

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078935937

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078919786 078931446 078936195 078936250 078937361

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Levetiracetam Tablets USP</b> <b>250 mg, 500 mg, 750 mg &amp; 1000 mg</b>
<b>Manufacturer</b>	<b>Lupin Limited, INDIA</b>
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 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>	None
<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>
Levetiracetam USP	102767-28-2

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

<b>Ingestion</b>	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.
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<b>Inhalation</b>	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Flush eyes with plenty of water. Get medical attention.
<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>	<p><b>Signs, Symptoms and Laboratory Findings of Acute Overdosage in Humans</b></p> <p>The highest known dose of levetiracetam received in the clinical development program was 6000 mg/day. Other than drowsiness, there were no adverse reactions in the few known cases of overdose in clinical trials. Cases of somnolence, agitation, aggression, depressed level of consciousness, respiratory depression and coma were observed with levetiracetam overdoses in postmarketing use.</p> <p><b>Management of Overdose</b></p> <p>There is no specific antidote for overdose with levetiracetam. If indicated, elimination of unabsorbed drug should be attempted by emesis or gastric lavage; usual precautions should be observed to maintain airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the patient's clinical status. A Certified Poison Control Center should be contacted for up to date information on the management of overdose with levetiracetam.</p> <p><b>Hemodialysis</b></p> <p>Standard hemodialysis procedures result in significant clearance of levetiracetam (approximately 50% in 4 hours) and should be considered in cases of overdose. Although hemodialysis has not been performed in the few known cases of overdose, it may be indicated by the patient's clinical state or in patients with significant renal impairment.</p>

## 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>	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
<b>Special Firefighting Procedures</b>	For single units (packages): No special requirements needed.

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

**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

**Handling**

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

Normal room ventilation is expected to be adequate for routine handling of this product.

**Storage**

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [see USP Controlled Room Temperature]

Dispense in a tight, light-resistant container with child-resistant closure along with medication guide provided separately.

## 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**

**How Supplied**

Levetiracetam tablets USP, 250 mg are blue coloured, oblong-shaped,

biconvex, film-coated tablets debossed with "L" and "U" on either side of the breakline on one side and "X01" on the other side.

They are supplied as follows:

NDC 68180-112-09	Bottles of 90's
NDC 68180-112-16	Bottles of 120's
NDC 68180-112-02	Bottles of 500's

Levetiracetam tablets USP, 500 mg are yellow coloured, oblong-shaped, biconvex, film-coated tablets debossed with "L" and "U" on either side of the breakline on one side and "X02" on the other side.

They are supplied as follows:

NDC 68180-113-09	Bottles of 90's
NDC 68180-113-16	Bottles of 120's
NDC 68180-113-02	Bottles of 500's

Levetiracetam tablets USP, 750 mg are orange coloured, oblong-shaped, biconvex, film-coated tablets debossed with "L" and "U" on either side of the breakline on one side and "X03" on the other side.

They are supplied as follows:

NDC 68180-114-09	Bottles of 90's
NDC 68180-114-16	Bottles of 120's
NDC 68180-114-02	Bottles of 500's

Levetiracetam tablets USP, 1000 mg are white to off-white coloured, oblong-shaped, biconvex, film-coated tablets debossed with "L" and "U" on either side of the breakline on one side and "X04" on the other side.

They are supplied as follows:

NDC 68180-115-07	Bottles of 60's
NDC 68180-115-02	Bottles of 500's

## 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

##### Carcinogenesis

Rats were dosed with levetiracetam in the diet for 104 weeks at doses of 50, 300 and 1800 mg/kg/day. The highest dose is 6 times the maximum recommended daily human dose (MRHD) of 3000 mg on a mg/m<sup>2</sup> basis and it also provided systemic exposure (AUC) approximately 6 times that achieved in humans receiving the MRHD. There was no evidence of carcinogenicity. In mice, oral administration of levetiracetam for 80 weeks (doses up to 960 mg/kg/day) or 2 years

(doses up to 4000 mg/kg/day, lowered to 3000 mg/kg/day after 45 weeks due to intolerability) was not associated with an increase in tumors. The highest dose tested in mice for 2 years (3000 mg/kg/day) is approximately 5 times the MRHD on a mg/m<sup>2</sup> basis.

#### **Mutagenesis**

Levetiracetam was not mutagenic in the Ames test or in mammalian cells *in vitro* in the Chinese hamster ovary/HGPRT locus assay. It was not clastogenic in an *in vitro* analysis of metaphase chromosomes obtained from Chinese hamster ovary cells or in an *in vivo* mouse micronucleus assay. The hydrolysis product and major human metabolite of levetiracetam (ucb L057) was not mutagenic in the Ames test or the *in vitro* mouse lymphoma assay.

#### **Impairment of Fertility**

No adverse effects on male or female fertility or reproductive performance were observed in rats at oral doses up to 1800 mg/kg/day (6 times the maximum recommended human dose on a mg/m<sup>2</sup> or systemic exposure [AUC] basis).

## **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 MSDS.