

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. This is especially important when Xenazine is started and when the dose is changed.

Do not take Xenazine if you have liver problems or are taking monoamine oxidase inhibitors or reserpine. At least 20 days should pass after stopping reserpine before starting Xenazine. Tell your doctor if you are pregnant, breast-feeding or have breast cancer.

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. 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 Xenazine is safe for you.

Neuroleptic malignant syndrome (NMS), restlessness, agitation, parkinsonism (slight shaking, body stiffness, trouble moving or keeping your balance), trouble swallowing, dizziness, and irregular heartbeat have also been reported with use of Xenazine. Do not use Xenazine with drugs known to cause irregular heart beat. Side effects associated with Xenazine, such as irregular heartbeat, NMS, and parkinsonism, may be increased if used together with drugs called dopamine antagonists. Uncontrolled movements called tardive dyskinesia (TD) may develop in patients treated with Xenazine. It is possible that the TD will not go away.

Xenazine may cause sleepiness or drowsiness, and may affect the ability to drive or use dangerous machinery. Some side effects, such as depression, tiredness, trouble sleeping, sleepiness/drowsiness, parkinsonism, and restlessness, 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/drowsiness, tiredness, trouble sleeping, depression, restlessness, anxiety, and nausea.

For more information, please see the [Xenazine Medication Guide](#) and [Full Prescribing Information, including Boxed Warning](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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