Deutetrabenazine (du tet ra BEN a zeen)

Austedo[®]

o Tablets: 6 mg, 9 mg, and 12 mg

Austedo XR[®]

o Tablets: 6 mg, 12 mg, and 24 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 <u>nami.org</u>.

What is deutetrabenazine and what does it treat?

Deutetrabenazine 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. Deutetrabenazine may also be used to treat abnormal involuntary movements associated with Huntington Disease.

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

Deutetrabenazine may help improve some or all of these symptoms.

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

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

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

Deutetrabenazine 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 experience any sudden changes in mood, behaviors, thoughts, or feelings, consult with your doctor immediately.

Only your health care provider can determine the length of deutetrabenazine treatment that is right for you. Do not stop taking deutetrabenazine 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 deutetrabenazine 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 deutetrabenazine in pregnancy. However, increased rates of stillbirths and postnatal mortality were seen when a closely related drug was administered 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 deutetrabenazine passes into your breast milk. Talk to your doctor about the best way to feed your baby during treatment with deutetrabenazine.

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

- 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 attacks, 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 deutetrabenazine?

Deutetrabenazine is usually taken twice a day, with food. The extended-release tablets are taken once a day, with or without food. Tablets should be swallowed whole; do not chew, crush or break.

Typically patients begin at 6 mg twice a day and dose may be increased weekly in increments of 6 mg per day to a maximum of 48 mg per day (given in 2 divided doses). If you are taking deutetrabenazine for Huntington's disease, you may start at an even lower dose. Patients starting on the extended-release tablets begin at 12 mg once a day and the dose may be increased weekly in increments of 6 mg per day to a maximum of 48 mg once a day. 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 deutetrabenazine?

If you miss a dose of deutetrabenazine, 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 deutetrabenazine?

Avoid drinking alcohol or using illegal drugs while you are taking deutetrabenazine. They may decrease the benefits (e.g., worsen your condition) and increase adverse effects (e.g., sedation) of the medication. When taking deutetrabenazine 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 deutetrabenazine?

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 deutetrabenazine does not exist.



What are the possible side effects of deutetrabenazine?

Common side effects

The most common side effects of taking deutetrabenazine are inflammation of the nose and throat, fatigue, drowsiness (in Huntington's disease patients), insomnia (in TD patients), diarrhea, and dry mouth.

Rare/serious side effects

Rare side effects may include slight shaking, stiffness, trouble moving, anxiety, depression, agitation, restlessness, constipation, urinary tract infection, and irregular heart rhythm.

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

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

What other medications may interact with deutetrabenazine?

Deutetrabenazine should not be taken with or within 2 weeks of taking monoamine oxidase inhibitors (MAOIs) or within 20 days of taking reserpine, as these medications can increase side effects and decrease the effectiveness of deutetrabenazine. MAOIs include phenelzine (Nardil®), tranylcypromine (Parnate®), isocarboxazid (Marplan®), and selegiline (Emsam®, Zelapar®).

Deutetrabenazine should not be taken with tetrabenazine (Xenazine®) or valbenazine (Ingrezza®)

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

- The antidepressants paroxetine (Paxil®), fluoxetine (Prozac®), quinidine (Quinate®), and bupropion (Wellbutrin ®)
- Some antiviral medications asunaprevir (Sunvepra®), darunavir (Prezista®), antibiotics such as minocycline (Minocin®)

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

Peginterferon Alfa-2b

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

The risk of parkinsonism, neuroleptic malignant syndrome, and akathisia may be increased by concomitant use of deutetrabenazine and antipsychotics.

How long does it take for deutetrabenazine 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 deutetrabenazine. It may take several weeks to see big enough changes in your symptoms to decide if deutetrabenazine is the right medication for you.

Summary of Black Box Warnings

Depression and Suicidal Thoughts in Patients with Huntington Disease

Deutetrabenazine can increase the risk of depression and suicidal thoughts in patients with Huntington's Disease. You should consider balancing the risks of depression and suicidality with the clinical need for treatment. You are encouraged to report behaviors of concern to your health care provider. Caution is advised in patients with a history of depression or prior suicide attempts, which are increased in frequency in Huntington's Disease. Deutetrabenazine is contraindicated in patients with Huntington's Disease who are suicidal, and in patients with untreated or inadequately treated depression.

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.