Safety Data Sheet
Galantamine Tablet ,USP

**Strength:** 4/8/12mg  **Pack Size:** 60/100/1000 Tablets per bottle & 10 * 10 unit dose blisters  **Revision No.:** 02

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**EMERGENCY OVERVIEW**

Each Galantamine Tablet intended for oral administration contains galantamine hydrobromide equivalent to galantamine 4 mg or 8 mg or 12 mg and excipients considered non-toxic and nonhazardous in small quantities and under conditions of normal occupational exposure.

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**Section 1. Identification**

**Identification of the product**

**Product name:** Galantamine Tablet, USP

**Formula:** C17H21NO3•HBr

**Chemical Name:** (4aS,6R,8aS)-4a,5,9,10,11,12-hexahydro-3-methoxy-11-methyl-6H-benzofuro[3a,3,2-e/f][2]benzazepin-6-ol hydrobromide

![Chemical structure of Galantamine]

**Manufacturer / supplier identification**

**Company:** Cadila Healthcare Ltd. Ahmedabad, India


**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319

**Emergency Telephone No.** Tel.: +91 79 6868100

**Recommended use / Therapeutic Category**

Treatment of mild to moderate dementia of the Alzheimer’s type. A reversible, competitive acetylcholinesterase inhibitor.

**Restriction on Use / Contraindications:**

Galantamine tablets are contraindicated in patients with known hypersensitivity to galantamine or to any excipients used in the formulation.
Section 2. Hazard (s) Identification

Dose and Administration

The Galantamine tablets should be administered twice a day, preferably with morning and evening meals.

Adverse Effects

Adverse Events Leading To Discontinuation
Nausea, Vomiting, Anorexia, Dizziness, Syncope, Anorexia, Weight decrease

Adverse Events Reported in Controlled Trials

Body as whole: Fatigue, Syncope

Central and peripheral nervous system disorders: Dizziness, Headache, Tremor

Gastrointestinal system disorder: Nausea, vomiting, diarrhea, abdominal pain, dyspepsia

Heart rate and rhythm disorder: bradycardia

Metabolic and nutritional disorder: weight decrease

Psychiatric disorder: Anorexia, depression, insomnia, somnolence

Red blood cell disorder: Anemia

Respiratory system disorder: Rhinitis

Urinary system disorder: Urinary tract infection, Hematuria

Other Adverse Events Observed During Clinical Trials

General disorder:
Frequent: chest pain, asthenia, fever, malaise

Cardiovascular system disorder
Infrequent: postural hypotension, hypotension, dependent edema, cardiac failure, myocardial ischemia or infarction

Central and peripheral nervous system disorders
Infrequent: vertigo, hypertonia, convulsions, involuntary muscle contractions, parasthesia, ataxia, hypokinesia, hyperkinesias, apraxia, aphasia, leg cramps, tinnitus, transient ischemic attack or cerebrovascular accident

Gastrointestinal system disorder
Frequent: flatulence
Infrequent: gastritis, melena, dysphagia, rectal hemorrhage, dry mouth, saliva increased, diverticulitis, gastroenteritis, hiccup

Rare: esophagel perforation

Heart rate & Rhythm disorder:
Infrequent: AV block, palpitation, atrial arrhythmias including atrial fibrillation and supraventricular tachycardia, QT prolonged, bundle branch block, T wave inversion, ventricular tachycardia

Rare: severe bradycardia

Metabolic & Nutritional disorder:
Infrequent: hyperglycemia, alkaline phosphate increased
Platelet bleeding & clotting disorder: Infrequent:
purpura, epistaxis, thrombocytopenia

Psychiatric disorder:
Infrequent: apathy, paroniria, paranoid reaction, libido increased,
delirium: Rare: suicidal ideation, suicide

Urinary system disorder:
Frequent: incontinence
Infrequent: hematuria, micturition frequency, cystitis, urinary retention, nocturia, renal calculi

Post marketing experience:
Other adverse events from post approval controlled and uncontrolled clinical trials and post marketing experience observed in patients treated with galantamine includes:

Body as a whole:
General disorders: dehydration
Psychiatric disorders: aggression
Gastrointestinal system disorders: upper and lower GI bleeding
Metabolic and nutritional disorders: hypokalemia

Over Dose Effect
Muscle weakness or fasciculations, severe nausea, vomiting, gastrointestinal cramping, salivation, lacrimation, urination, defecation, sweating, bradycardia, hypotension, respiratory, depression, collapse and convulsions, Increasing muscle weakness is a possibility and may result in death if respiratory muscles are involved.

