TETRABENAZINE
TABLETS

To most, "generics" means bland, ordinary, and uninteresting. To us, it means the opportunity to be remarkable.

MAKING
GENERICS
REMARKABLE

PRODUCT DETAILS

- Strength: Available in 12.5 mg and 25 mg tablets
- Therapeutic Class: Monoamine Depletor

NDC Numbers:

12.5 mg| Bottle of 112: **70436-101-09**

25 mg | Bottle of 112: **70436-102-09**

See reverse side for important safety information.

To place an order or learn more, call **844-529-8988 (Toll Free)** or email **sales@slaterunpharma.com**

6am – 7pm CST (Monday - Friday)

Available through your wholesaler:

NDC: 70436-101-09

Cardinal Health:	5610670
McKesson:	1525260
Amerisource:	10234588

NDC: 70436-102-09

Cardinal Health:	5610688
McKesson:	1525286
Amerisource:	10234589

IMPORTANT SAFETY INFORMATION FOR:

TETRABENAZINE TABLETS

WARNING: DEPRESSION AND SUICIDALITY
Tetrabenazine can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Anyone considering the use of tetrabenazine tablets must balance the risks of depression and suicidality with the clinical need for control of chorea. Close observation of patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior should accompany therapy. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician.

Particular concern should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington's disease. Tetrabenazine tablets are contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.

Tetrabenazine Tablets are contraindicated in patients:

- Who are actively suicidal, or in patients with untreated or inadequately treated depression.
- With hepatic impairment.
- Taking monoamine oxidase inhibitors (MAOIs). Tetrabenazine tablets should not be used in combination with an MAOI, or within a minimum of 14 days of discontinuing therapy with an MAOI.
- Taking reserpine. At least 20 days should elapse after stopping reserpine before starting tetrabenazine tablets.
- Taking deutetrabenazine or valbenazine.

Prescribers should periodically re-evaluate the need for tetrabenazine tablets in their patients by assessing the effect on chorea and possible adverse effects, including depression and suicidality, cognitive decline, parkinsonism, dysphagia, sedation/somnolence, akathisia, restlessness, and disability. It may be difficult to distinguish between adverse reactions and progression of the underlying disease; decreasing the dose or stopping the drug may help the clinician distinguish between the two possibilities.

Before prescribing a daily dose of tetrabenazine tablets that is greater than 50 mg per day, patients should be genotyped to determine if they express the drug metabolizing enzyme, CYP2D6.. In patients who are identified as CYP2D6 poor metabolizers, the maximum recommended totally daily dose is 50 mg and the maximum single recommended dose is 25 mg.

A potentially fatal symptoms complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with tetrabenazine tablets and other drugs that reduce dopaminergic transmission. Tetrabenazine tablets should be immediately discontinued if this occurs.

Tetrabenazine tablets may increase the risk of restlessness, agitation, akathisia, and parkinsonism. The dose should be reduced or tetrabenazine tablets should be discontinued if this occurs.

The most common adverse reactions (greater than 10% and at least 5% greater than placebo) were: sedation/somnolence, fatigue, insomnia, depression, akathisia, anxiety/anxiety aggravated, and nausea.

Please see the package insert for Tetrabenazine Tablets for full prescribing information.