Ajuben™

Deutetrabenazine

Presentation
Ajuben™6: Each tablet contains Deutetrabenazine INN 6 mg.
Ajuben™12: Each tablet contains Deutetrabenazine INN 12 mg.

Description
The precise mechanism by which deutetrabenazine 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. The major circulating metabolites (α-dihydrotetrabenazine and β-dihydrotetrabenazine) of deutetrabenazine, are reversible inhibitors of vesicular monoamine transporter 2 (VMAT2), resulting in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores.

Indications and Usage
Deutetrabenazine is a vesicular monoamine transporter 2 (VMAT2) inhibitor indicated for the treatment of Chorea associated with Huntington's disease & Tardive dyskinesia in adults.

Dosage and Administration
Patients not presently receiving Tetrabenazine:

Indication	Initial dose	Maintenance dose	Maximum dose
Chorea associated with Huntington's disease	6 mg/day	6 mg– 48 mg/day	48 mg/day
Tardive dyskinesia	12 mg/day	12 mg– 48 mg/day	48 mg/day

Titrate up at weekly intervals by 6 mg per day to a tolerated dose that reduces chorea, up to a maximum recommended daily dosage of 48 mg (24 mg twice daily). Administer total daily dosages of 12 mg or above in two divided doses and administer with foods.

Patients receiving Tetrabenazine: If switching patients from tetrabenazine, discontinue tetrabenazine and initiate deutetrabenazine the following day. The recommended initial dosing regimen of deutetrabenazine in patients switching from tetrabenazine to deutetrabenazine is shown in below table:

Current Tetrabenazine daily dosage	Initial regimen of Deutetrabenazine
12.5 mg	6 mg once daily
25 mg	6 mg twice daily
37.5 mg	9 mg twice daily
50 mg	12 mg twice daily
62.5 mg	15 mg twice daily
75 mg	18 mg twice daily
87.5 mg	21 mg twice daily
100 mg	24 mg twice daily

After patients are switched to deutetrabenazine, the dose may be adjusted at weekly intervals.

Patients with Hepatic & Renal Impairment: No clinical studies have been conducted to assess the effect of renal & hepatic impairment on the pharmacokinetics of deutetrabenazine.

Patients with poor CYP2D6 metabolizers: Maximum recommended dosage of deutetrabenazine in poor CYP2D6 metabolizers is 36 mg per day (i.e., 18 mg twice daily)

Use in Pregnancy & Lactation
Pregnancy: There are no adequate data on the developmental risk associated with the use of deutetrabenazine in pregnant women.
Lactation: There are no data on the presence of deutetrabenazine or its metabolites in human milk, the effects on the breastfed infant, or the effects of the drug on milk production.
Use in Children: Safety & effectiveness of deutetrabenzine in infants & children have not been established.

Side Effects
Most common adverse reactions (>8%) of deutetrabenzine's are somnolence, diarrhea, dry mouth, and fatigue.

Precautions
Patients may experience Neuroleptic Malignant Syndrome (discontinue deutetrabenazine if this occurs), Akathisia, agitation, restlessness, and Parkinsonism (reduce the daily dose of deutetrabenazine or discontinue if this occurs) and Sedation/somnolence.

Contraindications
Deutetrabenazine is contraindicated in patients with Suicidal, or untreated/inadequately treated depression, Hepatic impairment and in patients Taking MAOIs, reserpine, or tetrabenazine.

Drug Interactions
Concomitant use of strong CYP2D6 inhibitors: Maximum recommended dose of deutetrabenazine is 36 mg per day (18 mg twice daily) and alcohol or other sedating drugs- may have additive sedation and somnolence.

Overdose
The following adverse reactions occurred with overdosing: acute dystonia, oculogyric crisis, nausea and vomiting, sweating, sedation, hypotension, confusion, diarrhea, hallucinations, rubor, and tremor.

Storage
Do not store above 30 ºC. Keep away from light and out of the reach of children.

Commercial Pack
Ajuben™6 : Each box contains 1 blister strips of 10 tablets.
Ajuben™12: Each box contains 1 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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