

## [XENAZINE® (tetrabenazine) Tablets]

### Indications and Usage:

XENAZINE is a medicine that is used to treat the involuntary movements (chorea) of Huntington's disease. XENAZINE 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 XENAZINE is safe and effective in children.

### Important Safety Information:

- **XENAZINE can cause serious side effects, including:**
    - **depression**
    - **suicidal thoughts**
    - **suicidal actions**
  - You should not start taking XENAZINE 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, or worsening depression. This is especially important when XENAZINE is started and when the dose is changed.
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- Do not take XENAZINE if you have liver problems or are taking monoamine oxidase inhibitors (MAOIs) or reserpine. Ask your doctor or pharmacist if you are not sure. **At least 20 days should pass after stopping reserpine before starting XENAZINE.**
  - Tell your doctor if you are pregnant or plan to become pregnant, breast-feeding, have breast cancer or a history of breast cancer, or have heart disease or an irregular heartbeat.
  - **Tell your doctor about all the medicines you take. Do not start any new medicines while taking XENAZINE without talking to your doctor first.**
  - **Take XENAZINE exactly as prescribed by your doctor.** The need for therapy should be evaluated on an ongoing basis with your doctor. The dose of XENAZINE should be adjusted slowly over several weeks for a dose that is appropriate for you. Tell your doctor if you stop taking XENAZINE 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 XENAZINE each day, you will need to have a blood test to see if a higher dose is right for you.**
  - Neuroleptic Malignant Syndrome (NMS) is a potentially fatal side effect reported with XENAZINE. 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, or increased sweating. XENAZINE should be stopped immediately if NMS is diagnosed.
  - XENAZINE can also cause other serious side effects, including: parkinsonism (slight shaking, body stiffness, trouble moving, or keeping your balance), restlessness (akathisia), trouble swallowing, irregular heartbeat, and dizziness due to blood pressure changes when you change position (orthostatic hypotension). Trouble swallowing may increase the risk of pneumonia. Uncontrolled movements called tardive dyskinesia (TD) may also develop in patients treated with XENAZINE. It is possible that the TD will not go away.
  - The risk of side effects, such as irregular heartbeat, parkinsonism, NMS, and restlessness (akathisia), may be increased when using XENAZINE with other drugs (e.g., dopamine antagonists or antipsychotics).

- Sleepiness is a common side effect of XENAZINE; **do not drive a car or operate dangerous machinery until you know how XENAZINE affects you.** Alcohol and other drugs may increase sleepiness caused by XENAZINE.
- Some side effects, such as depression, tiredness, trouble sleeping, sleepiness, parkinsonism, agitation, and restlessness (akathisia), may be dose-dependent. If the side effects don't stop or lessen, your doctor should consider lowering the dose or stopping your XENAZINE. The most commonly reported side effects in studies with XENAZINE were sleepiness, trouble sleeping, depression, tiredness, anxiety, restlessness, agitation, and nausea.

[For more information, please see the [full Prescribing Information, including Boxed Warning, the Medication Guide](#), or go [www.xenazineusa.com](http://www.xenazineusa.com).]

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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