

SAFETY DATA SHEET

Date: 01/16/2023

Generic Name: Lacosamide Tablets, USP

 Brand Equivalent: VIMPAT[®]

1. IDENTIFICATION		
Product Name	Lacosamide Tablets, USP 50 mg, 100 mg, 150 mg and 200 mg	
Active substance	Lacosamide	
Synonyms	N/A	
Formula	C ₁₃ H ₁₈ N ₂ O ₃	
Intended Use	Lacosamide tablet is indicated for the treatment of partial-onset seizures in patients 4 years of age and older.	
Chemical Name	single (R)- enantiomer, is (R)- N- Benzyl-2- acetamido-3- methoxypropionamide	
How Supplied	50 mg: Pink, Oval shaped, film coated tablet debossed with SG on one side and 192 on other 100 mg: Yellow, Oval shaped, film coated tablet debossed with SG on one side and 193 on other 150 mg: Beige, Oval shaped, film coated tablet debossed with SG on one side and 194 on other 200 mg: Blue, Oval shaped, film coated tablet debossed with SG on one side and 195 on other	
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.	
Telephone No.	631-434-2723	
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)
Lacosamide, USP	175481-36-4	40
Microcrystalline Cellulose, NF (Pharmacel PH-101)	9004-34-6	*
Crospovidone, NF (Polyplasdone XL-10)	9003-39-8	*
Hydroxypropyl Cellulose, NF (Klucel LF)	9004-64-2	*
Microcrystalline Cellulose, NF (Pharmacel 102)	9004-34-6	*
Colloidal Silicon Dioxide, NF (Aerosil 200 Pharma)	7631-86-9	*
Magnesium Stearate, NF	557-04-0	*
Hypromellose 2910, USP 6 cP	9004653	*
Titanium Dioxide, USP	13463677	*
Macrogol / Polyethylene Glycol 3350, NF	25322683	*
Macrogol / Polyethylene Glycol 8000, NF	25322683	*

FD&C Red # 40/allura red AC Aluminum lake	25956176	*
FD&C Blue # 2/indigo carmine Aluminum lake	16521-38-3	*
FD&C Yellow # 6/Sunset yellow FCF Aluminum lake	2783940	*
Iron Oxide Yellow, NF**	51274-00-1	*
Iron Oxide Red, NF**	1309-37-1	*

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

4. FIRST AID MEASURES	
Eye contact	Flush eyes with plenty of water for at least 15 minutes. If irritation occurs or persists, get medical attention.
Skin contact	Remove contaminated clothing and wash 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	In case of unconsciousness place patient in side position for transportation.
Ingestion	Obtain medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
5. FIRE-FIGHTING MEASURES	
Fire and explosion hazards	NA
Fire Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Hazardous Combustion Products	Formation of Toxic gases is possible during heating or fire
Special Protective Actions For Fire-Fighters:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
6. ACCIDENTAL RELEASE MEASURES	
Health and safety precautions	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for cleaning and collecting	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly
Measures for environmental protections	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional consideration for Large spills	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should be undertaken by trained personnel
7. HANDLING AND STORAGE	
Handling	If tablets or capsules are crushed or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Minimize dust generation and accumulation. Use with

	adequate ventilation.
Storage	Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames
8. EXPOSURE CONTROLS/ PERSONNEL PROTECTION	
Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling	

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i>	tablets
Physical State	refer section 1
Color	
<i>Odor</i>	
Odor	No odor
Odor Threshold	Not available
pH	Not available
<i>Other information</i>	
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
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available

Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
Vapor Properties	Not available
Vapor Density	
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available
10. STABILITY AND REACTIVITY	
Chemical Stability	Stable under normal conditions of use
Conditions to Avoid	Not available
Incompatible Materials	As a precautionary measures, keep away from strong oxidizers an strong acids
11. TOXICOLOGICAL INFORMATION	
Carcinogenicity	Not listed by IARC, NTP and OSHA
LD/LC50 values that are relevant for classification	8 mg/kg (mouse) 3 mg/kg (rat)
12. ECOLOGICAL INFORMATION	
General notes	Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
13. DISPOSAL CONSIDERATIONS	
Waste Treatment/Disposal Methods	Must not be disposed of together with household garbage. Do not allow Product to reach sewage system.
Disposal Containers	Disposal must be made according to official regulations.
Precautions To Be Followed During Waste Handling	Wear proper protective equipment when handling waste materials.
U.S. EPA Waste Number	Not applicable

14. TRANSPORT INFORMATION	
U.S. D.O.T	UN2811
UN proper shipping name	
DOT	Toxic solids, Organic, n.o.s (Lacosamide)
IMDG	Toxic solids, Organic, N.O.S (Lacosamide)
IATA	Toxic solids, Organic, n.o.s (Lacosamide)
Transport Hazard classes	Not regulated
15. REGULATORY INFORMATION	
No further information available	

16. OTHER INFORMATION	
Recommended Restrictions for Use:	Not available
Prepared on	<i>01/16/2023</i>
Revision	00
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