiness caused by INGREZZA or INGREZZA SPRINKLE.

What are the possible side effects of INGREZZA or INGREZZA SPRINKLE?

INGREZZA or INGREZZA SPRINKLE can cause serious side effects, including:

- See **“What is the most important information I should know about INGREZZA or INGREZZA SPRINKLE?”**

- **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
- 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 right away and go to the nearest emergency room right away if you develop these signs and symptoms of allergic reactions and angioedema.

- **Sleepiness and tiredness that could cause slow reaction times (somnolence and sedation).** See **“What should I avoid while taking INGREZZA or INGREZZA SPRINKLE?”**
- **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
 - fainting or feeling like you are going to 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 signs and symptoms that do not have another obvious cause:
 - high fever
 - stiff muscles
 - problems thinking
 - irregular pulse or blood pressure
 - increased sweating
 - very fast or uneven heartbeat
- **Parkinson-like symptoms.** Tell your healthcare provider if you develop any Parkinson-like symptoms during treatment with INGREZZA or INGREZZA SPRINKLE, including:
 - body stiffness
 - drooling
 - trouble moving or walking
 - trouble keeping your balance
 - shaking (tremors)
 - falls

The most common side effect of INGREZZA or INGREZZA SPRINKLE in people with tardive dyskinesia are sleepiness and tiredness that could cause slow reaction times.

The most common side effects of INGREZZA or INGREZZA SPRINKLE in people with chorea associated with Huntington’s disease include sleepiness and tiredness that could cause slow reaction times, raised itchy red areas on your skin (hives), rash, and trouble getting to sleep or staying asleep.

Your doctor may change your dose, temporarily stop, or permanently stop treatment with INGREZZA or INGREZZA SPRINKLE if you develop certain side effects.

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

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 or INGREZZA SPRINKLE?

- Store INGREZZA between 59°F to 86°F (15°C to 30°C).
- Store INGREZZA SPRINKLE between 68°F to 77°F (20°C to 25°C).
- Keep the bottle tightly closed to protect INGREZZA SPRINKLE from moisture.
- INGREZZA SPRINKLE granules added to soft food can be stored for up to 2 hours at room temperature between 68°F to 77°F (20°C to 25°C). After 2 hours, throw away any unused portion.
- **Keep INGREZZA, INGREZZA SPRINKLE and all medicines out of the reach of children.**

General Information about the safe and effective use of INGREZZA or INGREZZA SPRINKLE.

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use INGREZZA or INGREZZA SPRINKLE for a condition for which it was not prescribed. Do not give INGREZZA or INGREZZA SPRINKLE 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 or INGREZZA SPRINKLE that is written for health professionals.

What are the ingredients in INGREZZA or INGREZZA SPRINKLE?

Active ingredient: valbenazine

INGREZZA inactive ingredients: 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.

INGREZZA SPRINKLE inactive ingredients: silicified microcrystalline cellulose, isomalt, pregelatinized maize starch, hypromellose, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, and talc. The hard gelatin capsule shells contain gelatin and candurin silver fine.

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 Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued 4/2024