

MEDICATION GUIDE

Tetrabenazine (TET-ra-BEN-a-zine) Tablets

Read the Medication Guide that comes with tetrabenazine tablets before you start taking it and each time you refill the prescription. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

What is the most important information I should know about tetrabenazine tablets?

- **Tetrabenazine tablets can cause serious side effects, including:**
 - **depression**
 - **suicidal thoughts**
 - **suicidal actions**
- You should not start taking tetrabenazine tablets if you 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 tetrabenazine tablets are started and when the dose is changed.

Call the doctor 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
- more irritable, angry or aggressive than usual
- 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 are tetrabenazine tablets?

Tetrabenazine tablets are a medicine that is used to treat the involuntary movements (chorea) of Huntington's disease. Tetrabenazine tablets does not cure the cause of the involuntary movements, and it does not treat other symptoms of Huntington's disease, such as problems with thinking or emotions.

It is not known whether tetrabenazine tablets are safe and effective in children.

Who should not take tetrabenazine tablets?

Do not take tetrabenazine tablets if you:

- are depressed or have thoughts of suicide. See **“What is the most important information I should know about tetrabenazine tablets?”**

- have liver problems.
- are taking a monoamine oxidase inhibitor (MAOI) medicine. Ask your doctor or pharmacist if you are not sure.
- are taking reserpine. **Do not take medicines that contain reserpine (such as Serpalan[®] and Renese[®]-R) with tetrabenazine tablets. If your doctor plans to switch you from taking reserpine to tetrabenazine tablets, you must wait at least 20 days after your last dose of reserpine before you start taking tetrabenazine tablets.**

What should I tell my doctor before taking tetrabenazine tablets?

Tell your doctor about all 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 disease.
- have any allergies. See the end of this Medication Guide for a complete list of the ingredients in tetrabenazine tablets.
- have breast cancer or a history of breast cancer.
- have heart disease that is not stable, have heart failure or recently had a heart attack.
- have an irregular heartbeat (cardiac arrhythmia).
- are pregnant or plan to become pregnant. It is not known if tetrabenazine can harm your unborn baby.
- are breastfeeding. It is not known if tetrabenazine passes into breast milk.

Tell your doctor about all the medicines you take, including prescription medicines and nonprescription medicines, vitamins and herbal products. Using tetrabenazine tablets with certain other medicines may cause serious side effects. Do not start any new medicines while taking tetrabenazine tablets without talking to your doctor first.

How should I take tetrabenazine tablets?

- Tetrabenazine is a tablet that you take by mouth.
- **Take tetrabenazine tablets exactly as prescribed by your doctor.**
- You may take tetrabenazine tablets with or without food.
- Your doctor will increase your dose of tetrabenazine tablets each week for several weeks, until you and your doctor find the best dose for you.
- If you stop taking tetrabenazine tablets or miss a dose, your involuntary movements may return or worsen in 12 to 18 hours after the last dose.
- Before starting tetrabenazine tablets, you should talk to your healthcare provider about what to do if you miss a dose. If you miss a dose and it is time for your next dose, do not double the dose.
- Tell your doctor if you stop taking tetrabenazine tablets for more than **5** days. **Do not take another dose until you talk to your doctor.**
- **If your doctor thinks you need to take more than 50 mg of tetrabenazine tablets each day, you will need to have a blood test to see if it is safe for you.**

What should I avoid while taking tetrabenazine tablets?

Sleepiness (sedation) is a common side effect of tetrabenazine tablets. While taking tetrabenazine tablets, **do not drive a car or operate dangerous machinery until you know how tetrabenazine tablets affects you.** Drinking alcohol and taking other drugs that may also cause sleepiness while you are taking tetrabenazine tablets may increase any sleepiness caused by tetrabenazine tablets.

What are the possible side effects of tetrabenazine tablets?

Tetrabenazine tablets can cause serious side effects, including:

- **Depression, suicidal thoughts, or actions.** See “**What is the most important information I should know about tetrabenazine tablets?**”
- **Neuroleptic Malignant Syndrome (NMS).** Call your doctor right away and 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
 - very fast or uneven heartbeat
 - increased sweating
- **Parkinsonism.** Symptoms of Parkinsonism include: slight shaking, body stiffness, trouble moving or keeping your balance.
- **Restlessness.** You may get a condition where you feel a strong urge to move. This is called akathisia.
- **Irregular heartbeat.** Tetrabenazine tablets increases your chance of having certain changes in the electrical activity in your heart which can be seen on an electrocardiogram (EKG). These changes can lead to a dangerous abnormal heartbeat. Taking tetrabenazine tablets with certain medicines may increase this chance.
- **Dizziness due to blood pressure changes when you change position (orthostatic hypotension).** Change positions slowly from lying down to sitting up and from sitting up to standing when taking tetrabenazine tablets. Tell your doctor right away if you get dizzy or faint while taking tetrabenazine tablets. Your doctor may need to watch your blood pressure closely.

Common side effects with tetrabenazine tablets include:

- sleepiness (sedation)
- trouble sleeping
- depression
- tiredness (fatigue)
- anxiety
- restlessness
- agitation
- nausea

Tell your doctor if you have any side effects. Do not stop taking tetrabenazine tablets without talking to your doctor first.

Call your doctor for medical advice about side effects. You may report side effects to the Food and Drug Administration (FDA) at 1-800-FDA-1088. You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

General information about tetrabenazine tablets

Tetrabenazine tablets contain the active ingredient tetrabenazine. It also contains these inactive ingredients: anhydrous lactose, colloidal silicon dioxide, corn starch, magnesium stearate, sodium starch glycolate, and talc. The 25 mg strength tablet also contains yellow iron oxide as an inactive ingredient.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use tetrabenazine tablets for a condition for which it was not prescribed. Do not give tetrabenazine tablets to other people, even if they have the same symptoms that you have. It may harm them. Keep tetrabenazine tablets out of the reach of children.

This Medication Guide summarizes the most important information about tetrabenazine tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about tetrabenazine tablets that is written for healthcare professionals.

For more information about tetrabenazine tablets, ask your pharmacist or doctor, visit www.lupinpharmaceuticals.com on the Internet, or call **1-800-399-2561**.

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

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