SAFETY DATA SHEET

Section 1: Identification	
Material	**Rufinamide Oral Suspension**
Manufacturer	**Hetero Labs Limited, Unit-III** **22-110, IDA,** Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854

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
Anhydrous Citric Acid	77-92-9
Microcrystalline cellulose and Carboxymethylcellulose sodium	9004-34-6 9004-32-4
Hydroxyethyl cellulose	9004-62-0
Methylparaben	99-76-3
Orange 051941A	1936-15-8
Poloxamer	9003-11-6
Potassium sorbate	24634-61-5
Propylene glycol	57-55-6
Propylparaben	94-13-3
Simethicone Emulsion	8050-81-5
Noncrystallizing Sorbitol solution 70% USP-NF (Sorbidex 71205)	50-70-4
Purified Water	7732-18-5

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. 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. 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. 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. 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

Physical Form	Oral suspension
Description	Rufinamide oral suspension is a white orange flavoured 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 31722-688-46

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/m2 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

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Version: 00

Further information

Revision date: NA

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