Patients with Huntington's disease are at increased risk for depression, suicidal ideation or behaviors (suicidality). Tetrabenazine disease; decreasing the dose or stopping the drug may help the clinician distinguish between the two possibilities. In some patients,Prescribers should periodically re-evaluate the need for tetrabenazine in their patients by assessing the beneficial effect on chorea capacity over time. In a 12-week controlled trial, tetrabenazine was also shown to cause slight worsening in mood, cognition,
**Usage in Pregnancy**

Advise patients and their families that alcohol may potentiate the sedation induced by tetrabenazine. Patients should be advised to use condoms and avoid conception during treatment with tetrabenazine. Patients should use non-oral contraception when considering pregnancy.

**Interaction with Alcohol**

Tell patients to avoid using alcohol during treatment with tetrabenazine.

**Driving and Other Activities**

Doing activities that require alertness should be avoided when patients are taking tetrabenazine. Patients should be advised to use caution when driving and operating machinery. Patients should inform their physicians of any activities they cannot perform due to the effects of tetrabenazine.

**Sedation**

Sedation, akathisia, parkinsonism, depression, and difficulty swallowing may occur. Such symptoms should be promptly reported to the patient's physician and may dose need to be reduced or discontinued.

**Sedation, akathisia, parkinsonism, depression, and difficulty swallowing**

Inform patients and their families that tetrabenazine may increase the risk of suicidal thinking and behaviors. Counsel patients and their families to be alert for any indication of suicidal thinking or behaviors and to report such symptoms immediately to their healthcare provider.

**Use in Specific Populations**

**Impairment of Fertility**

Impairment of fertility in male or female patients exposed to tetrabenazine during pregnancy was not systematically evaluated, and it is unknown whether tetrabenazine will impair fertility in humans.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Carcinogenicity studies were conducted in mice and rats at doses up to 30 or 60 mg/kg/day (about 2 or 4 times the maximum recommended human dose on a mg/m² basis).

**Carcinogenesis**

No increase in tumors was observed in p53 transgenic mice treated orally with tetrabenazine at doses of 0, 5, 15 and 30 mg/kg/day for 26 weeks. When compared to humans receiving a 50 mg dose of tetrabenazine, mice dosed with a 30 mg/kg dose may not have adequately characterized the potential of tetrabenazine to be carcinogenic in people.

**Mutagenesis**

The bacterial mutagenicity assay was negative in Salmonella typhimurium and Escherichia coli with and without metabolic activation. The in vitro chromosome aberration assay in Chinese hamster lung cells in the presence of metabolic activation was negative. No increase in tumors was observed in p53 transgenic mice treated orally with tetrabenazine at doses of 0, 5, 15 and 30 mg/kg/day for 26 weeks. When compared to humans receiving a 50 mg dose of tetrabenazine, mice dosed with a 30 mg/kg dose may not have adequately characterized the potential of tetrabenazine to be carcinogenic in people.

**Impairment of Fertility**

Impairment of fertility in male or female patients exposed to tetrabenazine during pregnancy was not systematically evaluated, and it is unknown whether tetrabenazine will impair fertility in humans.

**What are the possible side effects of tetrabenazine tablets?**

Common side effects of tetrabenazine tablets include:

- Nausea
- Anorexia
- Anxiety
- Insomnia
- Fatigue
- Dry mouth
- Headache
- Constipation
- Abdominal pain
- Stomatitis
- Rash

Other side effects include:

- Tardive dyskinesia (TD)
- Impairment of fertility
- Troubled swallowing

If you experience any of these side effects, please talk to your doctor. You can ask your doctor or pharmacist for information about tetrabenazine tablets that is written for healthcare professionals.
Each tablet contains 12.5 mg of tetrabenazine.
Usual Dosage: See package insert for full dosage information.
Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) (see USP Controlled Room Temperature).
Do not accept if seal over bottle opening is missing or broken.
Dispense in tight, light-resistant, child-resistant containers (USP).
KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Distributed by
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512
Manufactured by
Sun Pharmaceutical Industries Limited
Dadra 396 191 (U T of D & NH), India

Each tablet contains 12.5 mg of tetrabenazine.
Usual Dosage: See package insert for full dosage information.
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KEEP THIS AND ALL MEDICINES OUT OF THE REACH OF CHILDREN.
Each tablet contains 25 mg of tetrabenazine.

Usual Dosage: See package insert for full dosage information.

Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].

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NDC 47335-179-23

Tetrabenazine Tablets

25 mg

Rx only

112 Tablets

Manufactured by:
Sun Pharmaceutical Industries Limited
Survey No. 259/15,
Dada-396 191 (U.T. of D & NH),
India.

Dosage: See package insert for full dosage information.

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Pharmacist: Please dispense with Medication Guide provided separately to each patient.

Each tablet contains 25 mg of tetrabenazine.

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