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

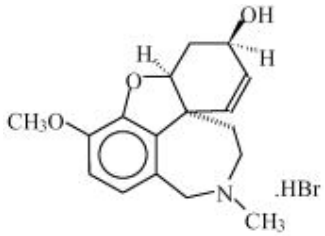
EMERGENCY OVERVIEW

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

Identification of the product

Product name:	Galantamine Tablet, USP
Formula:	$C_{17}H_{21}NO_3$•HBr
Chemical Name:	(4a*S*,6*R*,8a*S*)-4a,5,9,10,11,12-hexahydro-3-methoxy-11-methyl-6*H*-benzofuro[3a,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:	**Cadila Healthcare Ltd. Ahmedabad, India**
Contact for information:	Tel.: +91 79 6868100 Fax: +91 79 3750319
Emergency telephone No.	Tel.: +91 79 6868100

Section 2. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Galantamine hydrobromide	Not Found	1953-04-4
Inactive Ingredients :		
Colloidal silicon dioxide	Not Found	7631-86-9
Crospovidone	Not Found	9003-39-8
Hydroxypropyl Methylcellulose	Not Found	9004-65-3
Lactose Monohydrate	Not Found	5989-81-1
Magnesium Stearate	Not Found	577-04-0
Propylene Glycol	Not Found	57-55-6
Titanium Dioxide	Not Found	13463-67-2
Iron Oxide Red	Not Found	NA
Iron oxide yellow	Not Found	NA

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

Gastorintenstinal 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 **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.

Section 5. Fire – fighting measures

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

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**	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.		

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 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) : 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

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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.