

SAFETY DATA SHEET

Section 1: Identification		
Material	Memantine Hydrochloride Tablets 5 mg and 10 mg	
Recommended use	Pharmaceutical	
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India (IND)	
Distributor	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854	
Section 2: Hazard(s) Identification		
Hazard statements	Suspected of causing cancer (Inhalation) Obtain special instructions before use Do not handle until all safety precautions have been read and understood If exposed or concerned: Get medical advice/attention. Store locked up Dispose of contents/container to an authorised waste collection point	
Section 3: Composition/Information on Ingredients		
CAS	Memantine hydrochloride	41100-52-1
Section 4: First-Aid Measures		
After inhalation	If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.	
After skin contact	Wash with plenty of soap and water.	
After eye contact	In case of contact, immediately flush eyes with plenty of water.	
After ingestion	Get medical advice/attention if you feel unwell.	
Most important symptoms and effects, both acute and delayed		
Symptoms/injuries after inhalation	May cause cancer by inhalation.	
Indication of any immediate medical attention and special treatment needed	All treatments should be based on observed signs and symptoms of distress in the patient.	

Section 5: Fire-Fighting Measures	
Suitable extinguishing media	Use extinguishing media appropriate for surrounding fire
Unsuitable extinguishing media	None known
Advice for firefighters Firefighting instructions	Do not allow run-off from firefighting to enter drains or water courses.
Protection during firefighting	Do not enter fire area without proper protective equipment, including respiratory protection.
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid contact with skin and eyes. Avoid creating or spreading dust.
Environmental precautions	Avoid release to the environment.
Methods and material for containment and cleaning up For containment Methods for cleaning up	Sweep or shovel into suitable containers. Minimize generation of dust.
Section 7: Handling and Storage	
Precautions for safe handling	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.
Hygiene measures	Always wash your hands immediately after handling this product, and once again before leaving the workplace.
Conditions for safe storage, including any incompatibilities Storage conditions Incompatible products Storage area	Keep container closed when not in use. Strong bases. Strong acids. Strong oxidizers. Store in dry, cool, well-ventilated area.
8. Exposure controls / personal protection	
Appropriate engineering controls	Avoid dispersal of dust in the air (ie, clearing dust surfaces with compressed air). Either local exhaust or general room ventilation is usually required.

Personal protective equipment	Avoid all unnecessary exposure.
Hand protection	Wear dust impervious gloves
Eye protection	In case of dust production: protective goggles
Respiratory protection	In case of inadequate ventilation wear respiratory protection. Use air-purifying respirator equipped with particulate filtering cartridges. Wear appropriate mask.

Section 9: Physical and Chemical Properties

Physical State	Solid
Appearance	Tablet
Description	<p>5 mg Tablets:</p> <p>Tan colored, modified capsule shaped, biconvex, film coated tablets debossed with 'J' on one side and '47' on the other side.</p> <p>Bottles of 60 NDC 31722-807-60</p> <p>Bottles of 200 NDC 31722-807-02</p> <p>Carton of 100 (10 x 10) Unit dose tablets NDC 31722-807-32</p> <p>10 mg Tablets:</p> <p>Gray colored, modified capsule shaped, biconvex, film coated tablets debossed with 'J' on one side and '48' on the other side.</p> <p>Bottles of 60 NDC 31722-808-60</p> <p>Bottles of 200 NDC 31722-808-02</p> <p>Carton of 100 (10 x 10) Unit dose tablets NDC 31722-808-32</p> <p>Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].</p>

Section 10: Stability and Reactivity

Reactivity	No dangerous reactions known.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization will not occur
Conditions to avoid	Avoid dust production.
Incompatible materials	Strong acids. Strong bases. Strong oxidizers.

Hazardous decomposition products	Carbon dioxide. Carbon monoxide.
Section 11: Toxicological Information	
Information on toxicological effects	
Likely routes of exposure	Ingestion; Dermal
Acute toxicity	Not classified
Memantine hydrochloride (41100-52-1)	
LD50 oral rat	328 mg/kg 437 mg/kg mouse
ATE US (oral)	328.000 mg/kg bodyweight
Skin corrosion/irritation	Not classified
Serious eye damage/irritation	Not classified
Respiratory or skin sensitisation	Not classified
Germ cell mutagenicity	Not classified
Carcinogenicity	Not classified
Reproductive toxicity	Not classified
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified
Symptoms/injuries after inhalation	May cause cancer by inhalation
Section 12: Ecological Information	
Toxicity No additional information available	
Persistence and degradability No additional information available	
Bioaccumulative potential No additional information available	
Mobility in soil No additional information available	
Other adverse effects Effect on the global warming: No know ecological damage caused by this product.	

Section 13: Disposal Considerations	
Waste treatment methods	Waste disposal recommendations: Dispose in a safe manner in accordance with local/national regulations
Section 14: Transport Information	
Department of Transportation (DOT)	In accordance with DOT - Not considered a dangerous good for transport regulations
ADR	- No additional information available
Transport by sea	- No additional information available
Air transport	- No additional information available
Section 15: Regulatory Information	
US Federal regulations	Not listed on the United States TSCA (Toxic Substances Control Act) inventory
International regulations	
CANADA	Not listed on the Canadian DSL (Domestic Substances List) inventory. Not listed on the Canadian Non-Domestic Substances List (NDSL).
EU-Regulations	Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)
Section 16: Other Information, including date of preparation or last revision	
Issue Date: 16-12-2022 Version: 00 Further information Revision date: NA Revision note: NA <p>The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.</p> <p>Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.</p>	