**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.

### Section 1. Identification of the substance

<table>
<thead>
<tr>
<th><strong>Identification of the product</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name:</strong></td>
</tr>
<tr>
<td><strong>Formula:</strong></td>
</tr>
<tr>
<td><strong>Chemical Name:</strong></td>
</tr>
<tr>
<td><strong>Therapeutic Category</strong></td>
</tr>
</tbody>
</table>

![Galantamine Hydrobromide](image)

**Manufacturer / supplier identification**

<table>
<thead>
<tr>
<th><strong>Company:</strong></th>
<th>Cadila Healthcare Ltd. Ahmedabad, India</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contact for information:</strong></td>
<td>Tel.: +91 79 6868100  Fax: +91 79 3750319</td>
</tr>
<tr>
<td><strong>Emergency telephone No.</strong></td>
<td>Tel.: +91 79 6868100</td>
</tr>
</tbody>
</table>
Material Safety Data Sheet
Galantamine Tablet ,USP

Strength: 4/8/12 mg Pack Size: 60/100/1000 Tablets per bottle & 10 * 10 unit dose blisters Revision No.: 00

Section 2. 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>13463-67-2</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 3. Health Hazards Information

**Dose and Administration**
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 infraction

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: esophageal 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
Gastointestinal 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 Conditions
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
Category B

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.
Material Safety Data Sheet  
Galantamine Tablet ,USP

Strength: 4/8/12 mg  Pack Size: 60/100/1000 Tablets per bottle & 10 * 10 unit dose blisters  Revision No.: 00

### Section 5. Fire – fighting measures

<table>
<thead>
<tr>
<th>Flash point</th>
<th>Not Found</th>
<th>Upper Flammable Limit:</th>
<th>Not Found</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-Ignition Temperature:</td>
<td>Not Found</td>
<td>Lower Flammable Limit:</td>
<td>Not Found</td>
</tr>
<tr>
<td>Extinguishing Media</td>
<td>Water Spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and material.</td>
<td>Fire and Explosion Hazard</td>
<td>Not Found</td>
</tr>
</tbody>
</table>

**Fire Fighting Procedure**

As with all fires, evacuate personnel to a safe area. Fire fighter should use self-contained breathing equipment and protective clothing.

### Section 6. Accidental Release Measures

**Spill Response**

Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

### Section 7. Handling and Storage

**Storage**

Store at 20° to 25°C (68° to 77°F)  
Dispense in a tight container.

### Section 8. Exposure controls and personal protection

**Respiratory Protection**

Protection from inhalation is not normally necessary. If ventilation is inadequate or dust is likely to generate, use of suitable dust mask would be appropriate.

**Skin Protection**

Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

**Eye protection**

Eye protection is not normally necessary. If concerned wear protective goggles or glasses. Wash hands prior to touching eye and in particular handling contact lenses.

**Protective Clothing**

Protective clothing is not normally necessary, however it is good practice to use apron.
Section 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>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.</td>
</tr>
<tr>
<td>Solubility in water</td>
<td>soluble</td>
</tr>
<tr>
<td>Odour</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Boiling point</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Vapour density</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Reactivity in water</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Percentage volatile by volume</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Specific gravity</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No Data Available</td>
</tr>
<tr>
<td>Other information</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

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. |
| Hazardous Decomposition         | Oxides of carbon, oxide of nitrogen, hydrogen bromide                       |
| Hazardous polymerization        | Oxides of carbon, oxide of nitrogen, hydrogen bromide                       |
| Incompatibilities               | No data available.                                                          |

Section 11. Toxicological 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 specific 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) : 75 mg/kg

Carcinogenicity
Not listed as a carcinogen by NTO, IARC monographs or OSHA

Section 12. Ecological information

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

Section 13. Disposal Consideration

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

Section 14. Transport Information

May be shipped normally as a non hazardous material.

Section 15. Regulatory Information

Galantamine Tablet, USP approved by USFDA & the ANDA Number is 078898

Section 16. Other information

None

Date of issue: 12/09/2011


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.