# LUPIN LIMITED

## SAFETY DATA SHEET

## Section 1: Identification

**Section 1, Identification**

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| **Material** | **Lamivudine Tablets, 150 mg and 300 mg** |
| **Manufacturer** | **Lupin Limited**<br>Goa - 403 722<br>INDIA. |
| **Distributor** | Lupin Pharmaceuticals, Inc.<br>Harborplace Tower, 21st Floor<br>111, South Calvert Street<br>Baltimore, MD 21202<br>United States<br>Tel. 001-410-576-2000 |

## Section 2: Hazard(s) Identification

**Section 2, Hazard(s) identification**

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| **Fire and Explosion** | Expected to be non-combustible. |
| **Health** | Lamivudine tablets are contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., anaphylaxis) to any of the components of the products. |
| **Environment** | No information is available about the potential of this product to produce adverse environmental effects. |

## Section 3: Composition / Information on Ingredients

**Section 3, Composition/information on ingredients**

| **Ingredients** | **CAS** |
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| Lamivudine | 134678-17-4 |

## Section 4: First-Aid Measures

**Section 4, First-aid measures**

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| **Ingestion** | If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention. |
| **Inhalation** | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. |
| **Skin Contact** | Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs. |
| **Eye Contact** | Flush eyes with plenty of water. Get medical attention. |

**NOTES TO HEALTH PROFESSIONALS**

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| **Medical Treatment** | Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. |
| **OVERDOSAGE** | There is no known antidote for lamivudine. One case of an adult ingesting 6 g of lamivudine was reported; there were no clinical signs or symptoms noted and hematologic tests remained normal. Two cases of pediatric overdose were reported in Study ACTG300. One case involved a single dose of 7 mg/kg of lamivudine; the second case involved use of 5 mg/kg of lamivudine twice daily for 30 days. There were no clinical signs or symptoms noted in either case. Because a negligible amount of lamivudine was removed via (4-hour) hemodialysis, continuous ambulatory peritoneal dialysis, and automated peritoneal dialysis, it is not known if continuous hemodialysis would provide clinical benefit in a lamivudine overdose event. If overdose occurs, the patient should be monitored, and standard supportive treatment applied as required. |

## Section 5: Fire-Fighting Measures

**Section 5, Fire-fighting measures**

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| **Fire and Explosion Hazards** | Assume that this product is capable of sustaining combustion. |
| **Extinguishing Media** | Water spray, carbon dioxide, dry chemical powder or appropriate foam. |
| **Special Firefighting Procedures** | For single units (packages): No special requirements needed. |

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| | For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters. |
| **Hazardous Combustion Products** | Hazardous combustion or decomposition products are expected when the product is exposed to fire. |

## Section 6: Accidental Release Measures

**Section 6, Accidental release measures**

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| **Personal Precautions** | Wear protective clothing and equipment consistent with the degree of hazard. |
| **Environmental Precautions** | For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems. |
| **Clean-up Methods** | Collect and place it in a suitable, properly labeled container for recovery or disposal. |

## Section 7: Handling and Storage

**Section 7, Handling and storage**

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| **Handling** | No special control measures required for the normal handling of this product. |
| **Storage** | Store lamivudine tablets at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. |

## Section 8: Exposure Controls/Personal Protection

**Section 8, Exposure controls/personal protection**

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## Section 9: Physical and Chemical Properties

**Section 9, Physical and chemical properties**

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| **Physical Form** | **Lamivudine Tablets, 150 mg**<br>White to off white scored capsule shaped, film coated tablets, debossed on both tablet faces, such that, when broken in half “L” and “5” code is present on both halves of the tablet ( “L” on one face and “5” on the opposite face of the tablet).<br><br>Bottle of 60 tablets (NDC 68180-602-07) with child-resistant closure.<br>Bottle of 100 tablets (NDC 68180-602-01) with child-resistant closure. |

**Lamivudine Tablets, 300 mg**
Gray coloured capsule shaped, film coated tablets, debossed with "L" on one side and "6" on the other side.

Bottle of 30 tablets (NDC 68180-603-06) with child-resistant closure.

## Section 10: Stability and Reactivity

**Section 10, Stability and reactivity**

Stable under recommended storage conditions.

## Section 11: Toxicological Information

**Section 11, Toxicological information**

**Carcinogenesis, Mutagenesis, Impairment of Fertility**

Long-term carcinogenicity studies with lamivudine in mice and rats showed no evidence of carcinogenic potential at exposures up to 10 times (mice) and 58 times (rats) those observed in humans at the recommended therapeutic dose for HIV-1 infection. Lamivudine was not active in a microbial mutagenicity screen or an in vitro cell transformation assay, but showed weak in vitro mutagenic activity in a cytogenetic assay using cultured human lymphocytes and in the mouse lymphoma assay. However, lamivudine showed no evidence of in vivo genotoxic activity in the rat at oral doses of up to 2,000 mg/kg, producing plasma levels of 35 to 45 times those in humans at the recommended dose for HIV-1 infection. In a study of reproductive performance, lamivudine administered to rats at doses up to 4,000 mg/kg/day, producing plasma levels 47 to 70 times those in humans, revealed no evidence of impaired fertility and no effect on the survival, growth, and development to weaning of the offspring.

## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

## Section 14: Transport Information

**IATA/ICAO - Not Regulated**

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|---|---|---|
| IATA Proper shipping Name | : | N/A |
| IATA UN/ID No | : | N/A |
| IATA Hazard Class | : | N/A |
| IATA Packaging Group | : | N/A |
| IATA Label | : | N/A |

**IMDG - Not Regulated**

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|---|---|---|
| IMDG Proper shipping Name | : | N/A |
| IMDG UN/ID No | : | N/A |
| IMDG Hazard Class | : | N/A |
| IMDG Flash Point | : | N/A |
| IMDG Label | : | N/A |

**DOT - Not Regulated**

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|---|---|---|
| DOT Proper shipping Name | : | N/A |
| DOT UN/ID No | : | N/A |
| DOT Hazard Class | : | N/A |
| DOT Flash Point | : | N/A |
| DOT Packing Group | : | N/A |
| DOT Label | : | N/A |

## Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

**Section 16, Other information**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

**Lupin** shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this MSDS.