

# TetraZin

Tetrabenazine

## COMPOSITION

**TetraZin Tablet:** Each tablet contains Tetrabenazine INN 12.5 mg.

**TetraZin 25 Tablet:** Each tablet contains Tetrabenazine INN 25 mg.

## PHARMACOLOGICAL INFORMATION

### Mechanism of Action

The precise mechanism by which 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. Tetrabenazine reversibly inhibits the human Vesicular Monoamine Transporter type 2 (VMAT2), resulting in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores. Human VMAT2 is also inhibited by dihydroTetrabenazine (HTBZ), a mixture of  $\alpha$ -HTBZ and  $\beta$ -HTBZ.  $\alpha$ - and  $\beta$ -HTBZ, major circulating metabolites in humans, exhibit high in vitro binding affinity to bovine VMAT2. Tetrabenazine exhibits weak in vitro binding affinity at the dopamine D2 receptor.

## CLINICAL INFORMATION

### Indication & Uses

Tetrabenazine is a Vesicular Monoamine Transporter (VMAT2) inhibitor indicated for the treatment of Hyperkinetic movement disorder.

### Dosage and 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.

## Use in the specific Population

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

## Adverse Reaction

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

## Overdose

The dose of Tetrabenazine in these patients ranged from 100 mg to 1g. 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. The physician should consider contacting a poison control center on the treatment of any overdose.

## Drug Interactions

The dose of Tetrabenazine should be reduced in patients co-administered a strong CYP2D6 inhibitor.

## Contraindications

- ⌚ Actively suicidal or who have depression which is untreated or undertreated
- ⌚ Hepatic impairment
- ⌚ Taking MAOIs or Reserpine

## PHARMACEUTICAL INFORMATION

### Storage Conditions

Store below 30°C & dry place, away from light. Keep out of the reach of children.

### Presentation & Packaging

**Tetrazin Tablet:** Each commercial box contains 30 tablets in Alu-Alu blister pack. Each blister supplied in sachet.

**Tetrazin 25 Tablet:** Each commercial box contains 30 tablets in Alu-Alu blister pack. Each blister supplied in sachet.

Manufactured By

**BEACON**<sup>®</sup>

Pharmaceuticals PLC

Bhaluka, Mymensingh, Bangladesh

0000000000