

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Identification

<b>Material</b>	<b>Rufinamide Tablets</b> <b>100 mg, 200 mg and 400 mg</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Goa - 403 722 India
<b>Distributor</b>	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

### Section 2: Hazard(s) Identification

#### Hazard(s) identification

<b>Classification</b>	Not classified as hazardous.  Do not handle until all safety precaution have been read and understood
-----------------------	---

### Section 3: Composition/Information on Ingredients

#### Composition/information on ingredients

Strength	CAS No.	100 mg	200 mg	400 mg
Rufinamide USP (Qua. in mg/tab)	10630-84-4	100	200	400
Rufinamide USP (%w/w)	10630-84-4	51.78	51.78	51.78

### Section 4: First-Aid Measures

#### First-aid measures

<b>General advice</b>	Consult a physician. Show this safety data sheet to the doctor in attendance.
<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 skin with copious amounts of water for at least 15 minutes. Use Soap. Obtain medical attention if skin reaction occurs.

<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<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.
<b>Note to physicians</b>	Most important symptoms and effects, both acute and delayed - May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.

## Section 5: Fire-Fighting Measures

### Fire-fighting measures

<b>Suitable Extinguishing Media</b>	Use carbon dioxide, dry chemical.
<b>Advise for fire fighters</b>	Fight fire from a safe distance. Wear full protective clothing. Use water spray to keep exposed containers and equipment cool. Toxic, corrosive of flammable thermal decomposition products are expected when the product is exposed to fire. Self-contained breathing apparatus and full protective equipment is recommended for firefighters

## Section 6: Accidental Release Measures

### Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.  Gloves must be inspected prior to use. Use proper glove removal technique (without touching gloves outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
<b>Environmental Precautions</b>	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Wash clothing and equipment after handling</b>	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel
<b>Disposal Methods</b>	Dispose of in accordance with local, state, and national regulations.

## Section 7: Handling and Storage

### Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE.
<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice.

**Storage Conditions**

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Protect from moisture.

Replace cap securely after opening.

## Section 8: Exposure Controls/Personal Protection

**Exposure controls/personal protection**

Use appropriate personal protective equipment for protection.

**Appropriate engineering controls**

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

**Individual protection measures, such as personal protective equipment**

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands**

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

**Eyes**

Wear safety glasses or goggles if eye contact is possible.

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Skin**

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL

**Respiratory protection**

If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL. Gas mask with filter type A.

## Section 9: Physical and Chemical Properties

**Physical and chemical properties****How Supplied**

Rufinamide tablets USP, 100 mg (containing 100 mg rufinamide) are pink, oblong shaped, film-coated, with a score on both sides, and debossed with 'L', 'U' on each side of the score on one side and 'P', '71' on each side of the score on the other side. They are available in bottles of 30 tablets (NDC 68180-802-06) and 120 tablets (NDC 68180-802-16).

Rufinamide tablets USP, 200 mg (containing 200 mg rufinamide) are pink, oblong shaped, film-coated, with a score on both sides, and debossed with 'L', 'U' on each side of the score on one side and 'P', '72' on each side of the score on the other side. They are available in bottles of 30 tablets (NDC 68180-803-06) and 120 tablets (NDC 68180-803-16).

Rufinamide tablets USP, 400 mg (containing 400 mg rufinamide) are pink, oblong shaped, film-coated, with a score on both sides, and debossed with 'L', 'U' on each side of the score on one side and 'P', '73' on each side of the score on the other side. They are available in bottles of 120 tablets (NDC 68180-804-16).

**Appearance**

Tablets

Odor	Not available
Odor threshold	Not available
Melting point/freezing point	Not available
Boiling point / boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available
Flammability Limit in Air	Not available.
Upper flammability limit	Not available
Lower flammability limit	Not available
Vapor pressure	Not available.
Vapor density	Not available.
Specific Gravity	Not available
Water solubility	Not available
Solubility in other solvent	Not available
Partition coefficient	Not available
Auto ignition temperature	Not available
Decomposition temperature	Not available
Kinematic viscosity	Not available
Dynamic viscosity	Not available
Explosive properties	Not available
Oxidizing properties	Not available

## Section 10: Stability and Reactivity

### Stability and reactivity

<b>Reactivity</b>	No data available
<b>Chemical stability</b>	Stable under normal conditions of use
<b>Possibility of Hazardous Reactions</b>	None known
<b>Incompatible materials</b>	As a precautionary measure, keep away from strong oxidizers.
<b>Hazardous Decomposition Products</b>	No data available.

## Section 11: Toxicological Information

### Toxicological information

The Toxicological effect of this product have not been thoroughly studied.

## Section 12: Ecological Information

### Ecological Information

Avoid release into the environment.

<b>Eco toxicity</b>	Not available.
<b>Persistence and degradability</b>	Not available.
<b>Bioaccumulation</b>	Not available.
<b>Mobility</b>	Not available.
<b>Other adverse effects</b>	Not available.

## Section 13: Disposal Considerations

### Disposal Considerations

Disposal of wastes: Disposal should be in accordance with applicable regional, national and local laws and regulations.

## Section 14: Transport Information

### Transport Information

Not Regulated

:

## Section 15: Regulatory Information

### Regulatory Information

NA

## Section 16: Other Information

### 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.