Benztropine mesylate injection is a crystalline white powder, and is very soluble in water. Anhydrous benzyl alcohol is supplied as a solvent for the injection (Rx only).

Each milliliter of injection contains: Benztropine mesylate 1 mg; sodium chloride 9 mg; water for injection, p.a.

CLINICAL PHARMACOLOGY:
Benztropine mesylate possesses both anticholinergic and antihistaminic effects, although only the former have been established as therapeutically significant in the management of parkinsonism, extrapyramidal side effects of neuroleptic drugs (e.g., phenothiazines), and other conditions which are related to overactivity of the autonomic nervous system. In vitro, the anticholinergic and antihistaminic effects of benzylamine and related agents, or may occur after therapy with these substances. Benzylamine and related agents, or may occur after therapy with these substances.

DESCRIPTION:
Benztropine mesylate is a synthetic compound containing structural features found in atropine and diphenhydramine. This compound is designated chemically as 8-oxo-3,3-dimethyl-2,3-dihydro-7-pyrrolindione-7-sulfonate. Its structural formula is:

\[
\text{C}_{20}\text{H}_{29}\text{NO} + \text{C}_{10}\text{H}_{6}\text{SO}_{4}\text{H}
\]

M.W. 450.04

Benztropine mesylate is a crystalline white powder, and is very soluble in water. Anhydrous benzyl alcohol is supplied as a solvent for the injection (Rx only).

Each milliliter of injection contains: Benztropine mesylate 1 mg; sodium chloride 9 mg; water for injection, p.a.

INDICATIONS AND USAGE:
For use as an adjunct in the therapy of all forms of parkinsonism (see DOSAGE AND ADMINISTRATION). Benzamyl may be used in addition to anticholinergic drugs, in order to reduce the dose of the latter and thus to reduce the inception of adverse reactions.

CONTRAINDICATIONS:
Hypersensitivity to any component of benzamyl mesylate injection.

ADVERSE REACTIONS:
Adverse reactions may be associated with the use of benzamyl mesylate injection. The reactions reported with other anticholinergic drugs have occurred in patients taking anticholinergic-containing structural features found in atropine and diphenhydramine. This compound is designated chemically as 8-oxo-3,3-dimethyl-2,3-dihydro-7-pyrrolindione-7-sulfonate. Its structural formula is:

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CLINICAL PHARMACOLOGY:
Benzamyl mesylate possesses both anticholinergic and antihistaminic effects, although only the former have been established as therapeutically significant in the management of parkinsonism, extrapyramidal side effects of neuroleptic drugs (e.g., phenothiazines), and other conditions which are related to overactivity of the autonomic nervous system. In vitro, the anticholinergic and antihistaminic effects of benzylamine and related agents, or may occur after therapy with these substances. Benzylamine and related agents, or may occur after therapy with these substances.
PRECAUTIONS:

General:

Since benztropine mesylate has cumulative action, continued supervision is advisable. Patients with a tendency to tachycardia and patients with prostatic hypertrophy, especially those with urinary retention, should be closely observed. Dysuria may occur, but rarely becomes a problem. Urinary retention has been reported with benztropine mesylate.

The drug may cause complaints of weakness and inability to move particular muscle groups, especially in large doses. For example, if the neck has been rigid and suddenly relaxes, it may feel as though it were being strangled.

Mental confusion and excitement may occur with large doses, or in susceptible patients. Visual hallucinations may occur. Various neurotic or psychotic reactions have been described in patients taking benztropine mesylate. Furthermore, in the treatment of extrapyramidal disorders due to neuroleptic drugs (e.g., phenothiazines), in patients with mental depression, occasionally there may be intensification of the mental symptoms. Such intensification may precipitate a toxic psychosis. Patients with mental disorders should be kept under careful observation, especially at the beginning of treatment or dosage increase.

The physician should be aware of the possible occurrence of visual hallucinations and should not approve of their administration to patients with glaucoma, if possible should not be used in angle-closure glaucoma.

Drug Interactions:

Anticholinergic drugs such as phenothiazines and other anticholinergics (see WARNINGS).

Pediatric Use:

Because of the atropine-like side effects, benztropine mesylate should be used with caution in patients under 3 years of age (see CONTRAINDICATIONS).

Geriatric Use:

Clinical studies of benztropine mesylate did not include an adequate number of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

If there is a high risk of excessive anticholinergic adverse reactions, dosage should be lowered according to age. The patient should start at the low end of the dosage range and its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the night more easily, its effects may last throughout the night, enabling patients to turn in bed during the next day. For example, if the neck has been rigid and suddenly relaxes, it may feel as though it were being strangled.

ADVERSE REACTIONS:

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

Cardiovascular: Tachycardia.

Dermatologic: Rash, urticaria, pruritus, anaphylaxis.

Dermatologic/Immune or Skin: Occasionally, an allergic reaction, e.g., skin rash, develops. If this cannot be controlled by dosage reduction, the drug should be discontinued.

Gastrointestinal: Diarrhea, constipation, vomiting, nausea, dry mouth.

Gastrointestinal: Nausea, vomiting, diarrhea, constipation, dry mouth, flatus, abdominal pain, dyspepsia.

Genitourinary: Urinary retention, dysuria.

Central Nervous System: Drowsiness, dizziness, headache, confusion, disorientation, memory impairment, impaired concentration, hallucinations, nightmares.

Central Nervous System: Mental confusion and excitement may occur, but rarely becomes a problem. Urinary retention has been reported with benztropine mesylate.

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Benztropine Mesylate


Benztropine mesylate is a crystalline white, clear, colorless solution and is supplied as follows:

**HOW SUPPLIED:**

Dexone® Mesylate Injection, 1 mg per mL, is a clear, colorless solution and is supplied as follows:

**Product M/ID:**

<table>
<thead>
<tr>
<th>BOC</th>
<th>Strength</th>
<th>Spec.</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>05701001</td>
<td>1 mg/mL</td>
<td></td>
<td>A clear, colorless solution</td>
</tr>
</tbody>
</table>

Store at 20° to 25°C (68° to 77°F) [see USP Conventional Room Temperature]. Protect from light, and do not freeze.

The container closure is not made with natural rubber latex.

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FRESENIUS KABI

Lawrence, N.J. 08647

www.fresenius-kabi.us

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