

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

<b>Material</b>	<b>Eslicarbazepine Acetate Tablets</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Verna, (Goa) - 403722 Goa, India
<b>Manufactured for</b>	<b>Lupin Pharmaceuticals, Inc.</b> Naples, FL 34108 United States.
<b>Use of the Substance/mixture</b>	Pharmaceuticals

### Section 2: Hazard(s) Identification

<b>Fire and Explosion</b>	No unusual fire or explosion hazards were noted.
<b>Health</b>	Hypersensitivity to eslicarbazepine acetate or oxcarbazepine. Do not handle until all safety precautions have been read and understood. please refer product packing insert / seek medical advice before use.
<b>Environment</b>	No information available.

### Section 3: Composition/Information on Ingredients

<b>Name</b>	<b>CAS No.</b>
Eslicarbazepine Acetate	236395-14-5
Lactose Monohydrate NF	63-42-3
Croscarmellose sodium psd (ac-di-sol) NF/EP	74811-65-7
Hydroxy propyl Cellulose NF	9004-64-2
Hypromellose 2910 USP	9004-65-3
Colloidal Silicon Dioxide NF	7631-86-9
Magnesium Stearate NF	557-04-0

\* The exact percentage composition of this mixture has been withheld as a trade secret.

### Section 4: First-Aid Measures

<b>Eye contact</b>	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Skin Contact</b>	In case of contact, remove contaminated clothing. Immediately flush the skin with copious amounts of water for at least 15 minutes. Use Soap. Obtain medical attention if a skin reaction occurs.
<b>Inhalation</b>	Move the individual to fresh air. If irritation or discomfort persists, seek medical attention. If not breathing, provide artificial respiration assistance.
<b>Ingestion</b>	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Rinse mouth with Water- Immediately after ingestion give lots of water to drink.

## Section 5: Fire-Fighting Measures

<b>Flammability</b>	No unusual fire or explosion hazards were noted.
<b>Hazardous Combustion Products</b>	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, and other pyrolysis products typical of burning organic material.
<b>Extinguishing Media</b>	Use carbon dioxide, dry chemical powder, or water spray.
<b>Fire Fighting Procedure</b>	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Fire / Explosion Hazard</b>	No unusual fire or explosion hazards were noted.

## Section 6: Accidental Release Measures

<b>Health and Safety Precautions</b>	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Dispose of in accordance with local, state, and national regulations.

## Section 7: Handling and Storage

<b>Precautions for safe handling:</b>	No special control measures are required for the normal handling of the product. Normal room ventilation is expected to be adequate for routine handling of this product. Keep it in its original package and away from light. Keep eslicarbazepine acetate tablets and all medicines out of reach of children.
<b>Storage</b> :	Store at 25°C (77°F); excursions permitted between 15° to 30°C (59° to 86°F). Keep the container tightly closed.

## Section 8: Exposure Controls/Personal Protection

<b>Protective Measures</b>	Handle in accordance with good industrial hygiene and safety practice.
<b>Respiratory Protection</b>	Choose respiratory protection appropriate to the task.
<b>Skin Protection</b>	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
<b>Eye Protection</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Engineering Controls</b>	Normal room ventilation is expected to be adequate for routine handling of this product.

## Section 9: Physical and Chemical Properties

<b>HOW SUPPLIED</b>	<b>Eslicarbazepine acetate tablets</b> Eslicarbazepine acetate tablets are white to off white color, oblong shaped and with functional scoring on one side (200 mg, 600 mg, and 800 mg) or white to off white color, circular biconvex and plain on one side (400 mg) and identified with one-sided engraving on the other side.
---------------------	---

Tablet Strength	Package Configuration	NDC Code
200 mg	Bottles of 30	68180-290-06
400 mg	Bottles of 30	68180-291-06
600 mg	Bottles of 60	68180-292-07
800 mg	Bottles of 30	68180-293-06

## Section 10: Stability and Reactivity

<b>Stability</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Incompatible Material</b>	As a precautionary measure, keep away from strong oxidizers.

## Section 11: Toxicological Information

<b>Acute Toxicity</b>	: Knowledge about health hazard is incomplete.
<b>Skin Corrosion/Skin Irritation</b>	: Hypersensitivity to eslicarbazepine acetate or oxcarbazepine. Knowledge about health hazard is incomplete.
<b>Respiratory/ Skin Sensitization</b>	: Knowledge about health hazard is incomplete.
<b>Mutagenicity</b>	: Knowledge about mutagenicity is incomplete
<b>Carcinogenicity</b>	: Knowledge about carcinogenicity is incomplete.
<b>Specific Target Organ Toxicity</b>	: No data available.
<b>Reproductive Toxicity</b>	: No data available.

## Section 12: Ecological Information

<b>Environmental Overview</b>	: Avoid release into the environment. The environmental characteristics of this product have not been fully evaluated.
-------------------------------	--

## Section 13: Disposal Considerations

<b>Waste Disposal</b>	: Dispose of contents/ waste in accordance with local regulations.
-----------------------	--

## Section 14: Transport Information

<b>IATA/ICAO - Not Regulated</b>	
<b>IATA Proper shipping Name</b>	: N/A
<b>IATA UN/ID No</b>	: N/A
<b>IATA Hazard Class</b>	: N/A
<b>IATA Packaging Group</b>	: N/A
<b>IATA Label</b>	: N/A
<b>IMDG - Not Regulated</b>	
<b>IMDG Proper shipping Name</b>	: N/A
<b>IMDG UN/ID No</b>	: N/A
<b>IMDG Hazard Class</b>	: N/A
<b>IMDG Flash Point</b>	: N/A
<b>IMDG Label</b>	: N/A
<b>DOT - Not Regulated</b>	
<b>DOT Proper shipping Name</b>	: 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

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.

**Lupin** shall not be held liable for any damage resulting from handling or contact with the above product. Lupin reserves the right to revise this SDS.