

**Safety Data Sheet**  
**LAMOTRIGINE TABLETS**

**Strength:** 25mg.

**Strength:** 50mg and 100mg

**Strength:** 150mg, 200mg and 250mg

**Pack Size:** 25, 90, 100, 500 and 1000 Tablets per bottle

**Pack Size:** 90,100, 500 and 1000 Tablets per bottle

**Pack Size:** 60, 90 and 500 Tablets per bottle

**Revision No.:** 02

**EMERGENCY OVERVIEW**

Each Lamotrigine tablets 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.

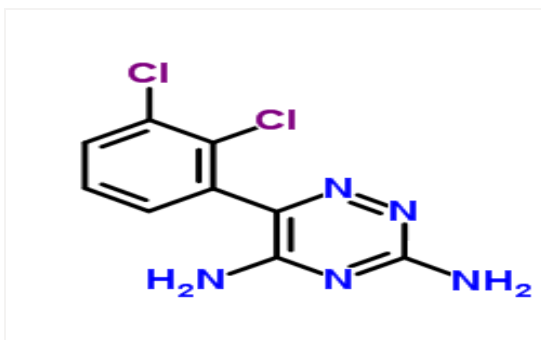
**Section 1. Identification**

**Identification of the product**

**Product name:** Lamotrigine Tablets

**Formula:** C<sub>9</sub>H<sub>7</sub>N<sub>5</sub>Cl<sub>2</sub>

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



**Manufacturer / supplier identification**

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

**Address:** Sarkhej – Bavla. N.H. 8A, Moraiya. Tal. Sanand.  
Dist. Ahmedabad – 382210. State: Gujarat. India

**Contact for information:** Tel.: +91 79 6868100 Fax: +91 79 3750319

**Emergency Telephone No.** Tel.: +91 79 6868100

**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.

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The risk of serious rashes requiring hospitalization and discontinuation 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, increasedseizures, decreased level of consciousness, coma, and 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

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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/m<sup>2</sup> 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 :**

Lactose monohydrate

Not Found

78-11-5

Magnesium stearate

Not Found

557-04-0

Microcrystalline cellulose

Not Found

9004-34-6

Povidone

Not Found

9003-39-8

Sodium starch glycolate

Not Found

9063-38-1

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**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.

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**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, 25 mg are white to off-white, round, flat, beveled-edged tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "79" and other side is plain.

Lamotrigine Tablets, 50 mg are white to off-white, round, flat, beveled-edged tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "90" and other side is plain.

Lamotrigine Tablets, 100 mg are white to off-white, round, flat, beveled-edged tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "80" and other side is plain.

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Lamotrigine Tablets, 150 mg are white to off-white, round, flat, beveled-edged tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "81" and other side is plain.

Lamotrigine Tablets, 200 mg are white to off-white, round, flat, beveled-edged tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "82" and other side is plain.

Lamotrigine Tablets, 250 mg are white to off-white, round, flat, beveled-edged tablets with bisect on one side; one side of the bisect is debossed with logo of "ZC" and other side is debossed with "91" and other side is plain.

<b>Solubility in water</b>	No Data Available	<b>Odour</b>	Odourless
<b>Boiling point</b>	No Data Available	<b>Melting Point</b>	No Data Available
<b>Evaporation rate</b>	No Data Available	<b>Vapour density</b>	No Data Available
<b>Reactivity in water</b>	No Data Available	<b>Evaporation rate</b>	No Data Available
<b>% Volatile by volume</b>	No Data Available	<b>Specific gravity</b>	No Data Available
		<b>Vapour pressure</b>	No Data Available
<b>Other information</b>	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

<b>Condition to avoid</b>	Avoid exposure to extreme heat, light and moisture.	<b>Stable</b>	Stable under normal ambient and anticipated storage and handling conditions.
<b>Decomposition Products</b>	No Data Available	<b>Hazardous Reaction</b>	No data available.
<b>Incompatibilities:</b>	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

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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.

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**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 077633

**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.