

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

|                     |                                                                                                                                                                                            |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Material</b>     | <b>Oseltamivir Phosphate Capsule USP</b><br><b>30mg, 45mg and 75 mg</b>                                                                                                                    |
| <b>Manufacturer</b> | <b>Lupin Limited</b><br><b>MADE IN INDIA</b>                                                                                                                                               |
| <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>             | Oseltamivir phosphate is contraindicated in patients with known serious hypersensitivity to oseltamivir or any component of the product. Severe allergic reactions have included anaphylaxis and serious skin reactions including toxic epidermal necrolysis, Stevens-Johnson Syndrome, and erythema multiforme. |
| <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>  |
|---------------------------|-------------|
| Oseltamivir Phosphate USP | 204255-11-8 |

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

|                   |                                                                 |
|-------------------|-----------------------------------------------------------------|
| <b>Ingestion</b>  | Flush out mouth with water, consult a physician immediately.    |
| <b>Inhalation</b> | In case of inhalation remove to fresh air and seek medical aid. |

|                                      |                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Skin Contact</b>                  | Remove immediately contaminated clothes, wash affected skin with plenty of water.                                                                                                                                                                                                                                                                                         |
| <b>Eye Contact</b>                   | In case of contact with eyes rinse thoroughly with plenty of water and get medical advice.                                                                                                                                                                                                                                                                                |
| <b>NOTES TO HEALTH PROFESSIONALS</b> |                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Medical Treatment</b>             | 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. |
| <b>OVERDOSAGE</b>                    | Reports of overdoses with oseltamivir phosphate have been received from clinical trials and during postmarketing experience. In the majority of cases reporting overdose, no adverse reactions were reported. Adverse reactions reported following overdose were similar in nature to those observed with therapeutic doses of oseltamivir phosphate.                     |

## Section 5: Fire-Fighting Measures

### Section 5, Fire-fighting measures

|                                        |                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Fire and Explosion Hazards</b>      | Assume that this product is capable of sustaining combustion.                                                                                                                                                                                                                                                                                             |
| <b>Extinguishing Media</b>             | Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.                                                                                                                                                                                                                |
| <b>Special Firefighting Procedures</b> | For single units (packages): No special requirements needed.<br><br>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. |
| <b>Hazardous Combustion Products</b>   | Hazardous combustion or 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>      | Avoid excessive contact and contact with eyes. Wear safety goggles or shield.                                     |
| <b>Environmental Precautions</b> | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.          |
| <b>Clean-up Methods</b>          | This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids. |

## Section 7: Handling and Storage

### Section 7, Handling and storage

**Handling**

No special control measures required for the normal handling of this product.

**Storage**

Store at 25°C (77°F); excursions permitted between 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

**Physical Form**

30-mg capsules (30 mg free base equivalent of the phosphate salt): size '4' hard gelatin capsules with light yellow cap imprinted with '30 mg' in blue ink and light yellow body imprinted with 'LU' in blue ink containing white to off white granular powder. Available in HDPE bottle pack of 10 (NDC 68180-675-10) and blister packages of 10 (NDC 68180-675-11).

45-mg capsules (45 mg free base equivalent of the phosphate salt): size '4' hard gelatin capsules with grey opaque cap imprinted with '45 mg' in blue ink and grey opaque body imprinted with 'LU' in blue ink containing white to off white granular powder. Available in HDPE bottle pack of 10 (NDC 68180-676-10) and blister packages of 10 (NDC 68180-676-11).

75-mg capsules (75 mg free base equivalent of the phosphate salt): size '2' hard gelatin capsules with light yellow cap imprinted with '75 mg' in blue ink and grey opaque body imprinted with 'LU' in blue ink containing white to off white granular powder. Available in HDPE bottle pack of 10 (NDC 68180-677-10) and blister packages of 10 (NDC 68180-677-11).

## 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

In 2-year carcinogenicity studies in mice and rats given daily oral doses of the prodrug oseltamivir phosphate up to 400 mg/kg and 500 mg/kg, respectively, the prodrug and the active form oseltamivir carboxylate induced no statistically significant increases in tumors over controls. The mean maximum daily exposures to the prodrug in mice and rats were approximately 130- and 320-fold, respectively, greater than those in humans at the recommended clinical dose based on AUC comparisons. The respective safety margins of the exposures to the active oseltamivir carboxylate were 15- and 50-fold.

Oseltamivir was found to be non-mutagenic in the Ames test and the human lymphocyte chromosome assay with and without enzymatic activation and negative in the mouse micronucleus test. It was found to be positive in a Syrian Hamster Embryo (SHE) cell transformation test. Oseltamivir carboxylate was non-mutagenic in the Ames test and the L5178Y mouse lymphoma assay with and without enzymatic activation and negative in the SHE cell transformation test.

In a fertility and early embryonic development study in rats, doses of oseltamivir at 50, 250, and 1500 mg/kg/day were administered to females for 2 weeks before mating, during mating and until day 6 of pregnancy. Males were dosed for 4 weeks before mating, during mating, and for 2 weeks after mating. There were no effects on fertility, mating performance or early embryonic development at any dose level. The highest dose in this study was approximately 100 times the human systemic exposure (AUC<sub>0-24h</sub>) of oseltamivir carboxylate that occurs after administration of the maximum recommended human dose.

## Section 12: Ecological Information

### Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Section 13: Disposal Considerations

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

## Section 14: Transport Information

### 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

### 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.