Drug Interactions

Anticholinergic drugs such as phenothiazines or haloperidol, tricyclic antidepressants (see WARNINGS).

Pediatric Use

Because of the atropine-like side effects, benztropine mesylate should be used with caution in pediatric patients over three years of age (see CONTRAINDICATIONS).

ADVERSE REACTIONS

The adverse reactions below, most of which are anticholinergic in nature, have been reported and within each category are listed in order of decreasing severity.

Cardiovascular/Thyroidic

Dyspepsia, dry mouth, constipation, vomiting, nausea, dizziness, dry mucous membranes, visual disturbances.

Nervous System

Tardive dyskinesia may appear in some patients on long-term therapy with phenothiazines and related agents, or may occur after therapy with these drugs has been discontinued. Antiparkinsonism agents do not alleviate the symptoms of tardive dyskinesia, and in some instances may aggravate them. Benztropine mesylate is not recommended for use in patients with tardive dyskinesia.

The physicians should be aware of the possible occurrence of glaucoma. Although the drug does not appear to have any adverse effect on simple glaucoma, it probably should not be used in angle closure glaucoma.

HOW SUPPLIED

Benztropine Mesylate Tablets, USP are available as follows:

Benzene mesylate tablets, 0.5 mg, 1 mg and 2 mg white, round, bisected, compressed tablets, debossed “EP 138”, in bottles of 100 (NDC 76385-103-01) and 1000 (NDC 76385-103-10) tablets. 2 mg white round, round, compressed tablets, debossed “EP 138”, in bottles of 100 (NDC 76385-105-01) and 1000 (NDC 76385-105-10) tablets. Dispense in a well-closed container as defined in the USP, with a child-resistant closure.

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