



- **Ingrezza**®
 - Capsules: 40 mg, 60 mg and 80 mg

If you or someone you know is in crisis, please call 911 and/or the toll-free National Suicide Prevention Lifeline at 800-273-TALK (8255) to speak with a trained crisis counselor 24/7. A help line and other resources are also available through the National Alliance on Mental Illness at nami.org.

What is valbenazine and what does it treat?

Valbenazine is a medication that is used to decrease the frequency and severity of involuntary, uncontrollable muscle movements that are related to a condition known as Tardive Dyskinesia (TD). TD is associated with chronic use of certain medications, such as antipsychotics.

Symptoms of TD include:

- Lip smacking, puckering, or pursing
- Tongue rolling or darting in and out of mouth
- Jaw clenching or grimacing
- Trunk and hip rocking, jerking, or thrusting
- Twisting or rhythmic movement in fingers and toes

Valbenazine may help improve some or all of these symptoms.

What is the most important information I should know about valbenazine?

For valbenazine to work properly, it should be taken every day as prescribed by your health care provider.

Missing doses of valbenazine may increase your risk for a relapse in your symptoms.

Valbenazine may cause drowsiness. Avoid activities that require alertness, such as driving a car or operating machinery until you learn how your body respond to it.

If you feel faint or have heart palpitations, consult with your doctor immediately.

Only your health care provider can determine the length of valbenazine treatment that is right for you. Do not stop taking valbenazine or change your dose without talking to your health care provider first.

All FDA warnings are at the end of this fact sheet. Please consult them before taking this medication.

Are there specific concerns about valbenazine and pregnancy?

If you are planning on becoming pregnant, notify your health care provider to best manage your medications. People living with TD who wish to become pregnant face important decisions. Currently, there are no well-controlled human studies of valbenazine in pregnancy. However, increased rates of stillbirths were seen in animal studies. It is important to discuss the risk and benefits of treatment with your doctor and caregivers.

Caution is advised with breast-feeding since it is not known if valbenazine passes into your breast milk. However, increased rates of fetal and newborn mortality were seen in animal studies. Therefore, the manufacturer recommends against breastfeeding during treatment with valbenazine and for 5 days after the last dose. Talk to your doctor about the best way to feed your baby during treatment with valbenazine.

What should I discuss with my health care provider before taking valbenazine?

- Symptoms of your condition that bother you the most
- If you have thoughts of suicide or harming yourself
- Medications you have taken in the past for your condition, whether they were effective or caused any adverse effects
- If you experience side effects from your medications, discuss them with your provider. Some side effects may pass with time, but others may require changes in the medication
- Any other psychiatric or medical problems you have, such as depression, heart rhythm problems, long QT syndrome, heart failure, heart attacks, kidney disease, or liver disease
- All other medications you are currently taking (including over the counter products, herbal and nutritional supplements) and any medication allergies
- Other non-medication treatment you are receiving, such as talk therapy or substance abuse treatment
- If you are pregnant, plan to become pregnant, or are breast-feeding
- If you drink alcohol or use illegal drugs

How should I take valbenazine?

Valbenazine is usually taken once a day, with or without food.

Typically patients begin at 40 mg once a day and dose may be increased to 80 mg once a day after a week of treatment. Only your health care provider can determine the correct dose for you.

Use a calendar, pillbox, alarm clock, or cell phone alert to help you remember to take your medication. You may also ask a family member to remind you or check in with you to be sure you are taking your medication.

What happens if I miss a dose of valbenazine?

If you miss a dose of valbenazine, take it as soon as you remember, unless it is closer to the time of your next dose. Discuss this with your health care provider. Do not double your next dose or take more than what is prescribed.

What should I avoid while taking valbenazine?

Avoid drinking alcohol or using illegal drugs while you are taking valbenazine. They may decrease the benefits (e.g., worsen your condition) and increase adverse effects (e.g., sedation) of the medication. When taking valbenazine for the first time, do not drive or operate dangerous machinery until you know how the medication affects you.

What happens if I overdose with valbenazine?

If an overdose occurs call your doctor or 911. You may need urgent medical care. You may also contact the poison control center at 1-800-222-1222.

A specific treatment to reverse the effects of valbenazine does not exist.

What are the possible side effects of valbenazine?

Common side effects

The most common side effects of taking valbenazine are fatigue, drowsiness, sleepiness, dry mouth, constipation, restlessness, nausea, vomiting, and joint pain

Rare/serious side effects

Rare/serious side effects may include dizziness, muscle aches, increases in weight or blood sugar, abnormal muscle movements, irregular heart rhythm, rash, and swelling of the face, lips, and mouth.

Are there any risks for taking valbenazine for long periods of time?

To date, there are no known problems associated with long term use of valbenazine. It is a safe and effective medication when used as directed.

What other medications may interact with valbenazine?

Valbenazine should not be taken with or within 2 weeks of taking monoamine oxidase inhibitors (MAOIs), as these medications can increase side effects and decrease the effectiveness of valbenazine. MAOIs include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®), and selegiline (Emsam®).

Valbenazine should not be taken with tetrabenazine (Xenazine®) or deutetabenazine (Austedo®)

The following medications may **increase** the levels and effects of valbenazine:

- The antidepressants paroxetine (Paxil®), fluoxetine (Prozac®), and quinidine (Quinate®)
- Antifungal medications itraconazole (Sporanox®) and ketoconazole (Nizoral®) and antibiotics like clarithromycin (Biaxin®)

The following medications may **decrease** the levels and effects of valbenazine:

- Certain seizure medications, such as carbamazepine (Tegretol®) or phenytoin (Dilantin®)
- The antibiotic rifampin (Rifadin®)
- Herbal supplements containing St. John's wort

Concurrent use of valbenazine may **increase** the level of the antiarrhythmic medication digoxin (Lanoxin®)

Using valbenazine with antipsychotics, tricyclic antidepressants, certain heart medications and antibiotics may increase the risk of developing irregular heart rhythms.

How long does it take for valbenazine to work?

It is very important to tell your doctor how you feel things are going during the first few weeks after you start taking valbenazine. It may take several weeks to see big enough changes in your symptoms to decide if valbenazine is the right medication for you.

Summary of Black Box Warnings

No black box warnings exist for this medication at this time.

Important Disclosure: This information is being provided as a community outreach effort of the American Association of Psychiatric Pharmacists. This information is for educational and informational purposes only and is not medical advice. This information contains a summary of important points and is not an exhaustive review of information about the medication. Always seek the advice of a physician or other qualified medical professional with any questions you may have regarding medications or medical conditions. Never delay seeking professional medical advice or disregard medical professional advice as a result of any information provided herein. The American Association of Psychiatric Pharmacists disclaims any and all liability alleged as a result of the information provided herein.