

Ticstop™

Tetrabenazine

Composition

Ticstop™ 12.5 Tablet: Each tablet contains Tetrabenazine INN 12.5 mg.

Ticstop™ 25 Tablet: Each tablet contains Tetrabenazine INN 25 mg.

Pharmacology

The precise mechanism by which **Ticstop™** (Tetrabenazine) exerts its anti-chorea effects is unknown but is believed to be related to its effect as a reversible depletor of monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals. It is used primarily in the symptomatic treatment of various hyperkinetic disorders. It is a vesicular monoamine transporter-2 (VMAT-2) inhibitor that used as symptomatic treatment of chorea associated with Huntington's disease.

Indication

Ticstop™ (Tetrabenazine) is indicated for the treatment of hyperkinetic disorders. It is also indicated for chorea associated with Huntington's disease.

Dosage & Administration

Route of Administration: Oral
Recommended dosing: Individualization of dose with careful weekly titration is required. The 1st week's starting dose is 12.5 mg daily; 2nd week, 25 mg (12.5 mg twice daily); then slowly titrate at weekly intervals by 12.5 mg to a tolerated dose that reduces chorea. Doses of 37.5 mg and up to 50 mg per day should be administered in three divided doses per day with a maximum recommended single dose not to exceed 25 mg. Patients requiring doses above 50 mg per day should be genotyped for the drug metabolizing enzyme CYP2D6 to determine if the patient is a poor metabolizer or an extensive metabolizer. Maximum daily dose in poor metabolizers: 50 mg with a maximum single dose of 25 mg. Maximum daily dose in extended and intermediate metabolizers: 100 mg with a maximum single dose of 37.5 mg. If serious adverse reactions occur, titration should be stopped and the dose should be reduced. If the adverse reactions do not resolve, consider withdrawal of Tetrabenazine.

Contraindications

- Actively suicidal or who have depression which is untreated or undertreated
- Hepatic impairment
- Taking monoamine oxidase inhibitors (MAOIs) or reserpine
- Taking deutetetrabenazine or valbenazine

Warnings & precautions

Periodically reevaluate the benefit and potential for adverse effects such as worsening mood, cognition, rigidity, and functional capacity. Do not exceed 50 mg/day and the maximum single dose should not exceed 25 mg if administered in conjunction with a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine). For Neuroleptic Malignant Syndrome, treatment should be discontinued. The dose should be reduced or discontinued if patient experience restlessness, agitation, akathisia and parkinsonism. The treatment may impair patient's ability to drive or operate complex machinery, Tetrabenazine is not recommended in combination with other drugs that prolong QTc.

Side-effects

Common: Most common adverse reactions (>10% and at least 5% greater than placebo) were Sedation/somnolence, fatigue, insomnia, depression, akathisia, anxiety/anxiety aggravated & nausea.

Rare: Suicidal thoughts, neuroleptic malignant syndrome, a reaction characterized by fever, muscle rigidity and confusion & pneumonia.

Drug interactions

With medicine: Strong CYP2D6 Inhibitors: A reduction in Tetrabenazine dose may be necessary when adding a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine,quinidine) in patients maintained on a stable dose of Tetrabenazine. Reserpine: Reserpine binds irreversibly to VMAT2, and the duration of its effect is several days. At least 20 days should elapse after stopping reserpine before starting Tetrabenazine. Tetrabenazine and Reserpine should not be used concomitantly. MAOIs: Tetrabenazine should not be used in combination with an MAOI or within a minimum of 14 days of discontinuing therapy with an MAOI. With food & others: No interaction with food, can be taken with or without food.

Use in specific populations

Pregnancy: Based on animal data, may cause fetal harm.

Storage

Store below 30° C., protect from light & moisture. Keep all medicines out of the reach of children.

How supplied

Ticstop™ 12.5 Tablet: Each box contains 20 tablets in blister pack.

Ticstop™ 25 Tablet: Each box contains 20 tablets in blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH