# HETERO LABS LIMITED

## SAFETY DATA SHEET

## Section 1: Identification

| | |
|---|---|
| **Material** | **Rufinamide Oral Suspension**<br>40 mg/mL |
| **Manufacturer** | **Hetero Labs Limited, Unit III**<br>Plot No. 22-110, Part-II, IDA,<br>Jeedimetla, Hyderabad,<br>Telangana-500055, INDIA |
| **Distributor** | Lupin Pharmaceuticals, Inc.<br>111 South Calvert Street,<br>Harborplace Tower, 21st Floor,<br>Baltimore, Maryland 21202<br>United States<br>Tel. 001-410-576-2000<br>Fax. 001-410-576-2221 |

## Section 2: Hazard(s) Identification

| | |
|---|---|
| **Fire and Explosion** | Expected to be non-combustible. |
| **Health** | Rufinamide is contraindicated in patients with Familial Short QT syndrome |
| **Environment** | No information is available about the potential of this product to produce adverse environmental effects. |

## Section 3: Composition/Information on Ingredients

| **Ingredients** | **CAS** |
|---|---|
| Rufinamide | 106308-44-5 |

## Section 4: First-Aid Measures

| | |
|---|---|
| **Ingestion** | Get medical attention. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |
| **Inhalation** | Remove to fresh air, if not breathing, give artificial respiration. Get medical attention. |
| **Skin Contact** | Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. |
| **Eye Contact** | Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persist, get medical attention. |

**NOTES TO HEALTH PROFESSIONALS**

| | |
|---|---|
| **Medical Treatment** | Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc. |
| **OVERDOSAGE** | Because strategies for the management of overdose are continually evolving, it is advisable to contact a Certified Poison Control Center to determine the latest recommendations for the management of an overdose of any drug.<br><br>One overdose of 7200 mg per day rufinamide was reported in an adult during the clinical trials. The overdose was associated with no major signs or symptoms, no medical intervention was required, and the patient continued in the study at the target dose.<br><br>Treatment or Management of Overdose: There is no specific antidote for overdose with rufinamide. If clinically indicated, elimination of unabsorbed drug should be attempted by induction of emesis or gastric lavage. Usual precautions should be observed to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient.<br><br>Hemodialysis: Standard hemodialysis procedures may result in limited clearance of rufinamide. Although there is no experience to date in treating overdose with hemodialysis, the procedure may be considered when indicated by the patient's clinical state. |

## Section 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.<br>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. |

## Section 6: Accidental Release Measures

| | |
|---|---|
| **Personal Precautions** | Wear suitable protective clothing, gloves and eye/face protection. |
| **Environmental Precautions** | Avoid release to the environment. |
| **Clean-up Methods** | Collect and place it in a suitable, properly labeled container for recovery or disposal. |

## Section 7: Handling and Storage

**Handling**

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

**Storage**

Store the oral suspension at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature].

Replace cap securely after opening.

The cap fits properly in place when the adapter is in place.

## Section 8: Exposure Controls/Personal Protection

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

## Section 9: Physical and Chemical Properties

Rufinamide oral suspension is an orange flavored liquid supplied in a polyethylene terephthalate (PET) bottle with child-resistant closure.

The oral suspension is packaged with a dispenser set which contains a calibrated oral dosing syringe and an adapter. Store the oral suspension in an upright position. Use within 90 days of first opening the bottle, then discard any remainder. The oral suspension is available in bottles of 460 mL (NDC 68180-797-01).

## Section 10: Stability and Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

## Section 11: Toxicological Information

Rufinamide was given in the diet to mice at 40, 120, and 400 mg/kg per day and to rats at 20, 60, and 200 mg/kg per day for 2 years. The doses in mice were associated with plasma AUCs 0.1 to 1 times the human plasma AUC at the maximum recommended human dose (MRHD, 3200 mg/day). Increased incidences of tumors (benign bone tumors (osteomas) and/or hepatocellular adenomas and carcinomas) were observed in mice at all doses. Increased incidences of thyroid follicular adenomas were observed in rats at all but the low dose; the low dose is < 0.1 times the MRHD on an mg/m$^2$ basis.

Rufinamide was not mutagenic in the *in vitro* bacterial reverse mutation (Ames) assay or the *in vitro* mammalian cell point mutation assay. Rufinamide was not clastogenic in the *in vitro* mammalian cell chromosomal aberration assay or the *in vivo* rat bone marrow micronucleus assay.

Oral administration of rufinamide (doses of 20, 60, 200, and 600 mg/kg per day) to male and female rats prior to mating and throughout mating, and continuing in females up to day 6 of gestation resulted in impairment of fertility (decreased conception rates and mating and fertility indices; decreased numbers of corpora lutea, implantations, and live embryos; increased preimplantation loss; decreased sperm count and motility) at all doses tested. Therefore, a no-effect dose was not established. The lowest dose tested was associated with a plasma AUC ≈ 0.2 times the human plasma AUC at the MRHD.

## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

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

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