



SAFETY DATA SHEET

Section 1: Identification	
Material	Eslicarbazepine Acetate Tablets, 200mg, 400mg, 600mg and 800mg
Recommended use	Pharmaceutical use.
Manufacturer	Hetero Labs Limited Unit V, Survey. No 439, 440, 441 & 458, Polepally Village, Mahabubnagar, Telangana 509301 India
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statements	May cause drowsiness or dizziness.
Precautionary statements	Avoid breathing dust/fume/gas/mist/vapours/spray. Use only outdoors or in a well-ventilated area Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell. Store in a well-ventilated place. Keep container tightly closed. Store locked up. Dispose of contents/container through a waste management company authorized by the local government.
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Eslicarbazepine Acetate	236395-14-5
Croscarmellose Sodium	74811-65-7
Glyceryl Monostearate	31566-31-1
Povidone	9003-39-8
Sodium stearyl Fumarate	4070-80-8
Section 4: First-Aid Measures	
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
Skin contact	Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention.



Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention
Ingestion	Get medical advice/attention if you feel unwell. Rinse mouth
Protection of first-aiders	A rescuer should wear personal protective equipment, such as rubber gloves and air-tight goggles
Most important symptoms and effects, both acute and delayed	No data available
Indication of any immediate medical attention and special treatment needed	No data available
Section 5: Fire-Fighting Measures	
Extinguishing media Suitable extinguishing media	Dry chemical, foam, water spray, carbon dioxide
Special hazards arising from the substance or mixture	Take care as it may decompose upon combustion or in high temperatures to generate poisonous fume. Carbon dioxide, Carbon monoxide, Nitrogen oxides (NOx)
Advice for firefighters	Fire-extinguishing work is done from the windward and the suitable fire-extinguishing method according to the surrounding situation is used. Uninvolved persons should evacuate to a safe place. In case of fire in the surroundings: Remove movable containers if safe to do so. When extinguishing fire, be sure to wear personal protective equipment
Section 6: Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Use personal protective equipment. Keep people away from and upwind of spill/leak. Entry to non-involved personnel should be controlled around the leakage area by roping off, etc
Environmental precautions	Prevent product from entering drains
Methods and materials for containment and cleaning up	Sweep dust to collect it into an airtight container, taking care not to disperse it. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.
Reference to other sections	For disposal see section 13.
Section 7: Handling and Storage	
Precautions for safe handling	Handling is performed in a well ventilated place. Wear suitable protective equipment. Prevent dispersion of dust. Wash hands and face thoroughly after handling. Use a closed system if possible. Use a local exhaust if dust or aerosol will be generated. Avoid contact with skin, eyes and clothing



Conditions for safe storage, including any incompatibilities	Keep container tightly closed. Store in a refrigerator. Store locked up. Store away from incompatible materials such as oxidizing agents. Heat-sensitive
Specific end use(s)	No further relevant information available
Section 8: Exposure Controls/Personal Protection	
Control parameters	No data available
Exposure controls	Install a closed system or local exhaust. Also install safety shower and eye bath
Respiratory protection	Dust respirator, self-contained breathing apparatus (SCBA), supplied air respirator, etc. Use respirators approved under appropriate government standards and follow local and national regulations
Hand protection	Impervious gloves
Eye protection	Safety goggles. A face-shield, if the situation requires
Skin and body protection	Impervious protective clothing. Protective boots, if the situation requires
Section 9: Physical and Chemical Properties	
Physical Form	Tablet
Description	<p>Eslicarbazepine acetate tablets, 200 mg are white to off-white, oblong tablets, with functional scoring on both the side and engraved with 'E31' on one side and 'H' on the other side. They are supplied as follows:</p> <p>Bottle of 30 tablets NDC 31722-428-30</p> <p>Cartons of 100 (10x10) unit-dose tablets NDC 31722-428-32</p> <p>Eslicarbazepine acetate tablets, 400 mg are white to off-white, circular bi-convex tablets, engraved with 'E32' on one side and 'H' on the other side. They are supplied as follows:</p> <p>Bottle of 30 tablets NDC 31722-429-30</p> <p>Cartons of 80 (10x8) unit-dose tablets NDC 31722-429-32</p> <p>Eslicarbazepine acetate tablets, 600 mg are white to off-white, oblong tablets, with functional scoring on both the side and engraved with 'E33' on one side and 'H' on the other side. They are supplied as follows:</p>



	Bottle of 60 tablets	NDC 31722-430-60
	Bottle of 90 tablets	NDC 31722-430-90
	Cartons of 100 (10x10) unit-dose tablets	NDC 31722-430-32
	Eslicarbazepine acetate tablets, 800 mg are white to off-white, oblong tablets, with functional scoring on both the side and engraved with 'E34' on one side and 'H' on the other side. They are supplied as follows:	
	Bottle of 30 tablets	NDC 31722-431-30
	Bottle of 90 tablets	NDC 31722-431-90
	Cartons of 100 (10x10) unit-dose tablets	NDC 31722-431-32

Section 10: Stability and Reactivity

Reactivity	No data available
Chemical stability	Stable under proper conditions
Possibility of hazardous reactions	No special reactivity has been reported
Conditions to avoid	No data available
Incompatible materials	Oxidizing agents
Hazardous decomposition products	Carbon dioxide, Carbon monoxide, Nitrogen oxides (NO _x)

Section 11: Toxicological Information

Information on toxicological effects	
Acute Toxicity:	No data available
Skin corrosion/irritation:	No data available
Serious eye damage/irritation:	No data available
Respiratory or skin sensitization:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	No data available
IARC =	No data available
NTP =	No data available
Reproductive toxicity:	No data available
STOT-single exposure:	No data available
STOT-repeated exposure:	No data available



Aspiration hazard:	No data available
Section 12: Ecological Information	
Toxicity Fish: Crustacea: Algae:	No data available No data available No data available
Persistence and degradability	No data available
Bioaccumulative potential	No data available
Mobility in soil Log Pow: Soil adsorption (Koc): Henry's Law (PaM³/mol):	No data available No data available No data available
Results of PBT and vPvB assessment PBT: vPvB:	Not applicable Not applicable
Other adverse effects	No data available
Section 13: Disposal Considerations	
Waste treatment methods	Recycle to process, if possible. Consult your local regional authorities. You may be able to dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber system. Observe all federal, state and local regulations when disposing of the substance.
Section 14: Transport Information	
UN number	Not listed
UN proper shipping name ADR/RID IMDG/IMO ICAO/IATA	Not listed Not listed Not listed
Transport hazard class(es) ADR/RID IMDG/IMO ICAO/IATA	Does not correspond to the classification standard of the United Nations Does not correspond to the classification standard of the United Nations Does not correspond to the classification standard of the United Nations
Packaging group ADR/RID IMDG/IMO ICAO/IATA	- - -
Environmental hazards Marine pollutant	-



Special precautions for user	No data available
Section 15: Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	
Substance of Very High Concern (SVHC) according to the REACH Regulations (EC) No.1907/2006	Not listed
Chemical safety assessment	A chemical safety assessment has not been carried out
Section 16: Other Information	
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Further information	
Revision date: New issue	
Revision note: New issue	
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