Safety Data Sheet
Pyridostigmine Bromide Tablets, USP

Strength: 60 mg  Pack Size: 30/90/100/500 Tablets per bottle  Revision No.: 00

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**EMERGENCY OVERVIEW**
Each Pyridostigmine Bromide Tablets intended for oral administration contains Pyridostigmine Bromide 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:** Pyridostigmine Bromide Tablets, USP

**Formula:** C₉H₁₃BrN₂O₂

**Chemical Name:** 3-hydroxy-1-methylpyridinium bromide dimethylcarbamate

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**Manufacturer / supplier identification**

**Company:** Cadila Healthcare Ltd., Baddi, India

**Address:** Cadila Healthcare Limited, Swaraj Majra, Judi Kalan, Post - Baddi, Tehsil - Nalagarh, District - Solan, Himachal Pradesh 173205.

**Contact for information:** Tel: +91-1795-246841  Fax: +91-1795-246842

**Emergency Telephone No.:** Tel: +91-1795-246841

**Recommended use / Therapeutic Category:** Orally active cholinesterase inhibitor

**Restriction on Use / Contraindications:** Pyridostigmine bromide tablets, USP are contraindicated in mechanical intestinal or urinary obstruction, and particular caution should be used in its administration to patients with bronchial asthma. Care should be observed in the use of atropine for counteracting side effects.
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<table>
<thead>
<tr>
<th><strong>Section 2. Hazard(s) Identification</strong></th>
<th></th>
</tr>
</thead>
</table>
| **Dose and Administration** | Pyridostigmine bromide tablets, USP is available as Conventional Tablets - each containing 60 mg pyridostigmine bromide.  
Dosage: The size and frequency of the dosage must be adjusted to the needs of the individual patient. Conventional Tablets - The average dose is ten 60 mg tablets, spaced to provide maximum relief when maximum strength is needed. In severe cases as many as 25 tablets a day may be required, while in mild cases one to six tablets a day may suffice. |
| **Adverse Effects** | The side effects of pyridostigmine bromide are most commonly related to over dosage and generally are of two varieties, muscarinic and nicotinic. Among those in the former group are nausea, vomiting, diarrhea, abdominal cramps, increased peristalsis, increased salivation, increased bronchial secretions, miosis and diaphoresis. Nicotinic side effects are comprised chiefly of muscle cramps, fasciculation and weakness. Muscarinic side effects can usually be counteracted by atropine, but for reasons shown in the preceding section the expedient is not without danger. As with any compound containing the bromide radical, a skin rash may be seen in an occasional patient. Such reactions usually subside promptly upon discontinuance of the medication. |
| **Over Dose Effect** | Pyridostigmine is mainly excreted unchanged by the kidney. Therefore, lower doses may be required in patients with renal disease, and treatment should be based on titration of drug dosage to effect. |
| **Contraindications** | Pyridostigmine bromide tablets, USP are contraindicated in mechanical intestinal or urinary obstruction, and particular caution should be used in its administration to patients with bronchial asthma. Care should be observed in the use of atropine for counteracting side effects. |
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Pregnancy Comments  
The safety of pyridostigmine bromide during pregnancy or lactation in humans has not been established. Therefore, use of pyridostigmine bromide in women who may become pregnant requires weighing the drug's potential benefits against its possible hazards to mother and child.

Pregnancy Category  
No Data Available

Section 3. Composition / information on ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principle Component:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyridostigmine Bromide</td>
<td>Not Found</td>
<td>101-26-8</td>
</tr>
<tr>
<td><strong>Inactive Ingredients:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anhydrous Lactose</td>
<td>Not Found</td>
<td>63-42-3</td>
</tr>
<tr>
<td>Colloidal Silicon Dioxide</td>
<td>Not Found</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Low Substituted Hydroxypropyl Cellulose</td>
<td>Not Found</td>
<td>9004-64-2</td>
</tr>
<tr>
<td>Silicon Dioxide</td>
<td>Not Found</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Stearic Acid</td>
<td>Not Found</td>
<td>57-11-4</td>
</tr>
</tbody>
</table>

Section 4. First-aid measures

General

Inhalation:
Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact:
Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

Eye contact:
Rinse thoroughly with plenty of water for at least 15 minutes
Overdose Treatment

Indication of immediate medical attention and special treatment needed:
No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information:
In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

Section 5. Fire-fighting measures

| Flash point | Not Found | Upper Flammable Limit: Not Found |
| Auto-Ignition Temperature | Not Found | Lower Flammable Limit: Not Found |

Suitable extinguishing media

Specific hazards arising from the chemical
During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire-fighting equipment/instructions
Move containers from fire area if you can do so without risk.

Specific methods
Use standard firefighting procedures and consider the hazards.
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of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted

Section 6. Accidental Release Measures

Spill Response
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up
Stop the flow of material, if this is without risk. Prevent product from entering drains. Following product recovery, flush area with water.

Environmental precautions
Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

Section 7. Handling and Storage

Storage:
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in original container.

IMPORTANT: These tablets are hygroscopic. Keep in a dry place with the silica gel enclosed.

Precautions for safe handling
Do not get this material in contact with eyes. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Avoid release to the environment. Observe good industrial hygiene practices.
Section 8. Exposure controls / personal protection

Respiratory Protection
Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Skin protection
For prolonged or repeated skin contact use suitable protective gloves.

Eye/face protection
If contact is likely, safety glasses with side shields are recommended.

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

Biological limit values
No biological exposure limits noted for the ingredient(s).

Exposure guidelines
General ventilation normally adequate.

Thermal hazards
Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations
Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Engineering controls
Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance
Pyridostigmine Bromide Tablets USP, 60 mg are white to off-white, round, flat, uncoated tablets with quadrisection break line on one side and debossed with '659' on the other side.
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<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Solubility</strong></td>
<td>It is very soluble in water and in alcohol, slightly soluble in hexane, practically insoluble in ether.</td>
</tr>
<tr>
<td><strong>Odour</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Boiling point</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Melting Point</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Vapour density</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Reactivity in water</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Vapour pressure</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>% Volatile by volume</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Specific gravity</strong></td>
<td>Not available.</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>0.00003hPa estimated</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>Pyridostigmine bromide is a white or almost white crystalline, deliquescent powder.</td>
</tr>
</tbody>
</table>

**Section 10. Stability and Reactivity**

**Conditions to avoid**  
Contact with incompatible materials.

**Stable**

**Reactivity**  
The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability**  
Material is stable under normal conditions.

**Hazardous reactions**  
No dangerous reaction known under conditions of normal use.

**Decomposition products**  
None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

**Incompatible materials**  
Fluorine, Chlorine.

**Section 11. Toxicological information**

**General**  
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.
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**Target Organ**  
Eye contact, Skin contact and inhalation is not great risk as this product is Tablets.

**Ingestion**  
Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

**Other**  

**Symptoms related to the physical, chemical and Toxicological characteristics**  
Rash. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Permanent eye damage including blindness could result. Difficulty in breathing. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis.

**Information on toxicological effects**

**Acute toxicity**  
Fatal if swallowed. May cause an allergic skin reaction.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Oral LD50</td>
<td>Rat</td>
<td>37.5 mg/kg</td>
</tr>
</tbody>
</table>

**Reproductive toxicity**  
This product is not expected to cause reproductive or developmental effects.

**Further information**  
Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**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 205650
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</table>

**Section 16. Other information**

None

**Date of issue:** 27/07/2015  
**Supersedes edition:** New Edition

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