

# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>MESTINON 60 mg</b>
<b>Other means of identification</b>	
<b>Product Code</b>	DIN00869961, NDC 0187-3010-30
<b>Synonyms</b>	PYRIDOSTIGMINE BROMIDE TABLETS, USP 60 mg
<b>Recommended use</b>	Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

<b>Company name</b>	Valeant Pharmaceuticals International, Inc.	
<b>Address</b>	2150 St. Elzéar Blvd. West Laval, Quebec H7L 4AB Canada	
<b>Telephone</b>	Customer Support	1-800-321-4576
<b>E-mail</b>	Not available.	
<b>Emergency phone number</b>	3E Emergency Response Hotline	1-866-951-9833

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
LACTOSE		5965-66-2	70 - < 80
PYRIDOSTIGMINE BROMIDE		101-26-8	16.32
SILICON DIOXIDE		7631-86-9	5 - < 10
STEARIC ACID		57-11-4	3 - < 5

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

## 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

<b>Ingestion</b>	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.
<b>Most important symptoms/effects, acute and delayed</b>	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.
<b>Indication of immediate medical attention and special treatment needed</b>	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.
<b>General information</b>	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.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	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. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Prevent product from entering drains. Following product recovery, flush area with water. For waste disposal, see section 13 of the SDS.
<b>Environmental precautions</b>	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.

## 7. Handling and storage

<b>Precautions for safe handling</b>	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.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store in a well-ventilated place. Keep out of the reach of children. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m <sup>3</sup>
		20 mppcf

#### US. ACGIH Threshold Limit Values

Components	Type	Value
STEARIC ACID (CAS 57-11-4)	TWA	10 mg/m <sup>3</sup>

**US. NIOSH: Pocket Guide to Chemical Hazards**

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3
Biological limit values	No biological exposure limits noted for the ingredient(s).	
Exposure guidelines		
Appropriate engineering controls	General ventilation normally adequate.	
Individual protection measures, such as personal protective equipment		
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.	
Skin protection		
Hand protection	For prolonged or repeated skin contact use suitable protective gloves.	
Other	Wear suitable protective clothing as protection against splashing or contamination.	
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.	
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.	

**9. Physical and chemical properties**

<b>Appearance</b>	White, round, flat-faced tablet engraved "Mestinon 60" on the outer perimeter and "V" in the center on one side and quadrisect scored on the other side.
<b>Physical state</b>	Solid.
<b>Form</b>	Solid. Tablet.
<b>Color</b>	White
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	305.6 °F (152 °C) estimated
<b>Initial boiling point and boiling range</b>	4046 °F (2230 °C) estimated
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	0.00003 hPa estimated
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## Other information

Density	0.94 g/cm <sup>3</sup> estimated
Specific gravity	0.94 estimated

## 10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Fluorine. Chlorine.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
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.

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.
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### Information on toxicological effects

Acute toxicity	Fatal if swallowed. May cause an allergic skin reaction.
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Components	Species	Test Results
PYRIDOSTIGMINE BROMIDE (CAS 101-26-8)		
Acute		
Oral		
LD50	Rat	37.5 mg/kg
SILICON DIOXIDE (CAS 7631-86-9)		
Acute		
Oral		
LD50	Mouse	> 15000 mg/kg
	Rat	> 22500 mg/kg
STEARIC ACID (CAS 57-11-4)		
Acute		
Oral		
LD50	Rat	4.6 g/kg
Other		
LD50	Mouse	23 mg/kg
	Rat	21.5 mg/kg

\* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Causes skin irritation.
Serious eye damage/eye irritation	Causes serious eye damage.
Respiratory or skin sensitization	
Respiratory sensitization	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization	May cause an allergic skin reaction.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

<b>Carcinogenicity</b>	Carcinogenic effects are not expected as a result of occupational exposure.
<b>IARC Monographs. Overall Evaluation of Carcinogenicity</b>	
SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.
<b>OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)</b>	
Not listed.	
<b>Reproductive toxicity</b>	This product is not expected to cause reproductive or developmental effects.
<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	May cause damage to organs through prolonged or repeated exposure.
<b>Aspiration hazard</b>	Not available.
<b>Chronic effects</b>	Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.
<b>Further information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

## 12. Ecological information

<b>Ecotoxicity</b>	Harmful to aquatic life.
<b>Persistence and degradability</b>	
<b>Bioaccumulative potential</b>	
Partition coefficient n-octanol / water (log Kow)	
STEARIC ACID	8.23
<b>Mobility in soil</b>	
<b>Mobility in general</b>	
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

<b>UN number</b>	Not available.
<b>UN proper shipping name</b>	Consumer commodity
<b>Transport hazard class(es)</b>	
Class	ORM-D
<b>Subsidiary risk</b>	-
<b>Label(s)</b>	None
<b>Packing group</b>	Not applicable.
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling. For Bulk Product: shipping classification must be reviewed.
<b>Packaging exceptions</b>	156, 306
<b>Packaging non bulk</b>	156, 306
<b>Packaging bulk</b>	None

### IATA

<b>UN number</b>	ID8000
<b>UN proper shipping name</b>	Consumer commodity

**Transport hazard class(es)**

<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	Not applicable.
<b>Environmental hazards</b>	No.
<b>ERG Code</b>	9L
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Allowed.
<b>Cargo aircraft only</b>	Allowed.

**IMDG**

<b>UN number</b>	UN3249
<b>UN proper shipping name</b>	MEDICINE, SOLID, TOXIC, N..O.S. (PYRIDOSTIGMINE BROMIDE)
<b>Transport hazard class(es)</b>	
<b>Class</b>	6.1(PGIII)
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No.
<b>EmS</b>	F-A, S-A
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**  
Not applicable.

**IATA****IMDG****15. Regulatory information****US federal regulations****TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - Yes  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

SILICON DIOXIDE (CAS 7631-86-9)

**US. New Jersey Worker and Community Right-to-Know Act**

SILICON DIOXIDE (CAS 7631-86-9)

**US. Pennsylvania Worker and Community Right-to-Know Law**

SILICON DIOXIDE (CAS 7631-86-9)

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

**Issue date** 09-05-2014  
**Version #** 01

**Disclaimer**

Valeant cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.