

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material Identified uses of the substance or mixture	TOPIRAMATE (EXTENDED-RELEASE CAPSULES) Pharmaceutical
Manufacturer	Lupin Limited Chhatrapati Sambhajinagar - 431 210 India
Distributor	Lupin Pharmaceuticals, Inc. Naples FL, 34108 United States.

Section 2: Hazard(s) Identification

Health	Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Environment	May cause Visual field defects, Acute myopia, and secondary angle closure glaucoma. Prevent material from entering sewer or confined spaces.
Precautionary statements	Get medical advice/ attention if you feel unwell.

Section 3: Composition/Information on Ingredients

Ingredients	CAS No.	Ingredients	CAS No.
Topiramate	97240-79-4	Mannitol	69-65-8
Docusate sodium	577-11-7	Opadry AMB white	889676-18-0
Sodium benzoate	532-32-1	Sugar spheres	92004-84-7
Ethyl cellulose	9004-57-3	Talc	14807-96-6
Hypromellose	9004-65-3	Triethyl citrate	77-93-0

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

Section 4: First-Aid Measures

General advice	Immediate medical attention is required.
Protection of first aiders	First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.
Inhaled	After inhalation: fresh air. Consult a doctor if the person is feeling unwell.
Skin contact	In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.

Eye contact	After eye contact: rinse out with plenty of water. Remove contact lenses.
If swallowed	Immediately consult a physician.

Section 5: Fire-Fighting Measures

Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Flammability Hazards: This product is combustible and can ignite if highly heated or if exposed to direct flame.
Special Firefighting Procedures	In the event of fire, wear a self-contained breathing apparatus.
Hazardous Combustion Products	When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, iron, titanium, sulfur, and nitrogen oxides).

Section 6: Accidental Release Measures

Personal Precautions	In the event of an accidental release, the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Evacuate personnel to safe areas. It should not be released into the environment.
Environmental Precautions	
Clean-up Methods	Sweep up into a suitable labeled container for disposal.

Section 7: Handling and Storage

Handling	Keep out of the reach of children. Keep away from heat and sources of ignition. Avoid inhalation, ingestion, contact with skin, and eyes. Protect from moisture and light. Topiramate extended-release capsules should be stored in well-closed container at controlled room temperature [25°C (77°F); excursions 15°C to 30°C (59°F to 86°F)]
Storage	

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	All personal protective equipment should be based on a risk assessment. Use with adequate ventilation.
Personal Protective Equipment:	Respiratory: Respiratory protection is generally not needed during routine conditions. Eye/Face: When handling very small quantities of the material eye protection may not be required. Skin/Body: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Topiramate extended-release capsules USP are available in the following strengths and colors:

25 mg (white opaque body/white opaque cap with black print "LU" and "T42"):

Bottles of 30 count (NDC-70748-275-06) and 100 count (NDC-70748-275-01)

50 mg (white opaque body/white opaque cap with black print "LU" and with red print "F42"):

Bottles of 30 count (NDC-70748-276-06) and 100 count (NDC-70748-276-01)

100 mg (white opaque body/white opaque cap with black print "LU" and "T44"):

Bottles of 30 count (NDC-70748-277-06) and 100 count (NDC-70748-277-01)

200 mg (white opaque body/white opaque cap with black print "LU" and "T45"):

Bottles of 30 count (NDC-70748-278-06) and 100 count (NDC-70748-278-01)

Section 10: Stability and Reactivity

Stability

The product is chemically stable under standard ambient conditions (room temperature).

Reactivity

None reasonably foreseeable.

Hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

Incompatible with oxidizing agents, strong acids.

Hazardous decomposition products

Products of thermal decomposition may include carbon, iron, titanium, sulfur, and nitrogen oxides.

Section 11: Toxicological Information

Acute toxicity	
Acute oral toxicity	Mouse Oral LD50: M-2338 mg/kg, F-2915mg/kg
Acute inhalation toxicity	Accidental ingestion may be harmful or cause toxic effects.
Inhalation	Inhalation of airborne dusts generated by damaged capsules of this product may slightly irritate the nose, throat, and lungs. In addition, inhalation may result in adverse effects as described under 'Other Potential Health Effects'
Skin Contact	Symptoms of skin contact may include itching and redness.
Ingestion	Ingestion of this product (i.e., through poor hygiene practices) may be harmful or toxic by ingestion. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Other effects may occur as described under 'Other Potential Health Effects'.
Eye Contact	It is anticipated that this product may irritate contaminated skin or eyes. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).
Carcinogenicity	No evidence of carcinogenicity was seen in rats following oral administration of topiramate for 2 years at doses up to 120 mg/kg
Reproduction toxicity	No adverse effects on male or female fertility were observed in rats at doses up to 100 mg/kg.

Section 12: Ecological Information

Ecotoxicity	This product may be harmful or fatal to contaminated plant and animal life (especially if large quantities are released).
Hazardous reactions	No dangerous reaction is known under conditions of normal use.
Conditions to avoid	To avoid thermal decomposition, do not overheat, flames or sparks.
Hazardous decomposition products	Products of thermal decomposition may include carbon, iron, titanium, sulfur, and nitrogen oxides.

Section 13: Disposal Considerations

Dispose of contents/containers in accordance with local regulations.

Section 14: Transport Information

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
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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: 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 from contact with the above product. Lupin reserves the right to revise this SDS.