

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

|                     |  |
|---------------------|--|
| <b>Material</b>     | <b>Abacavir and Lamivudine Tablets<br/>600 mg and 300 mg</b>   |
| <b>Manufacturer</b> | <b>Lupin Limited</b><br>Goa - 403722<br>India  |
| <b>Distributor</b>  | Lupin Pharmaceuticals, Inc.<br>111 South Calvert Street,<br>Harborplace Tower, 21st Floor,<br>Baltimore, Maryland 21202<br>United States<br>Tel. 001-410-576-2000<br>Fax. 001-410-576-2221 |

### Section 2: Hazard(s) Identification

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

|                           |  |
|---------------------------|--|
| <b>Fire and Explosion</b> | Expected to be non-combustible.  |
| <b>Health</b>             | Abacavir and lamivudine tablets are contraindicated in patients: <ul style="list-style-type: none"><li>• who have the HLA-B*5701 allele</li><li>• with prior hypersensitivity reaction to abacavir or lamivudine.</li><li>• with moderate or severe hepatic impairment</li></ul> |
| <b>Environment</b>        | 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

| <b>Ingredients</b>   | <b>CAS</b>  |
|----------------------|-------------|
| Abacavir Sulfate USP | 188062-50-2 |
| Lamivudine USP       | 134678-17-4 |

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

|                  |   |
|------------------|---|
| <b>Ingestion</b> | Never attempt to 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. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention. |
|------------------|---|

**Inhalation**

Physical form suggests that risk of inhalation exposure is negligible

**Skin Contact**

Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

**Eye Contact**

Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

**NOTES TO HEALTH PROFESSIONALS****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 specific treatment for overdose with abacavir and lamivudine tablets. If overdose occurs, the patient should be monitored, and standard supportive treatment applied as required.

**Abacavir**

It is not known whether abacavir can be removed by peritoneal dialysis or hemodialysis.

**Lamivudine**

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.

## Section 5: Fire-Fighting Measures

**Section 5, Fire-fighting measures****Fire and Explosion Hazards**

Not expected for the product, although the packaging is combustible.

**Extinguishing Media**

Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

**Special Firefighting Procedures**

For single units (packages): No special requirements needed.  
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

**Hazardous Combustion Products**

Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

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

## Section 7: Handling and Storage

### Section 7, Handling and storage

|                 |  |
|-----------------|--|
| <b>Handling</b> | Avoid breaking or crushing tablets.<br>No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. |
| <b>Storage</b>  | Store 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

|                      |   |
|----------------------|---|
| <b>Physical Form</b> | Abacavir and lamivudine tablets USP are available as tablets. Each tablet contains 600 mg of abacavir as abacavir sulfate and 300 mg of lamivudine. The tablets are orange colored, oval shaped, biconvex, film-coated tablets debossed with "LU" on one side "C51" on the other side. They are packaged as follows:<br><br>Bottles (120cc) of 30 Tablets (NDC 68180-288-06)<br>Bottles (250cc) of 90 Tablets (NDC 68180-288-09)<br>Pouches of 750 Tablets (NDC 68180-288-33) |
|----------------------|---|

## 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

##### **Carcinogenicity**

Abacavir was administered orally at 3 dosage levels to separate groups of mice and rats in 2-year carcinogenicity studies. Results showed an increase in the incidence of malignant and non-malignant tumors. Malignant tumors occurred in the preputial gland of males and the clitoral gland of females of both species, and in the liver of female rats. In addition, non-malignant tumors also occurred in the liver and thyroid gland of female rats. These observations were made at systemic exposures in the range of 6 to 32 times the human exposure at the recommended dose of 600 mg.

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) the human exposures at the recommended dose of 300 mg.

##### **Mutagenicity**

Abacavir induced chromosomal aberrations both in the presence and absence of metabolic activation in an in vitro cytogenetic study in human lymphocytes. Abacavir was mutagenic in the absence of metabolic activation, although it was not mutagenic in the presence of metabolic activation in an L5178Y mouse lymphoma assay. Abacavir was clastogenic in males and not clastogenic in females in an in vivo mouse bone marrow micronucleus assay.

Abacavir was not mutagenic in bacterial mutagenicity assays in the presence and absence of metabolic activation.

Lamivudine was mutagenic in an L5178Y mouse lymphoma assay and clastogenic in a cytogenetic assay using cultured human lymphocytes. Lamivudine was not mutagenic in a microbial mutagenicity assay, in an in vitro cell transformation assay, in a rat micronucleus test, in a rat bone marrow cytogenetic assay, and in an assay for unscheduled DNA synthesis in rat liver.

##### **Impairment of Fertility**

Abacavir or lamivudine did not affect male or female fertility in rats at a dose associated with exposures approximately 8 or 130 times, respectively, higher than the exposures in humans at the doses of 600 mg and 300 mg (respectively).

## 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

|                           |   |     |
|---------------------------|---|-----|
| 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

|                           |   |     |
|---------------------------|---|-----|
| 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

|                          |   |     |
|--------------------------|---|-----|
| 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 SDS.