

## SAFETY DATA SHEET

### Memantine Hydrochloride Tablets 5 mg and 10 mg

#### EMERGENCY OVERVIEW

MEMANTINE HYDROCHLORIDE TABLETS contain an active drug substance hydrochloride and pharmaceutical excipients generally considered safe, non-toxic and hazardous. The quantities of the excipients used in the product are well within the IID (Ingredient Database) limits prescribed by USFDA for oral tablets.

WARNING: Accidental ingestion of large amounts may be harmful.

#### Section 1. Identification of the substance

##### Identification of the product

<b>Product name</b>	: Memantine Hydrochloride Tablets
<b>Potencies</b>	: 5 mg and 10 mg
<b>Chemical Name</b>	: Tricyclo (3.3.1.1 <sup>3,7</sup> ]decan-1-amine,3,5-dimethyl-, hydrochloride 1-Amino-3,5-dimethyladamantane hydrochloride
<b>Therapeutic Category</b>	: For treatment of Alzheimer
<b>Product Use</b>	: Moderate to severe dementia of the Alzheimer's type
<b><u>Marketed by</u></b>	: <b>Ajanta Pharma USA Inc.</b> Bridgewater, NJ 08807. Made in India
<b>Contact Information</b>	: 855-664-7744

#### Section 2. Health hazards information

**Potential Health Effects** : **Inhalation:** Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.  
**Eye Contact:** Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause respiratory irritation.  
**Skin Contact:** Not expected to be hazardous in final pharmaceutical form. Mechanical processing may generate dust. Inhalation of dusts may cause skin irritation.

**Ingestion:** Health injuries are not known or expected under normal use.

**Effects of Overexposure :** The potential for exposure is reduced in finished pharmaceutical dosage form.

<b>Section 3. Composition / information on ingredients</b>
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Active ingredient	Exposure Limit	CAS No.
Memantine Hydrochloride TWA: Time-Weighted Average	TWA-67 µg/m <sup>3</sup>	41100-52-1

**Inactive ingredients:** microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, talc and magnesium stearate. In addition, the following inactive ingredients are also present as components of the film coat: polyvinyl alcohol, polyethylene glycol 4000 (macrogol), titanium dioxide, talc, FD & C yellow #6 (sunset yellow) FCF aluminum lake (in 5 mg tablets), and iron oxide black (in 10 mg tablets).

<b>Section 4. First aid measures</b>
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- Inhalation** : Should not pose a hazard in the final form. If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.  
Call a physician if symptoms develop or persist.
- Skin Contact** : Rinse skin with soap and water. Get medical attention if irritation develops and persists.
- Eye Contact** : Rinse with water. Get medical attention. If irritation develop and persists
- 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.
- 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.
- Over dosage** : Signs and symptoms most often accompanying memantine overdosage in clinical trials and from worldwide marketing experience, alone or in combination with other drugs and/or alcohol, include agitation, asthenia, bradycardia, confusion, coma, dizziness, ECG changes, increased blood pressure, lethargy, loss of consciousness, psychosis, restlessness, slowed movement, somnolence, stupor, unsteady gait, visual

hallucinations, vertigo, vomiting, and weakness. The largest known ingestion of memantine worldwide was 2.0 grams in a patient who took memantine in conjunction with unspecified antidiabetic medications. The patient experienced coma, diplopia, and agitation, but subsequently recovered. Fatal outcome has been very rarely reported with memantine, and the relationship to memantine was unclear. Because strategies for the management of overdose are continually evolving, it is advisable to contact a poison control centre to determine the latest recommendations for the management of an overdose of any drug. As in any cases of overdose, general supportive measures should be utilized, and treatment should be symptomatic. Elimination of memantine can be enhanced by acidification of urine.

<b>Section 5. Fire-fighting measures</b>
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- Flash Point** : Not available.
- Extinguishing Media** : Water spray, dry chemical, carbon dioxide, or foam as appropriate foam.
- Special Fire Fighting Procedures** : For single units (packages): No special requirements needed. For larger amounts (multiple packages) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.
- General Fire Hazards/Hazardous Combustible Products** : Hazardous combustion or decomposition products are expected when the product is exposed to fire.

