Safety data sheet

Benztropine mesylate Injection, USP

**Strength:** 2mg/2mL.  **Pack Size:** Five (5) such Vials are packaged in a  **Revision No.:** 01

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**EMERGENCY OVERVIEW**

Benztropine Mesylate Injection intended for Intravenous or Intramuscular contains Benztropine Mesylate and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

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**Section 1. Identification**

**Identification of the product**

- **Product name:** Benztropine mesylate Injection
- **Formula:** C₂₁H₂₅NO·CH₄O·S
- **Chemical Name:** 8-azabicyclo[3.2.1] octane, 3-(diphenylmethoxy)-endo, methanesulfonate

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**Manufacturer / supplier identification**

- **Company:** Cadila Healthcare Ltd. Ahmedabad, India
- **Contact for information:** Tel.: +91 79 6868100  Fax: +91 79 3750319
- **Emergency Telephone No.:** Tel.: +91 79 6868100

**Recommended use / Therapeutic Category:** Anticholinergic and antihistaminic effects

**Restriction on Use / Contraindications**

Hypersensitivity to any component of Benztropine Mesylate Injection, because of its atropine-like side effects, this drug is contraindicated in pediatric patients under three years age, and should be used with caution in older pediatric patients.
Dose and Administration

Since there is no significant difference in onset of effect after intravenous or intramuscular injection, usually there is no need to use the intravenous route. The drug is quickly effective after either route, with improvement sometimes noticeable a few minutes after injection. In emergency situations, when the condition of the patient is alarming, 1 to 2 mL of the injection normally will provide quick relief. If the parkinsonian effect begins to return, the dose can be repeated.

Because of cumulative action, therapy should be initiated with a low dose which is increased gradually at five or six-day intervals to the smallest amount necessary for optimal relief. Increases should be made in increments of 0.5 mg, to a maximum of 6 mg, or until optimal results are obtained without excessive adverse reactions.

Postencephalitic and Idiopathic Parkinsonism

The usual daily dose is 1 to 2 mg, with a range of 0.5 to 6 mg parenterally.

As with any agent used in parkinsonism, dosage must be individualized according to age and weight, and the type of parkinsonism being treated. Generally, older patients, and thin patients cannot tolerate large doses. Most patients with postencephalitic parkinsonism need fairly large doses and tolerate them well. Patients with a poor mental outlook are usually poor candidates for therapy.

In idiopathic parkinsonism, therapy may be initiated with a single daily dose of 0.5 to 1 mg at bedtime. In some patients, this will be adequate; in others 4 to 6 mg a day may be required.

In postencephalitic parkinsonism, therapy may be initiated in most patients with 2 mg a day in one or more doses. In highly sensitive patients, therapy may be initiated with 0.5 mg at bedtime, and increased as necessary.

Some patients experience greatest relief when given the entire dose at bedtime; others react more favorably to divided doses, two to four times a day. Frequently, one dose a day is sufficient, and divided doses may be unnecessary or undesirable.

The long duration of action of this drug makes it particularly suitable for bedtime medication when its effects may last throughout the night, enabling patients to turn in bed during the night more easily, and to rise in the morning. When benzotropine mesylate is started, do not terminate therapy with other antiparkinsonian agents abruptly. If the other agents are to be reduced or discontinued, it must be done gradually. Many patients obtain greatest relief with combination therapy.
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Benztropine mesylate may be used concomitantly with SINEMET2 (Carbidopa-Levodopa), or with levodopa, in which case periodic dosage adjustment may be required in order to maintain optimum response.

Drug-Induced Extrapyramidal Disorders
In treating extrapyramidal disorders due to neuroleptic drugs (e.g., phenothiazines), the recommended dosage is 1 to 4 mg once or twice a day parenterally. Dosage must be individualized according to the need of the patient. Some patients require more than recommended; others do not need as much. In acute dystonic reactions, 1 to 2 mL of the injection usually relieves the condition quickly.

When extrapyramidal disorders develop soon after initiation of treatment with neuroleptic drugs (e.g., phenothiazines), they are likely to be transient. One to 2 mg of benztropine mesylate two or three times a day usually provides relief within one or two days. After one or two weeks, the drug should be withdrawn to determine the continued need for it. If such disorders recur, benztropine mesylate can be reinstituted. Certain drug-induced extrapyramidal disorders that develop slowly may not respond to benztropine mesylate. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

Adverse Effect
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
Tachycardia.

Digestive
Paralytic ileus, constipation, vomiting, nausea, dry mouth.

If dry mouth is so severe that there is difficulty in swallowing or speaking, or loss of appetite and weight, reduce dosage, or discontinue the drug temporarily.

Slight reduction in dosage may control nausea and still give sufficient relief of symptoms. Vomiting may be controlled by temporary discontinuation, followed by resumption at a lower dosage.

Nervous System
Toxic psychosis, including confusion, disorientation, memory impairment, visual hallucinations; exacerbation of pre-existing psychotic symptoms; nervousness; depression; listlessness; numbness of fingers.

Special Senses
Blurred vision, dilated pupils.

Urogenital
Urinary retention, dysuria.
Metabolic/Immune or Skin
Occasionally, an allergic reaction, e.g., skin rash, develops. If this cannot be controlled by dosage reduction, the medication should be discontinued.

Other
Heat stroke, hyperthermia, fever.

Over Dose Effect

Manifestations
May be any of those seen in atropine poisoning or antihistamine overdosage: CNS depression, preceded or followed by stimulation; confusion; nervousness; listlessness; intensification of mental symptoms or toxic psychosis in patients with mental illness being treated with neuroleptic drugs (e.g., phenothiazines); hallucinations (especially visual); dizziness; muscle weakness; ataxia; dry mouth; mydriasis; blurred vision; palpitations; tachycardia; elevated blood pressure; nausea; vomiting; dysuria; numbness of fingers; dysphagia; allergic reactions, e.g., skin rash; headache; hot, dry, flushed skin; delirium; coma; shock; convulsions; respiratory arrest; anhidrosis; hyperthermia; glaucoma; constipation.

Medical Condition

There is no information on pre-existing medical condition that may be aggravated by occupational exposure to this product, with therapeutic use, pre-existing narrow angle glaucoma & mental symptoms or toxic psychosis in patients with psychiatric illness may be aggravated.

Contraindications

Hypersensitivity to any component of Benztropine Mesylate Injection, because of its atropine-like side effects, this drug is contraindicated in pediatric patients under three years age, and should be used with caution in older pediatric patients.

Pregnancy Comments

Safe use in pregnancy has been established

Pregnancy Category

No Data Found
**Section 3. Composition / information on ingredients**

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Benztropine mesylate</td>
<td>Not Found</td>
<td>132-17-2</td>
</tr>
<tr>
<td><strong>Inactive Ingredients:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>Not Found</td>
<td>7647-14-5</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>Not Found</td>
<td>7732-18-5</td>
</tr>
</tbody>
</table>

**Section 4. First aid measures**

**General**

Since benztropine mesylate has cumulative action, continued supervision is advisable. Patients with a tendency to tachycardia and patients with prostatic hypertrophy should be observed closely during treatment.

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 weak, causing some concern. In this event, dosage adjustment is required.

Mental confusion and excitement may occur with large doses, or in susceptible patients. Visual hallucinations have been reported occasionally. Furthermore, in the treatment of extrapyramidal disorders due to neuroleptic drugs (e.g., phenothiazines), in patients with mental disorders, occasionally there may be intensification of mental symptoms. In such cases, antiparkinsonian drugs can precipitate a toxic psychosis. Patients with mental disorders should be kept under careful observation, especially at the beginning of treatment or if dosage is increased.

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 physician 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.
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**Overdose Treatment**

Phystostigmine salicylate, 1 to 2 mg, SC or IV, reportedly will reverse symptoms of anticholinergic intoxication.1 A second injection may be given after 2 hours if required. Otherwise treatment is symptomatic and supportive. Induce emesis or perform gastric lavage (contraindicated in precomatose, convulsive, or psychotic states). Maintain respiration. A short-acting barbiturate may be used for CNS excitement, but with caution to avoid subsequent depression; supportive care for depression (avoid convulsant stimulants such as picrotoxin, pentylentetrazol, or bemegride); artificial respiration for severe respiratory depression; a local miotic for mydriasis and cycloplegia; ice bags or other cold applications and alcohol sponges for hyperpyrexia, a vasopressor and fluids for circulatory collapse. Darken room for photophobia.

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**Section 5. Fire-fighting measures**

**Flash point:** Not Found  
**Upper Flammable Limit:** Not Found

**Auto-Ignition Temperature:** Not Found  
**Lower Flammable Limit:** Not Found

**Extinguishing Media:** Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.

**Fire and Explosion Hazard:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity. Generally none anticipated for this aqueous product.

**Fire fighting Procedure:** As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

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**Section 6. Accidental Release Measures**

**Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

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**Section 7. Handling and Storage**

**Storage:** Store at 20° to 25°C (68° to 77°F). Protect from light and moisture. Dispense in a tight, light-resistant container.

**Incompatibilities:** Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.
Section 8. Exposure controls / personal protection

**Respiratory Protection:** Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Skin protection:** Protective laboratory coat, apron, or disposable garment. Chemically compatible gloves for handling solutions ensure that the glove material is protective against the solvent being used. Use handling practice that minimize natural rubber (latex) should use nitrile or other synthetic non-latex glove. Use powdered latex gloves should be avoided to the risk of latex allergy.

**Eye protection:** Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Protective Clothing:** Protective clothing is not normally necessary, however it is good practice to use apron.

**Engineering Controls:** Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Section 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Liquid / Colorless.</td>
</tr>
<tr>
<td>Boiling point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not available.</td>
</tr>
<tr>
<td>Reactivity in Water</td>
<td>Not available.</td>
</tr>
<tr>
<td>Percentage Volatile by volume</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odour</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour density</td>
<td>Not available.</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not available.</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>Not available.</td>
</tr>
</tbody>
</table>
Section 10. Stability and Reactivity

<table>
<thead>
<tr>
<th>Condition to avoid</th>
<th>Stable</th>
<th>Decomposition products</th>
<th>Hazardous Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid exposure to extreme heat, light and moisture.</td>
<td>Stable under recommended storage condition.</td>
<td>No data available.</td>
<td>No data available.</td>
</tr>
</tbody>
</table>

| Incompatibilities | Oxidizers, acids, And bases. |

Section 11. Toxicological information

<table>
<thead>
<tr>
<th>General</th>
<th>Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target organ</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Other</td>
<td>The physician should be aware of the possible occurrence of Glucoma. Although The Drug does not appear to have any adverse effect on simple glaucoma, it probable should not be used in angle-closure glaucoma.</td>
</tr>
</tbody>
</table>

Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil.

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea(IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 091525

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**Section 16. Other Information**

None

**Revision Date:** 28/05/2015  **Revision No.: 00**

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The information contained herein is based on the state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.