HETERO LABS LIMITED
"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http//www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Product information	
Product Name	Levetiracetam Tablets, 250 mg, 500 mg, 750 mg & 1000 mg
Active substance	Levetiracetam
Intended Uses	Levetiracetam Tablet is indicated as adjunctive therapy in the treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy, myoclonic seizures in adults and adolescents12 years of age and older with juvenile myoclonic epilepsy.
Company Details	
Manufacturer	Hetero Labs limited Unit-III, 22-110, Industrial Development Area Jeedimetla, Hyderabad - 500 055
Distributor	Camber Pharmaceuticals, Inc, Piscatway, NJ 08854
Section 2: Hazard(s) Identification	
Precautionary Statements	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing. Avoid release to the environment. Collect spillage.
Fire and Explosion	Expected to be non-combustible
Hazard Statements	May be harmful if swallowed.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients	
Components	**CAS No.**
Levetiracetam USP	102767-28-2

Croscarmellose sodium	74811-65-7
Corn Starch	9005-25-8
colloidal silicon dioxide	7631-86-9
povidone	9003-39-8
Magnesium Stearate	557-04-0
Talc	14807-96-6
opadry II blue	Not Assigned
opadry II yellow	Not Assigned
opadry II orange	Not Assigned
opadry II white	Not Assigned

Section 4: First-Aid Measures

General	Check the vital functions-Unconscious: maintain adequate airway and respiration. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Allow the victim to rest in a well ventilated area. Seek immediate Medical attention.
Inhalation	Move to fresh air. Oxygen or artificial respiration if needed. If exposed or concerned: Get medical attention/advice.
Eye contact	Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. If exposed or concerned: Get medical attention/advice.
Skin contact	Take off contaminated clothing and shoes immediately. Wash off immediately with plenty of water for at least 15 minutes. Discard contaminated clothing or wash before re-use. If exposed or concerned: Get medical attention/advice.
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
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	**Signs, Symptoms and Laboratory Findings of Acute Overdosage in Humans** 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. **Management of Overdose** 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. **Hemodialysis** 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.
Section 5: Fire-Fighting Measures	
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.
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	
Container Requirements	Dispense in a tight, light-resistant container.
Storage Conditions	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
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	
General Information	
Appearance **Physical State** **Form**	 Solid Tablet
Odour	Not available
pH	Not available

Description & Availability	Levetiracetam tablets, 250 mg are blue coloured, oblong shaped, scored, film coated tablets debossed with 'H' on one side and '87' on other side. They are supplied in containers of 30 tablets NDC 31722-536-30 60 tablets NDC 31722-536-60 120 tablets NDC 31722-536-12 500 tablets NDC 31722-536-05 1000 tablets NDC 31722-536-10 Levetiracetam tablets, 500 mg are yellow coloured, oblong shaped, scored, film coated tablets debossed with 'H' on one side and '88' on other side. They are supplied in containers of 30 tablets NDC 31722-537-30 60 tablets NDC 31722-537-60 120 tablets NDC 31722-537-12 500 tablets NDC 31722-537-05 1000 tablets NDC 31722-537-10 Levetiracetam tablets, 750 mg are orange coloured, oblong shaped, scored, film coated tablets debossed with 'H' on one side and '90' on other side. They are supplied in containers of 30 tablets NDC 31722-538-30 60 tablets NDC 31722-538-60 120 tablets NDC 31722-538-12 500 tablets NDC 31722-538-05 Levetiracetam tablets, 1000 mg are white coloured, oblong shaped, scored, film coated tablets debossed with 'H' on one side and '91' on other side. They are supplied in containers of 30 tablets NDC 31722-539-30 60 tablets NDC 31722-539-60 120 tablets NDC 31722-539-12 500 tablets NDC 31722-539-05

Section 10: Stability and Reactivity	
Stable under recommended storage conditions	
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/m2 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/m2 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/m2 or systemic exposure [AUC] basis).
Section 12: Ecological Information	
No relevant studies identified.	
Section 13: Disposal Considerations	
Waste treatment methods	
Additional information	Wash clothing and equipment after handling

Ecology - waste materials	Take up liquid spill into absorbent material-Scoop absorbed substance into closing containers.

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.

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