

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

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.

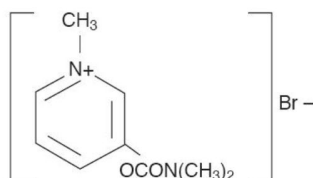
Section 1. Identification

Identification of the product

Product Name: Pyridostigmine Bromide Tablets, USP

Formula: C₉H₁₃BrN₂O₂

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



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.

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

Section 2. Hazard(s) Identification

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.

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

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

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

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

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

and consult a physician.

Ingestion:

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed:

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. Prolonged exposure may cause chronic effects.

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
Auto-Ignition Temperature Not Found

Upper Flammable Limit: Not Found
Lower Flammable Limit: Not Found

Suitable extinguishing media

Water. Foam. Dry chemical powder. Carbon dioxide (CO₂).

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

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

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.

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

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.
-------------------	--

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

Solubility	It is very soluble in water and in alcohol, slightly soluble in hexane, practically insoluble in ether.	Odour	Not available.
Boiling point	Not available.	Melting Point	Not available.
Evaporation rate	Not available.	Vapour density	Not available.
Reactivity in water	Not available.	Vapour pressure	Not available.
% Volatile by volume	Not available.	Specific gravity	Not available.
Vapor pressure	0.00003hPa estimated		
Other information	Pyridostigmine bromide is a white or almost white crystalline, deliquescent powder.		

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.
----------------	--

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

Strength: 60 mg

Pack Size: 30/90/100/500 Tablets per bottle

Revision No.: 00

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.

Components

Species

Test Results

Acute

Oral

Rat

37.5 mg/kg

LD50

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

Safety Data Sheet

Pyridostigmine Bromide Tablets, USP

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