ScieGen Pharmaceuticals, Inc.
89 Arkay drive
Hauppauge, New York 11788
Tel: 631-434-2723
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SAFETY DATA SHEET

Date: 12/07/2020

Generic Name: Levetiracetam Extended Release Tablets, USP

Brand Equivalent: KEPPRA XR®

SECTION 1: IDENTIFICATION	
Product Name	Levetiracetam Extended Release Tablets, USP 500 mg &750mg
Active substance	Levetiracetam
Synonyms	N/A
Formula	$C_8H_{14}N_2O_2$
Intended Use	Antiepileptic
Chemical Name	1-Pyrrolidineacetamide, α-ethyl-2-oxo-, (α *S*)-; (−)-*(S)*-α-Ethyl-2-oxo-1- pyrrolidineacetamide
How Supplied	**500mg:** White, oval Shape, film coated tablet **750mg:** White, oval Shape, film coated tablet
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

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2. 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

3. Composition/Information on ingredients		
Components	**CAS-No**	**Concentration (%w/w)**
Levetiracetam	102767-28-2	69.44
Microcrystalline Cellulose, NF	9004-34-6	*
Hypromellose, USP (Methocel K4M Premium CR)	9004-65-3	*
Povidone, USP (Kollidon® 90F)	9003-39-8	*
Colloidal Silicon Dioxide , NF(Aerosil 200 Pharma)	7631-86-9	*
Magnesium Stearate, NF	557040	*
Opadry white (03F180003)		*
Opadry White contains Hypromellose, USP 6 cP Titanium Dioxide , USP Macrogol / Polyethylene Glycol 400,NF Iron Oxide Red, NF	9004-65-3 13463677 25322683 1309371	*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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4. FIRST AID MEASURES	
Eye contact	Flush eyes with plenty of water. Get medical attention
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.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
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.
Injection	Not a likely route of exposure.
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.
Over dosage	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

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5. FIRE-FIGHTING MEASURES	
Fire and explosion hazards	Assume that this product is capable of sustaining combustion.
Fire Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
Special Protective Actions For Fire-Fighters:	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.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	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.
Methods For Clean-up and Containment:	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

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8. Exposure controls/Personal protection
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
Appearance **Physical State** **Color**	 tablets refer section 1
Odour **Odour** **Odor Threshold**	 Not available Not available
pH	Not available
Other information **Bulk density**	 Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Very soluble in water
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
Thermal/Stability properties **Autoignition temperature**	 Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL **Explosive limits, UEL**	Not available Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
Vapor Properties	Not available

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Vapor Density	
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
stability	
Chemical Stability	Stable under normal conditions
Conditions to Avoid	Not available
Materials to Avoid	alkali metals oxidizing agents, highly oxygenated or halogenated solvents, organic compounds containing reducible functional groups
Hazardous Decomposition products	Hazardous decomposition products: carbon oxides (COx), nitrogen oxides (NOx), sulphur Oxides (SOx), gaseous hydrogen chloride (HCl).
Hazardous Reactions	None known.

11. Toxicological Information	
Carcinogenicity	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/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. 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/m2 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

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	human dose on a mg/m2 or exposure basis).

12. Ecological Information	
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

13. Disposal considerations	
Waste Treatment/Disposal Methods	Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters.
Disposal Containers	Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.
Precautions To Be Followed During Waste Handling	Wear proper protective equipment when handling waste materials.
U.S. EPA Waste Number	Not applicable

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14. Transport Information	
U.S. D.O.T	This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101
Transport CANADA Transportation Of Dangerous Goods Regulations	This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.
IATA	This product does not meet the criteria as Dangerous Goods, per rules of IATA.
IMO Designation	This product is NOT classified as Dangerous Goods by the International Maritime Organization.
European Agreement Concerning The International Carriage of Dangerous Goods by Road (ADR):	This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.
Transport In Bulk According To The IBC CODE	Not applicable.
Environmental Hazards	This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN); components are not specifically listed in Annex III under MARPOL 73/78.

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15. Regulatory Information	
U.S. SARA Reporting Requirements	The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.
U.S. SARA Threshold Planning Quantity	There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.
U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21):	ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No
U.S. CERCLA Reportable Quantity (RQ)	Not applicable.
U.S. TSCA Inventory Status:	This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA
Other U.S. Federal Regulations	Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.
California Safe Drinking Water and Toxic Enforcement Act (Proposition 65)	No component is on the California Proposition 65 Lists.

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	*12/07/20*
Revision	00
Disclaimer	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.