

## XENAZINE<sup>®</sup> (tetrabenazine) Tablets

### Indications and Usage:

XENAZINE is indicated for the treatment of chorea associated with Huntington's disease.

### Important Safety Information:

#### **WARNING: DEPRESSION AND SUICIDALITY**

*See full prescribing information for complete boxed warning.*

- **Increases the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease.**
  - **Balance risks of depression and suicidality with the clinical need for control of choreiform movements when considering the use of XENAZINE.**
  - **Monitor patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior.**
  - **Inform patients, caregivers and families of the risk of depression and suicidality and instruct to report behaviors of concern promptly to the treating physician.**
  - **Exercise caution when treating patients with a history of depression or prior suicide attempts or ideation.**
  - **XENAZINE is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.**
- 
- XENAZINE is also contraindicated in patients who have impaired hepatic function or are taking monoamine oxidase inhibitors (MAOIs) or reserpine. XENAZINE should not be used in combination with an MAOI, or within a minimum of 14 days of discontinuing therapy with an MAOI. At least 20 days should elapse after stopping reserpine before starting XENAZINE.
  - Prescribers should periodically re-evaluate the need for XENAZINE in their patients by assessing the beneficial effect on chorea and possible adverse effects including worsening mood, cognition, rigidity and functional capacity. XENAZINE should be titrated slowly over several weeks for a dose that is appropriate for each patient.
  - Before a dose greater than 50 mg is administered, the patient's CYP2D6 metabolizer status should be determined. Do not exceed 50 mg/day or 25 mg/dose if XENAZINE is administered with a strong CYP2D6 inhibitor.
  - Neuroleptic malignant syndrome (NMS), akathisia, agitation, parkinsonism, dysphagia and aspiration pneumonia, and QT prolongation-related arrhythmias have been reported with use of XENAZINE. XENAZINE should not be used in combination with drugs known to prolong QTc (which in certain circumstances can lead to torsades de pointes and/or sudden death), in patients with congenital long QT syndrome, or in patients with a history of cardiac arrhythmias. A potentially irreversible syndrome of involuntary, dyskinetic movements called tardive dyskinesia (TD) may develop in patients treated with neuroleptic drugs. If signs and symptoms of TD appear in a patient treated with XENAZINE, drug discontinuation should be considered. Adverse reactions associated with XENAZINE, such as QTc prolongation, NMS, and extrapyramidal disorders, may be exaggerated by concomitant use of dopamine antagonists.
  - XENAZINE elevates serum prolactin concentrations. XENAZINE may induce sedation and somnolence (sleepiness or drowsiness) and may impair the ability to drive or operate dangerous machinery. Alcohol or other sedating drugs can worsen sedation and somnolence.
  - Some adverse events such as depression, fatigue, insomnia, sedation/somnolence, parkinsonism, and akathisia may be dose-dependent. If the adverse effect does not resolve or decrease, consideration should be given to lowering or discontinuing XENAZINE. The most commonly reported adverse events with XENAZINE compared to placebo were sedation/somnolence (31% vs 3%), fatigue (22% vs 13%), insomnia (22% vs 0%), depression (19% vs 0%), akathisia (19% vs 0%), anxiety (15% vs 3%), and nausea (13% vs 7%).

For more information, please see [Full Prescribing Information, including Boxed Warning](#).

®Xenazine is a registered trademark of Biovail Laboratories International (Barbados) S.R.L

**XZN048R6W**