VKT Pharma Private Limited
Survey No. 21-27, Derasam (Village)
Ranasthalam (Mandalam), Srikakulam (District)
AP, India - 532 409

Material Safety Data Sheet
Levetiracetam Tablets

Section 1: Medicinal Product Identification

Product Name: Levetiracetam Tablets USP
250 mg, 500 mg, 750 mg, 1000 mg.

Category: Anti-Epileptic.

Manufacturer: VKT Pharma Private Limited,
Survey No: 21-27, Derasam village,
Ranasthalam Mandal,
Srikakulam District,
Andhra Pradesh-532409
India.

Section 2: Composition and Information on Ingredients

Ingredients	CAS	Strength
Levetiracetam USP	**102767-28-2**	**250mg, 500mg, 750mg, 1000mg**
Excipients Q.S		

Section 3: Hazards Identification

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

Section 4: First Aid Measures

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 unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
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 highest known dose of Levetiracetam received in the clinical development program was 6000 mg/day. Other than drowsiness, there were no adverse events in the few known cases of overdose in clinical trials. Cases of somnolence, agitation, and aggression, depressed level of consciousness, respiratory depression and coma were observed with Levetiracetam overdoses in post marketing use.

There is no specific antidote for overdose with 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 Levetiracetam.

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 patients clinical state or in patients with significant renal impairment.

Section 5: Fire and Explosion Data

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

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 20°C to 25°C (68°F -77°F); excursions permitted to 15°-30°C (59°-86°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

Physical Form:

Levetiracetam Tablets *USP,* 250 mg are blue colored, oblong-shaped tablets debossed with "OL"bisect "250" on one side and plain on either side.

Levetiracetam Tablets *USP,* 500 mg are yellow colored, oblong-shaped tablets debossed with "OL"bisect "500" on one side and plain on either side.

Levetiracetam Tablets *USP,* 750 mg are dark pink colored, oblong-shaped tablets debossed with "OL"bisect "750" on one side and plain on either side.

Levetiracetam Tablets *USP,* 1000 mg are white colored, oblong-shaped tablets debossed with "OL"bisect "1000" on one side and plain on either side.

Chemical Form:

pH: No data available
Melting point: No data available
Boiling point: No data available
Flash point: No data available

Section 10: Stability and Reactivity Data

Stable under recommended storage conditions.

Section 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 is 6 times the maximum recommended daily human dose (MRHD) of 3000 mg on a mg/m^2 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 in the diet for 80 weeks at doses of 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^2 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 lactogenic 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^2 or system exposure (AUC) basis).

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

NOT Regulated as dangerous goods

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: Additional Information

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