

# MATERIAL SAFETY DATA SHEET

## 1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

<b>Material</b>	<b>Levetiracetam Extended-Release Tablets 500 mg and 750 mg</b>
<b>Manufacturer</b>	Lupin Limited Goa 403 722 INDIA.
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 <sup>st</sup> Floor 111, South Calvert Street Baltimore, MD 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

## 2. COMPOSITION / INFORMATION ON INGREDIENTS

<b>Ingredients</b>	<b>CAS</b>	<b>Quantity</b>
Levetiracetam	102767-28-2	500 mg and 750 mg

## 3. HAZARD IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible
<b>Health</b>	No contraindication is reported.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

## 4. FIRST AID MEASURE

<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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**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**

**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** The signs and symptoms for extended-release levetiracetam tablets overdose are expected to be similar to those seen with immediate-release levetiracetam tablets.

The highest known dose of oral immediate-release 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 immediate-release levetiracetam overdoses in postmarketing use.

There is no specific antidote for overdose with extended-release levetiracetam tablets. 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 extended-release levetiracetam tablets.

## **5. FIRE FIGHTING MEASURE**

**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.  
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.

## 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.

## 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°-30°C (59°-86°F) [see USP Controlled Room Temperature].

Dispense in a tight, light-resistant container with a child-resistant closure.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Physical Form

Levetiracetam Extended-Release Tablets, 500 mg are white to off white, oblong-shaped, biconvex, film coated tablets, imprinted 'L008' (in black ink) on one side and plain on the other side.

They are supplied in white HDPE bottles containing

60 tablets - NDC 68180-117-07.

500 tablets - NDC 68180-117-02.

Levetiracetam Extended-Release Tablets, 750 mg are white to off white, oblong-shaped, biconvex, film coated tablets, imprinted 'L009' (in black ink) on one side and plain on the other side.

They are supplied in white HDPE bottles containing

60 tablets - NDC 68180-118-07.

500 tablets - NDC 68180-118-02.

## 10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

## 11. TOXICOLOGICAL INFORMATION

### 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 corresponds to 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. A study was conducted in which mice received levetiracetam in the diet for 80 weeks at doses of 60, 240 and 960 mg/kg/day (high dose is equivalent to 2 times the MRHD on a mg/m<sup>2</sup> or exposure basis). Although no evidence for carcinogenicity was seen, the potential for a carcinogenic response has not been fully evaluated in that species because adequate doses have not been studied.

### 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 (approximately 6 times the maximum recommended human dose on a mg/m<sup>2</sup> or exposure basis).

## 12. ECOLOGICAL INFORMATION

No relevant studies identified.

## 13. DISPOSAL CONSIDERATION

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

## 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

## 15. REGULATORY INFORMATION

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

## 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.