

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material	Niacin Extended-release Tablets USP 500 mg, 750 mg and 1000 mg
Manufacturer	Lupin Limited Goa 403 722 INDIA.
Distributor	Lupin Pharmaceuticals, Inc. Harborplace Tower, 21 st Floor 111, South Calvert Street Baltimore, MD 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS
Niacin	59-67-6

3. HAZARDOUS IDENTIFICATION

Fire and Explosion	Assume that this product is capable of sustaining combustion.
Health	Niacin extended-release tablet is contraindicated in the following conditions: <ul style="list-style-type: none">▪ Active liver disease or unexplained persistent elevations in hepatic transaminases.▪ Patients with active peptic ulcer disease.▪ Patients with arterial bleeding.▪ Hypersensitivity to niacin or any component of this medication.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST AID MEASURES

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.
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Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
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.
Eye Contact	Flush eyes with plenty of water. Get medical attention.

NOTES TO HEALTH PROFESSIONALS

OVERDOSAGE	Supportive measures should be undertaken in the event of an overdose.
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5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
Special Firefighting Procedures	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.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	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.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE

Handling	No special precautions are necessary when handling packed product. In case of accident, avoid breathing dust from crushed tablets. Avoid contact with skin and eyes. Wash hands after use.
Storage	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [see USP Controlled Room Temperature].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL & CHEMICAL PROPERTIES

Physical Form

Niacin extended-release tablets USP are supplied as orange coloured, film-coated, capsule-shaped tablets containing 500 mg of niacin in an extended-release formulation. Tablets are debossed "LU" on one side and the "D11" on the other side. Tablets are supplied in bottles of 100 and 1000s as shown below.

500 mg tablets: bottles of 100 - NDC# 68180-221-01
500 mg tablets: bottles of 1000 - NDC# 68180-221-03

Niacin extended-release tablets USP are supplied as orange coloured, film-coated, capsule-shaped tablets containing 750 mg of niacin in an extended-release formulation. Tablets are debossed "LU" on one side and the "D12" on the other side. Tablets are supplied in bottles of 100 and 500s as shown below.

750 mg tablets: bottles of 100 - NDC# 68180-222-01
750 mg tablets: bottles of 500 - NDC# 68180-222-02

Niacin extended-release tablets USP are supplied as orange coloured, film-coated, oval-shaped tablets containing 1000 mg of niacin in an extended-release formulation. Tablets are debossed "LU" on one side and the "D13" on the other side. Tablets are supplied in bottles of 100 and 1000s as shown below.

1000 mg tablets: bottles of 100 - NDC# 68180-223-01
1000 mg tablets: bottles of 1000 - NDC# 68180-223-03

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

Niacin administered to mice for a lifetime as a 1% solution in drinking water was not carcinogenic. The mice in this study received approximately 6 to 8 times a human dose of 3000 mg/day as determined on a mg/m² basis. Niacin was negative for mutagenicity in the Ames test. No studies on impairment of fertility have been performed. No studies have been conducted with niacin extended-release tablets regarding carcinogenesis, mutagenesis, or impairment of fertility.

12. ECOLOGICAL INFORMATION

No information available

13. DISPOSAL CONSIDERATION

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

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
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

15. REGULATORY INFORMATION

No information available.

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 MSDS.