

## Safety Data Sheet

### Galantamine Tablet, USP

Strength: 4/8/12mg

Pack Size: 60 Tablets per bottle

Revision No.: 00

#### EMERGENCY OVERVIEW

Each Galantamine HBr Tablets 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

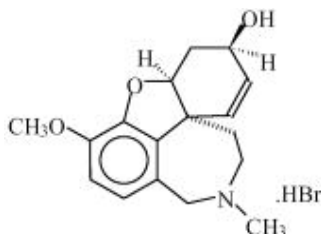
##### Identification of the product

**Product name:** Galantamine HBr Tablets, USP

**Formula:** C<sub>17</sub>H<sub>21</sub>NO<sub>3</sub>·HBr

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

**Therapeutic Category** Treatment of mild to moderate dementia of the Alzheimer's type



**Galantamine Hydrobromide**

##### Manufacturer / supplier identification

**Company:** Yabao Pharmaceutical Co., Ltd. Beijing

**Contact for information:** Tel.: +861058086000 Fax: +861058086013

**Emergency telephone No.** Tel.: +861058086094

**Safety Data Sheet****Galantamine Tablet, USP**

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**Section 2. Composition / information on ingredients**

<b>Component</b>	<b>Exposure Limit</b>	<b>CAS No.</b>
<b>Principle Component :</b>		
Galantamine hydrobromide	Not Found	1953-04-4
<b>Inactive Ingredients :</b>		
Colloidal silicon dioxide	Not Found	7631-86-9
Crospovidone	Not Found	9003-39-8
Hydroxypropyl cellulose	Not Found	N/A
Hypromellose	Not Found	9004-65-3
Lactose monohydrate	Not Found	5989-81-1
Magnesium stearate	Not Found	577-04-0
Microcrystalline cellulose	Not Found	9004-34-6
Pregelatinized starch	Not Found	9005-25-8
Titanium dioxide	Not Found	13463-67-7
The 4 mg tablets contain		
Polyethylene glycol	Not Found	25322-68-3
Polysorbate 80	Not Found	9005-65-6
The 8 mg tablets contain		
D&C red #27	Not Found	15876-58-1
FD&C blue #1	Not Found	68921-42-6
Triacetin	Not Found	102-76-1
The 12 mg tablets contain		
FD&C yellow #6	Not Found	15790-07-5
Iron oxide yellow	Not Found	51274-00-1
Triethyl citrate	Not Found	77-93-0

**Section 3. Health Hazards Information****Dose and Administration**

Galantamine HBr Tablets should be administered twice a day, preferably with morning and evening meals.

**Safety Data Sheet**  
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**Adverse Effects**

**Adverse Events Leading To Discontinuation**

Nausea, Vomiting, Diarrhea, Dizziness, Headache, and decreased Appetite.

**Metabolism and Nutrition Disorders:** Dehydration

**Nervous System Disorders:** Dysgeusia, Hypersomnia, Paresthesia

**Eye Disorders:** Blurred vision

**Cardiac Disorders:** First degree atrioventricular block, Palpitations, Sinus bradycardia, Supraventricular, extrasystoles

**Vascular Disorders:** Flushing, Hypotension

**Gastrointestinal Disorders:** Retching

**Skin and Subcutaneous Tissue Disorders:**

Hyperhidrosis

**Musculoskeletal and Connective Tissue Disorders:**

Muscular weakness

**Post marketing experience:**

**Immune System Disorders:** Hypersensitivity

**Psychiatric Disorders:** Hallucinations

**Nervous System Disorders:** Seizures

**Ear and Labyrinth Disorders:** Tinnitus

**Cardiac Disorders:** Complete atrioventricular block

**Vascular Disorders:** Hypertension

**Hepatobiliary Disorders:** Hepatitis, Increased hepatic enzyme

**Skin and Subcutaneous Tissue Disorders:**

Stevens-Johnson syndrome, Acute generalized exanthematous pustulosis, Erythema multiforme

**Over Dose Effect**

Signs and symptoms of significant overdosing of galantamine are predicted to be similar to those of overdosing of other cholinomimetics.

These effects generally involve the central nervous system, the parasympathetic nervous system, and the neuromuscular junction. In addition to muscle weakness or fasciculations, some or all of the following signs of cholinergic crisis may develop: 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.

**Safety Data Sheet**  
**Galantamine Tablet, USP**

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**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 HBr 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 in pregnant women. In studies conducted in animals, administration of galantamine during pregnancy resulted in developmental toxicity (increased incidence of morphological abnormalities and decreased growth in offspring) at doses similar to or greater than those used clinically. Galantamine HBr Tablets should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Pregnancy Category**

**Category C**

**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 overdose.

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#### Section 5. Fire – fighting measures

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

<b>Spill Response</b>	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 labeled container for disposal. Wash spill site.
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#### Section 7. Handling and Storage

<b>Storage</b>	Galantamine HBr Tablets USP should be stored at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F)
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#### Section 8. Exposure controls and personal protection

<b>Respiratory Protection</b>	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.
<b>Skin Protection</b>	Skin protection is not normally necessary, however it is good practice to avoid contact with chemical to use suitable gloves when handling.

**Safety Data Sheet**  
**Galantamine Tablet, USP**

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**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**

**Appearance**

4 mg white color coated, round, biconvex tablet, debossed "YB" on one side and "111" on the other side.  
 8 mg purple color coated, round, biconvex tablet, debossed "YB" on one side and "112" on the other side.  
 12 mg peach color coated, round, biconvex tablet, debossed "YB" on one side and "113" on the other side.

**Solubility in water**

soluble

**Odour**

No Data Available

**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

**Percentage Volatile by volume**

No Data Available

**Specific gravity**

No Data Available

**Vapour pressure**

No Data Available

**Other information**

Not Applicable

**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.

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**Section 11. Toxicological information**

<b>General</b>	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.
<b>Target organ</b>	Eye contact, Skin contact and inhalation is not great risk as this product is tablet.
<b>Carcinogenicity</b>	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**

<b>Disposal</b>	Dispose the waste in accordance with all applicable regulations.
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**Section 14. Transport Information**

May be shipped normally as a non-hazardous material.

**Section 15. Regulatory Information**

Galantamine HBr Tablets, USP approved by USFDA & the ANDA Number is 077604

**Section 16. Other information**

None

**Date of issue:** 09/08/2017

**Supersedes edition of:** New Edition

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.