



# HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018, A.P., INDIA.  
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250  
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

##### Material

**Donepezil hydrochloride Tablets, USP 5 mg and 10 mg**

##### Manufacturer

**Hetero Labs Limited** Unit V, APIIC Formulation SEZ,  
Survey. No 439, 440, 441 & 458, Polepally Village, Jadcherla  
(Mandal), Mahaboob Nagar (District). Pin-509301  
Telangana, India

##### Distributor

**Camber Pharmaceuticals, Inc.**, Piscatway, NJ 08854

### Section 2: Hazard(s) Identification

#### Section 2, Hazard(s)identification

##### Classification

Material may be irritating to the mucous membranes and upper respiratory tract.

May be harmful by inhalation, ingestion, or skin absorption.

May cause eye, skin, or respiratory system irritation.

##### Environment

No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

##### CAS

##### Ingredients

Donepezil Hydrochloride (Form-I) 120011-70-3

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

##### Ingestion

Wash out mouth with water provided person is conscious.  
Never give anything by mouth to an unconscious person.  
Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

##### Inhalation

Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel.  
Get immediate medical attention.

##### Skin Contact

Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

##### Eye Contact

Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.



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## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

<b>Fire and Explosion Hazards</b>	Not available
<b>Extinguishing Media</b>	Suitable extinguishing media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.
<b>Protection of Firefighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes.
<b>Other information</b>	Decontaminate protective clothing and equipment before reuse.

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

<b>Personal Precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). <b>Hands:</b> Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations. <b>Eyes:</b> Wear safety glasses or goggles if eye contact is possible. <b>Skin:</b> Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. <b>Respiratory protection:</b> If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Clean-up Methods</b>	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

## Section 7: Handling and Storage

### Section 7, Handling and storage



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## Handling

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

## Storage

Store Donepezil hydrochloride Tablets Store at 20 to 25°C (68 to 77° F) [see USP Controlled Room Temperature].

## Section 8: Exposure Controls/Personal Protection

### Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## Section 9: Physical and Chemical Properties

### Section 9, Physical and chemical properties

#### Physical Form

#### Donepezil hydrochloride Tablets, USP 5 mg

White round biconvex, film coated tablets debossed with 'I' on one side and '24' on another side.

Bottle of 30 Tablets (NDC 31722-737-30)

Bottle of 90 Tablets (NDC 31722-737-90)

Bottle of 100 Tablets (NDC 31722-737-01)

Bottle of 500 Tablets (NDC 31722-737-05)

Unit Dose Blister Package 100 (10x10) (NDC 31722-737-31)

#### Donepezil hydrochloride Tablets 10 mg

Yellow round biconvex, film coated tablets debossed with 'I' on one side and '21' on another side.

Bottle of 60 Tablets (NDC 31722-738-30)

Bottle of 500 Tablets (NDC 31722-738-90)

Bottle of 100 Tablets (NDC 31722-738-01)

Bottle of 500 Tablets (NDC 31722-738-05)

Unit Dose Blister Package 100 (10x10) (NDC 31722-738-31)

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.



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## Section 11: Toxicological Information

### Carcinogenesis

Donepezil hydrochloride

No evidence of carcinogenic potential was obtained in an 88-week carcinogenicity study of donepezil conducted in mice at oral doses up to 180 mg/kg/day (approximately 40 times the maximum recommended human dose [MRHD] of 23 mg/day on a mg/m<sup>2</sup> basis), or in a 104-week carcinogenicity study in rats at oral doses up to 30 mg/kg/day (approximately 13 times the MRHD on a mg/m<sup>2</sup> basis).

Donepezil was negative in a battery of genotoxicity assays (in vitro bacterial reverse mutation, in vitro mouse lymphoma *tk*, in vitro chromosomal aberration, and in vivo mouse micronucleus).

Donepezil had no effect on fertility in rats at oral doses up to 10 mg/kg/day (approximately 4 times the MRHD on a mg/m<sup>2</sup> basis) when administered to males and females prior to and during mating and continuing in females through implantation.

## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

Dispose in accordance with local, state, and federal regulations.

## Section 14: Transport Information

### IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

### IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A



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## **DOT - Not Regulated**

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

## **Section 15: Regulatory Information**

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## **Section 16: Other Information**

### **Section 16, Other information**

**Issue Date : 24-01-2020**

**Version : 01**

#### **Further information**

**Revision date: 24-01-2020**

**Revision note: Revision date included.**

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