Material Safety Data Sheet
Donepezil Hydrochloride Orally Disintegrating Tablets

Strength: 5 mg and 10 mg **Pack Size:** 30/90/100/500/1000 tablets per bottle & 10 * 10 unitdose blisters **Revision No.:** 00

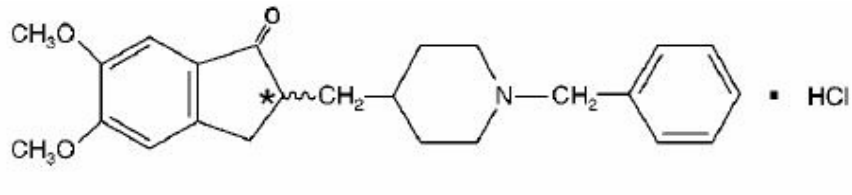
EMERGENCY OVERVIEW

Each donepezil hydrochloride orally disintegrating tablet intended for oral administration contains 5 mg or 10 mg of donepezil hydrochloride and excipients considered nontoxic and nonhazardous in small quantities and under conditions of normal occupational exposure..

Section 1. Identification of the substance

Identification of the product

Product name:	Donepezil Hydrochloride Orally Disintegrating Tablets
Formula:	C24H29NO3HCl
Chemical Name:	(±)-2, 3-dihydro-5, 6-dimethoxy-2-[[1-(phenylmethyl)-4-piperidinyl]methyl]-1*H*-inden-1-one hydrochloride
Therapeutic Category	Acetylcholinesterase inhibitor



Donepezil Hydrochloride

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 :		
Donepezil hydrochloride	Not Found	120011-70-3

Inactive Ingredients :		
Ammonium glycyrrhizate	Not Found	53956-04-0
Colloidal silicon dioxide	Not Found	7631-86-9
Crospovidone	Not Found	9003-39-8
Flavor firmenich powder Peppermint	Not Found	8006-90-4
Flavor strawberry	Not Found	NA
Magnesium stearate	Not Found	577-04-0
Mannitol	Not Found	69-65-8
Sucralose.	Not Found	56038-13-2

Section 3. Health Hazards Information

Dose and Administration

Mild to Moderate Alzheimer's disease – 5 mg or 10 mg administered once daily

Severe Alzheimer's disease - 10 mg administered once daily

Adverse Effects

Adverse Events Leading to Discontinuation
Nausea, Diarrhea ,Vomiting

Most Frequent Adverse Events Seen in Association with the Use of Donepezil Hydrochloride

Insomnia , muscle cramp, fatigue and anorexia

Adverse Events Reported in Controlled Clinical Trials in Mild to Moderate Alzheimer's Disease

Body as a Whole Headache Pain, various locations Accident Fatigue

Cardiovascular System Syncope

Digestive System Nausea ,Diarrhea ,Vomiting ,Anorexia

Hemic and Lymphatic System Ecchymosis

Metabolic and Nutritional Systems Weight Decrease

Musculoskeletal System Muscle Cramps Arthritis

Nervous System Insomnia ,Dizziness ,Depression Abnormal Dreams ,Somnolence

Urogenital System Frequent Urination

	Adverse Events Reported in Controlled Clinical Trials in Severe Alzheimer's Disease **Body as a Whole** Accident Infection, Headache Pain ,Back Pain, Fever Chest Pain **Cardiovascular System** Hypertension ,Hemorrhage ,Syncope **Digestive System** Diarrhea ,Vomiting ,Anorexia ,Nausea **Hemic and Lymphatic System** Ecchymosis **Metabolic and Nutritional Systems** Creatine Phosphokinase Increased Dehydration, Hyperlipemia **Nervous System** Insomnia ,Hostility ,Nervousness ,Hallucinations Somnolence ,Dizziness, Depression ,Confusion ,Emotional Lability Personality Disorder **Skin And Appendages** Eczema **Urogenital System** Urinary Incontinence
Over Dose Effect	severe nausea, vomiting, salivation, 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: Any heart problems including problems with irregular, slow, or fast, heartbeats ,Asthma or lung problems , seizure ,Stomach ulcers ,Difficulty passing urine ,Liver or kidney problems,Present pregnancy or plans to become pregnant. It is not known if donepezil hydrochloride can harm an unborn baby. ,Present breast-feeding. It is not known if donepezil hydrochloride passes into breast milk. Donepezil hydrochloride is not for women who are breast-feeding. Patient should inform the doctor about all the medicines the patient takes**,** including prescription and non-prescription medicines, vitamins, and herbal products.Donepezil hydrochloride and other medicines may affect each other. Patient should inform the doctor if the patient takes aspirin or medicines called nonsteroidal anti-inflammatory drugs (NSAIDs). There are many NSAID medicines, both prescription and non-prescription. Ask the doctor or pharmacist if you are not sure if any of the patient's medicines are NSAIDs. Taking NSAIDs and donepezil hydrochloride together may make the patient more likely to get stomach ulcers.

	Donepezil hydrochloride taken with certain medicines used for anesthesia may cause side effects. Tell the responsible doctor or dentist that the patient takes donepezil hydrochloride before the patient has: surgery ,medical procedures ,dental surgery or procedures. Know the medicines that the patient takes. Keep a list of all the patient's medicines. Show it to the doctor or pharmacist before the patient starts a new medicine.
Contraindications	Donepezil hydrochloride orally disintegrating tablets are contraindicated in patients with known hypersensitivity to donepezil hydrochloride or to piperidine derivatives.
Pregnancy Comments	There are no adequate or well-controlled studies in pregnant women. Donepezil hydrochloride 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 donepezil hydrochloride overdosage. Intravenous atropine sulfate titrated to effect is recommended: an initial dose of 1.0 to 2.0 mg IV with subsequent doses based upon clinical response. Atypical responses in blood pressure and heart rate have been reported with other cholinomimetics when co-administered with quaternary anticholinergics such as glycopyrrolate.

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**	This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with the dry material to dissipate the potential build up of static electricity.
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	Donepezil Hydrochloride Orally disintegrating Tablets, **5 mg** are white to off-white, round-shaped, biconvex, uncoated tablets engraved with 'ZF 14'on one side and plain on other side Donepezil Hydrochloride Orally Disintegrating Tablets, **10 mg** are white to off-white, round-shaped, biconvex, uncoated tablets engraved with 'ZF 15'on one side and plain on other side		
Solubility	soluble in chloroform, water and methanol; sparingly soluble in acetic acid.	**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.
Decomposition Products	No Data Available	**Hazardous Reaction**	No data available.

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	Not Applicable

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

Generic Medicine. Approved by USFDA & the ANDA Number is 090175

Section 16. Other information

None

Date of issue: 17/05/2011 **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.