Abridged Prescribing Information:

Active Ingredient: Each Ticstop tablet contains Tetrabenazine Tablets 25 mg **Indication:** In treatment of movement disorders associated with organic CNS conditions like Huntington's chorea, hemiballismus and senile chorea **Dosage & Administration:** 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 (PM) or an extensive metabolizer (EM).Maximum daily dose in PMs: 50 mg with a maximum single dose of 25 mg. Maximum daily dose in EMs and intermediate metabolizers (IMs): 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 reaction(s) 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 deutetrabenazine 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).Neuroleptic Malignant Syndrome (NMS): Discontinue if this occurs. Restlessness, agitation, akathisia and parkinsonism: Reduce dose or discontinue if occurs. Sedation/Somnolence: May impair patient's ability to drive or operate complex machinery, QTc prolongation: Not recommended in combination with other drugs that prolong QTc. **Pregnancy & Lactation:** Preganancy-Based on animal data, may cause fetal harm. Lactation-The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for tetrabenazine and any potential adverse effects on the breastfed infant from tetrabenazine or from the underlying maternal condition **Interaction:** Strong CYP2D6 inhibitors (e.g., paroxetine, fluoxetine, quinidine), Reserpine, Monoamine Oxidase Inhibitors (MAOIs), Alcohol or Other Sedating Drugs, Drugs That Cause QTc Prolongation(e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone, moxifloxacin, quinidine, procainamide, quinidine, procainamide, amiodarone, sotalol) Neuroleptic Drugs (chlorpromazine, haloperidol, olanzapine, risperidone, thioridazine, ziprasidone) Concomitant Deutetrabenazine or Valbenazine **Adverse Reactions:** Most common adverse reactions were: Sedation/somnolence, fatigue, insomnia, depression, akathisia, anxiety/anxiety aggravated, nausea **Overdose:** Adverse reactions associated with tetrabenazine overdose include acute dystonia, oculogyric crisis, nausea and vomiting, sweating, sedation, hypotension, confusion, diarrhea, hallucinations, rubor, and tremor. Treatment should consist of those general measures employed in the management of overdosage with any CNS-active drug. General supportive and symptomatic measures are recommended. Cardiac rhythm and vital signs should be monitored. In managing overdosage, the possibility of multiple drug involvement should always be considered. *(For details, please refer full prescribing information)*

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