Medical Condition
Patient should inform the doctor about all the present or past health problems. Include: Anesthesia, Cardiovascular Conditions, Gastrointestinal Conditions, Genitourinary, Neurological Conditions, Pulmonary Conditions.

Contraindications
Galantamine tablets are contraindicated in patients with known hypersensitivity to galantamine or to any excipients used in the formulation.

Pregnancy Comments
There are no adequate and well-controlled studies of galantamine in pregnant women. Galantamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Pregnancy Category
C
### Section 3. Composition / information on ingredients

<table>
<thead>
<tr>
<th>Component</th>
<th>Exposure Limit</th>
<th>CAS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Principle Component:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Galantamine hydrobromide</td>
<td>Not Found</td>
<td>1953-04-4</td>
</tr>
<tr>
<td><strong>Inactive Ingredients:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colloidal silicon dioxide</td>
<td>Not Found</td>
<td>7631-86-9</td>
</tr>
<tr>
<td>Crospovidone</td>
<td>Not Found</td>
<td>9003-39-8</td>
</tr>
<tr>
<td>Hydroxypropyl Methylcellulose</td>
<td>Not Found</td>
<td>9004-65-3</td>
</tr>
<tr>
<td>Lactose Monohydrate</td>
<td>Not Found</td>
<td>5989-81-1</td>
</tr>
<tr>
<td>Magnesium Stearate</td>
<td>Not Found</td>
<td>577-04-0</td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>Not Found</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Titanium Dioxide</td>
<td>Not Found</td>
<td>13463-67-7</td>
</tr>
<tr>
<td>Iron Oxide Red</td>
<td>Not Found</td>
<td>NA</td>
</tr>
<tr>
<td>Iron oxide yellow</td>
<td>Not Found</td>
<td>NA</td>
</tr>
</tbody>
</table>

### Section 4. First - aid measures

**General**

**Skin Contact:** Wash contaminated area with soap and water.

**Eye Contact:** Flush with running water for 15 minutes holding eyelids open.

**Inhalation:** No specific treatment is necessary since this product is not likely to be hazardous by inhalation if tablet is left intact.

**Ingestion:** Get medical attention immediately; induce vomiting if victim is conscious.

**Overdose Treatment**

Tertiary anticholinergics such as atropine may be used as an antidote for galantamine hydrobromide overdosage.
### Section 5. Fire - fighting measures

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash point</td>
<td>Not Found</td>
</tr>
<tr>
<td>Auto-Ignition Temperature:</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry</td>
</tr>
<tr>
<td></td>
<td>chemical, carbon dioxide or foam as</td>
</tr>
<tr>
<td></td>
<td>appropriate for surrounding fire and</td>
</tr>
<tr>
<td></td>
<td>material.</td>
</tr>
<tr>
<td>Fire Fighting Procedure</td>
<td>As with all fires, evacuate personnel to</td>
</tr>
<tr>
<td></td>
<td>a safe area. Fire fighter should use self-</td>
</tr>
<tr>
<td></td>
<td>contained breathing equipment and protective clothing.</td>
</tr>
</tbody>
</table>

### Section 6. Accidental Release Measures

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spill Response</td>
<td>Wear approved respiratory protection,</td>
</tr>
<tr>
<td></td>
<td>chemically compatible gloves and</td>
</tr>
<tr>
<td></td>
<td>protective clothing. Wipe up spillage or</td>
</tr>
<tr>
<td></td>
<td>collect spillage using high efficiency</td>
</tr>
<tr>
<td></td>
<td>vacuum cleaner. Avoid breathing dust.</td>
</tr>
<tr>
<td></td>
<td>Place spillage in appropriately labelled</td>
</tr>
<tr>
<td></td>
<td>container for disposal. Wash spill site.</td>
</tr>
</tbody>
</table>

### Section 7. Handling and Storage

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage</td>
<td>Store at 20° to 25°C (68° to 77°F).</td>
</tr>
<tr>
<td></td>
<td>Dispense in a tight container.</td>
</tr>
<tr>
<td>Incompatibilities:</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Section 8. Exposure controls / personal protection