<b>Section 6. Accidental release measures</b>
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- Personal Precautions** : For consumer use, no unusual precautions are necessary. In laboratory, medical or industrial setting wear protective clothing and equipment such as shoe covering, hood and head coverings may be necessary.
- Environmental Protections** : 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

- 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°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

## Section 8. Exposure controls/personal protection

- Exposure Limits** : TWA-67 µg/m<sup>3</sup>
- Engineering Controls** : For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use ventilation should be appropriate.
- Respiratory Protection** : For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection should be used if respirators are necessary.
- Personal Protection** : For consumer use, no unusual precaution are necessary for handling tablets. In laboratory, medical or industrial setting use of goggles, lab coat and gloves are recommended.
- Recommended Facilities** : Eye wash, washing facilities
- General Hygiene Considerations** : Handle in accordance with good hygiene and safety practice.

## Section 9. Physical and chemical properties

- Appearance** : **Memantine Hydrochloride Tablets 5 mg** Orange, capsule shaped, biconvex, film-coated tablets with "m5" engraved on one side and plain on other side. They are supplied in white HDPE bottles containing of 60 tablets (NDC 27241-070-06) and bottle of 500 tablets (NDC # 27241-070-05).
- Memantine Hydrochloride Tablets 10 mg** Grey, capsule shaped, biconvex, film-coated tablets with "m10" engraved on one side and plain on other side. They are supplied in white HDPE bottles containing 60 tablets (NDC 27241-071-06) and bottle of 500 tablets (NDC # 27241-071-05).
- Other Information** : Memantine Hydrochloride drug substance is white to off-white, colored powder. Slightly soluble in water. Its pKa was established 10.5.

### Section 10. Stability and reactivity

<b>Stability</b>	:	Stable
<b>Incompatibility</b>	:	None known
<b>Hazardous Decomposition</b>	:	NOx. CI-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions
<b>Conditions to Avoid</b>	:	None known.

### Section 11. Toxicological information

<b>Acute toxicity</b>	:	Product is toxic on ingestion. LD50 of Memantine hydrochloride is reported as 50 mg/kg (dog, oral).
<b>Carcinogenesis</b>	:	There was no evidence of carcinogenicity in a 113- week oral study in mice at doses up to 40 mg/kg/day (10 times the maximum recommended human dose [MRHD] on mg/m <sup>2</sup> basis). There was also no evidence of carcinogenicity in rats orally dosed at up to 40 mg/kg/day for 71 weeks followed by 20 mg/kg/day (20 and 10 times the MRHD on a mg/m <sup>2</sup> basis, respectively) through 128 weeks.
<b>Mutagenesis</b>	:	Memantine produced no evidence of genotoxic potential when evaluated in the <i>in vitro</i> <i>S. typhimurium</i> or <i>E. coli</i> reverse mutation assay, an <i>in vitro</i> chromosomal aberration test in human lymphocytes, an <i>in vivo</i> cytogenetics assay for chromosome damage in rats, and the <i>in vivo</i> mouse micronucleus assay. The results were equivocal in an <i>in vitro</i> gene mutation assay using Chinese hamster V79 cells.
<b>Impairment of Fertility</b>	:	No impairment of fertility or reproductive performance was seen in rats administered up to 18 mg/kg/day (9 times the MRHD on mg/m <sup>2</sup> basis) orally from 14 days prior to mating through gestation and lactation in females, or for 60 days prior to mating in males.

### Section 12. Ecological information

Eco toxicity of drug substance: The drug substance in tablet dosage form is not expected to present significant adverse environmental effects.

In the finished product form: There is no potential for air borne contamination since the drug substance is consolidated and contended as film coated tablet dosage form.

### Section 13. Disposal consideration

**Waste Disposal Considerations:** Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.

### **Section 14. Transport information**

This product is not subject to the regulations for the safe transport of hazardous chemicals

**DOT:** Not regulated for transport of dangerous goods.

**IATA:** Not regulated for transport of dangerous goods

**IMDG:** Not regulated for transport of dangerous goods

### **Section 15. Regulatory information**

**DEA:** Not Available.

**FDA:** Memantine Hydrochloride is an approved prescription medication.

Inventory Status: One or more components are not listed on the US TSCA Inventory

### **Section 16. Disclaimer**

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.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

**Date:** Apr 05, 2022

**SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION**