

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

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| Material | Donepezil Hydrochloride Tablets 23 mg |
| Manufacturer | Lupin Limited Goa 403 722 INDIA |
| Distributor | Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221 |

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification

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| Fire and Explosion | Expected to be non-combustible. |
| Health | Donepezil hydrochloride is contraindicated in patients with known hypersensitivity to donepezil hydrochloride or to piperidine derivatives. |
| 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

| Ingredients | CAS |
|-------------------------|-------------|
| Donepezil Hydrochloride | 120011-70-3 |

Section 4: First-Aid Measures

Section 4, First-aid measures

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| Ingestion | If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention. |
| Inhalation | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. |
| Skin Contact | Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs. |
| Eye Contact | Flush eyes with plenty of water. Get medical attention. |

NOTES TO HEALTH PROFESSIONALS

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| Medical Treatment | Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. |
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OVERDOSAGE

Because strategies for the management of overdose are continually evolving, it is advisable to contact a Poison Control Center to determine the latest recommendations for the management of an overdose of any drug.

As in any case of overdose, general supportive measures should be utilized. Overdosage with cholinesterase inhibitors can result in cholinergic crisis characterized by severe nausea, vomiting, salivation, sweating, bradycardia, hypotension, respiratory depression, collapse, and convulsions. Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved. Tertiary anticholinergics such as atropine may be used as an antidote for donepezil hydrochloride overdose. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1 to 2 mg IV with subsequent doses based upon clinical response. Atypical responses in blood pressure and heart rate have been reported with other cholinomimetics when co-administered with quaternary anticholinergics such as glycopyrrolate. It is not known whether donepezil hydrochloride and/or its metabolites can be removed by dialysis (hemodialysis, peritoneal dialysis, or hemofiltration).

Dose-related signs of toxicity in animals included reduced spontaneous movement, prone position, staggering gait, lacrimation, clonic convulsions, depressed respiration, salivation, miosis, tremors, fasciculation, and lower body surface temperature.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

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| Fire and Explosion Hazards | Assume that this product is capable of sustaining combustion. |
| Extinguishing Media | Water spray, carbon dioxide, dry chemical powder or appropriate foam. |
| Special Firefighting Procedures | For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters. |
| Hazardous Combustion Products | Hazardous combustion or decomposition products are expected when the product is exposed to fire. |

Section 6: Accidental Release Measures

Section 6, Accidental release measures

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| Personal Precautions | Wear protective clothing and equipment consistent with the degree of hazard. |
| Environmental Precautions | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. |
| Clean-up Methods | Collect and place it in a suitable, properly labeled container for recovery or disposal. |

Section 7: Handling and Storage

Section 7, Handling and storage

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| Handling | No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. |
| Storage | Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature]. Protect from moisture. |

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, 23 mg are reddish brown, round, film coated tablets, containing 23 mg of donepezil hydrochloride, debossed with 'G52' on one side and 'LU' on the other side, which are supplied as follows:

NDC 68180-527-06 Bottle of 30s

NDC 68180-527-09 Bottle of 90s

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

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/m² 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/m² 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/m² basis) when administered to males and females prior to and during mating and continuing in females through implantation.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

Section 14: Transport Information

IATA/ICAO - Not Regulated

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| 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

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| 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 |

DOT - Not Regulated

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|--------------------------|---|-----|
| 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

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

Section 16: Other Information

Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.