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Protection</td>
<td>Protection from inhalation is not normally</td>
</tr>
<tr>
<td></td>
<td>necessary. If ventilation is inadequate</td>
</tr>
<tr>
<td></td>
<td>or dust is likely to generate, use of</td>
</tr>
<tr>
<td></td>
<td>suitable dust mask would be appropriate.</td>
</tr>
<tr>
<td>Skin Protection</td>
<td>Skin protection is not normally necessary,</td>
</tr>
<tr>
<td></td>
<td>however it is good practice to avoid</td>
</tr>
<tr>
<td></td>
<td>contact with chemical to use suitable</td>
</tr>
<tr>
<td></td>
<td>gloves when handling.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Eye protection is not normally necessary.</td>
</tr>
<tr>
<td></td>
<td>If concerned wear protective goggles or</td>
</tr>
<tr>
<td></td>
<td>glasses. Wash hands prior to touching</td>
</tr>
<tr>
<td></td>
<td>eye and in particular handling contact</td>
</tr>
<tr>
<td></td>
<td>lenses.</td>
</tr>
<tr>
<td>Protective Clothing</td>
<td>Protective clothing is not normally</td>
</tr>
<tr>
<td></td>
<td>necessary, however it is good practice to</td>
</tr>
<tr>
<td></td>
<td>use apron.</td>
</tr>
<tr>
<td>Engineering Control</td>
<td>Engineering controls should be used as</td>
</tr>
<tr>
<td></td>
<td>the primary means to control exposures.</td>
</tr>
<tr>
<td></td>
<td>General room ventilation is adequate</td>
</tr>
<tr>
<td></td>
<td>unless the process generates dust, mist</td>
</tr>
<tr>
<td></td>
<td>or fumes. Keep airborne contamination</td>
</tr>
<tr>
<td></td>
<td>levels below the exposure limits listed</td>
</tr>
<tr>
<td></td>
<td>above in this section.</td>
</tr>
</tbody>
</table>
Section 9. Physical and chemical properties

Appearance
Galantamine Tablets, USP equivalent to 4 mg of galantamine are light pink, round, biconvex, film-coated tablets debossed with ‘77’ on one side and ‘Z’ on the other side

Galantamine Tablets, USP equivalent to 8 mg of galantamine are off-white, round, biconvex, film-coated tablets debossed with ‘78’ on one side and ‘Z’ on the other side

Galantamine Tablets, USP equivalent to 12 mg of galantamine are off-white, round, biconvex, film-coated tablets debossed with ‘79’ on one side and ‘Z’ on the other side

Solubility in water
Soluble

Odour
Odourless

Boiling point
No Data Available

Melting Point
No Data Available

Evaporation rate
No Data Available

Vapour density
No Data Available

Reactivity in water
No Data Available

Evaporation rate
No Data Available

% Volatile by volume
No Data Available

Specific gravity
No Data Available

Vapour pressure
No Data Available

Other information
Galantamine hydrobromide has a molecular formula of C_{17}H_{21}NO_{3}•HBr and a molecular weight of 368.27. Galantamine hydrobromide, USP is a white to almost white powder and is soluble in 0.1 N sodium hydroxide, sparingly soluble in water, very slightly soluble in alcohol and insoluble in n-propanol.

Section 10. Stability and Reactivity

Condition to avoid
Avoid exposure to extreme heat, light and moisture.

Stable
Stable under normal ambient and anticipated storage and handling conditions.

Decomposition Products
No Data Available

Hazardous Reaction
No data available.

Incompatibilities:
No Data Available

Section 11. Toxicology information

General
Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.

Target organ
Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Other
Acute Toxicity
Active Ingredient:
LD 50 oral (rat): 75mg/kg
Section 12. Ecological information

Do not allow product to enter drinking water supplies, waste water or soil

Section 13. Disposal Consideration

Dispose the waste in accordance with all applicable Federal, State and local laws.

Section 14. Transport Information

The product is not hazardous when shipping via air (IATA), ground (DOT), or sea(IMDG).

Section 15. Regulatory Information

Generic Medicine. Approved by USFDA & the ANDA Number is 078898

Section 16. Other information

None

Date of issue: 28/05/2015

Supersedes edition of: 01

The information contained herein is based on the state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.