Safety Data Sheet
LAMOTRIGINE TABLETS (CHEWABLE, DISPERSIBLE)

Strength: 2mg. **Pack Size:** 90 and 100 Tablets per bottle
Strength: 5mg and 25mg **Pack Size:** 90,100 and 500 Tablets per bottle **Revision No.:** 02

EMERGENCY OVERVIEW

Each Lamotrigine tablet (chewable, dispersible) intended for oral administration contains Lamotrigine and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

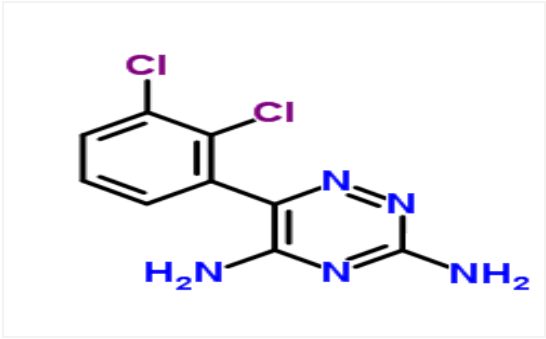
Section 1. Identification

Identification of the product

Product name: Lamotrigine Tablets (Chewable, Dispersible)

Formula: $C_9H_7N_5Cl_2$

Chemical Name: 3,5-diamino-6-(2,3-dichlorophenyl)-as-triazine



Manufacturer / supplier identification

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

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Recommended use / Therapeutic Category an antiepileptic drug (AED)

Restriction on Use / Contraindications:	Lamotrigine tablets are contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients. The risk of serious rashes requiring hospitalization and dis-continuation of lamotrigine.

Section 2. Hazard(s) Information

Dose and Administration	The dose is dependent on the age, weight and adjunct therapy given to the patient. The initial dose starts from 25mg/day to the maintenance dose up to 500mg / day in the divided doses. Tablets are meant for oral administration.
Adverse Effects	Serious rash requiring hospitalization and discontinuation of lamotrigine, including stevens-johnson syndrome and toxic epidermal necrolysis, have occurred in association with therapy with lamotrigine. Rare deaths have been reported, but their numbers are too few to permit a precise estimate of the rate.
Over Dose Effect	Overdoses involving quantities up to 15 g have been reported for lamotrigine, some of which have been fatal. Overdose has resulted in ataxia, nystagmus, increased seizures, decreased levelof consciousness,comaand intraventricular conduction delay.
Medical Conditions	• Life-threatening serious rash and/or rash-related death: Discontinue at the first sign of rash, unless the rash is Clearly not drug related. • Fatal or life-threatening hypersensitivity reaction: Multiorgan hypersensitivity reactions, also known as drug reaction with eosinophilia and systemic symptoms (DRESS), may be fatal or life threatening. Early signs may include rash, fever, and lymphadenopathy. These reactions may be associated with other organ involvement, such as hepatitis, hepatic failure, blood dyscrasias, or acute multiorgan failure. Lamotrigine should be discontinued if alternate etiology for this reaction is not found. • Blood dyscrasias (e.g.,neutropenia, thrombocytopenia, pancytopenia): May occur, either with or without an associated hypersensitivity syndrome. Monitor for signs of anemia, unexpected infection, or bleeding. • Suicidal behavior and ideation: Monitor for suicidal thoughts or behaviors.

- Clinical worsening, emergence of new symptoms, and suicidal ideation/behaviors may be associated with treatment of bipolar disorder. Patients should be closely monitored, particularly early in treatment or during dosage changes.
- Aseptic meningitis: Monitor for signs of meningitis.
- Medication errors due to product name confusion: Strongly advise patients to visually inspect tablets to verify the received drug is correct.

Contraindications Lamotrigine tablets are contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients. The risk of serious rashes requiring hospitalization and discontinuation of lamotrigine.

Pregnancy Comments No evidence of teratogenicity was found in mice, rats, or rabbits when lamotrigine was orally administered to pregnant animals during the period of organogenesis at doses up to 1.2, 0.5, and 1.1 times, respectively, on a mg/m2 basis, the highest usual human maintenance dose (i.e., 500 mg/day). However, maternal toxicity and secondary fetal toxicity producing reduced fetal weight and/or delayed ossification were seen in mice and rats, but not in rabbits at these doses.

Pregnancy Category C

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component :		
Lamotrigine	Not Found	84057-84-1
Inactive Ingredients :		
Aspartame	Not Found	22839-47-0
Croscarmellose sodium	Not Found	74811-65-7
Flavour black currant	Not Found	-

Magnesium stearate	Not found	557-04-0
Mannitol	Not Found	87-78-5
Microcrystalline cellulose	Not Found	9004-34-6
Silicon dioxide	Not Found	7631-89-9
Tribasic calcium phosphate	Not Found	7758-87-4

Section 4. First - aid measures

General Remove from exposure. Remove contaminated Clothing. Person developing serious hypersensitivity reaction must receive medical attention

Overdose Treatment There are no specific antidotes for lamotrigine. Following a suspected overdose, hospitalization of the patient is advised. General supportive care is indicated, including frequent monitoring of vital signs and close observation of the patient. If indicated, emesis should be induced or gastric lavage should be performed; usual precautions should be taken to protect the airway. It should be kept in mind that lamotrigine is rapidly absorbed. It is uncertain whether hemodialysis is an effective means of removing lamotrigine from the blood. In 6 renal failure patients, about 20% of the amount of lamotrigine in the body was removed by hemodialysis during a 4-hour session. A Poison Control Center should be contacted for information on the management of overdosage of lamotrigine.

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) in a dry place. Protect from light**.**
Incompatibilities:	No Data available.

Section 8. Exposure controls / 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.
Engineering Control	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance	Lamotrigine Tablets (Chewable, Dispersible), 2 mg are white to off-white, round, flat- faced, radial-edged tablets debossed with “Z” and “15”on one side and plain on the other side.

Lamotrigine Tablets (Chewable, Dispersible), 5 mg are white to off-white, round, flat- faced, radial-edged tablets with bisect on one side and plain on other side; one side of the bisect is debossed with "Z" and other side is debossed with "13" .

Lamotrigine Tablets (Chewable, Dispersible), 25 mg are white to off-white, round, flat- faced, radial-edged tablets debossed with logo of "Z" and "12" on one side and plain on the other side.

Solubility in water	No Data Available	**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 Lamotrigine is off-white to white crystalline powder and has a pKa of 5.7. Lamotrigine is soluble in dimethyl sulphoxide.

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 **Central Nervous System Adverse Effects**
Inform patients that lamotrigine may cause dizziness, somnolence, and other symptoms and signs of central nervous system depression. Accordingly, instruct them neither to drive a car nor to operate other complex machinery until they have gained sufficient experience on lamotrigine to gauge whether or not it adversely affects their mental and/or motor performance.

Lamotrigine tablets are contraindicated in patients who have demonstrated hypersensitivity to the drug or its ingredients. The risk of serious rashes requiring hospitalization and discontinuation of lamotrigine.

Other Not available.

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 078009

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.