



# HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.  
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250  
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

## SAFETY DATA SHEET

### Section 1: Identification

#### Product Information

<b>Product Name</b>	<b>Rufinamide Tablets USP, 200 mg and 400mg</b>
<b>Manufacturer</b>	<b>Hetero Labs Limited</b> Unit III, 22-110, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
<b>Distributor</b>	<b>Camber Pharmaceuticals, Inc.</b> , Piscatway, NJ 08854

### Section 2: Hazard(s) Identification

#### Classification of the substance or mixture

#### **Classification according to regulation (EC)**

Not classified

#### **Classification according to Directive 67/548/EEE or 1999/45/EC**

Carc.Cat3;R40

#### **Adverse physicochemical, human health and environmental effects**

No additional information available

<b>Hazard statements (CLP)</b>	H302 - Harmful if swallowed H312 - Harmful in contact with skin
<b>Precautionary statements (CLP)</b>	H332 - Harmful if inhaled P101- if medical advice is needed, have product container or labelled at hand P102- keep out of reach of children P103- Read label before use
<b>EUH phrases</b>	P201-Obtain special instruction before use
<b><u>Other hazards</u></b>	P202-Do not handle until all safety precaution have been read and understood
No I information available	P233-keep container tightly closed EUH210- Safety data sheet available on request

### Section 3: Composition/Information on Ingredients

<b>Active Ingredient</b>	Rufinamide (Premix)
<b>Contains</b>	Mixture of Rufinamide and Hydroxypropyl Methylcellulose

### Section 4: First-Aid Measures

<b>First-aid measures general</b>	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
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<b>Inhalation</b>	Allow the victim to rest in a well ventilated area. Seek immediate Medical attention. Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention. Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Skin Contact</b>	Immediately wash skin with soap and copious Amounts of water for at least 15 minutes. If Irritation persists seek medical attention. Wash immediately with lots of water-Soap May be used-Do not apply (chemical) neutralizing agents-Take victim to a doctor if irritation persists.
<b>Eye Contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately. Rinse immediately with lots of water-Do not apply neutralizing agents-Take victim to an ophthalmologist if irritation persists.
<b>Ingestion</b>	If swallowed, wash out mouth with water, provided Person is conscious. Seek medical advice. Rinse mouth with water-Immediately after ingestion give lots of water to drink.

## Section 5: Fire-Fighting Measures

### Extinguishing media

**Suitable extinguishing media** Use carbon dioxide, dry chemical.

### Special hazards arising from the substance or mixture

**Fire hazard** Flammable with air within explosion limits  
Indirect fire hazard may be ignited by sparks  
Gas/vapour spreads at floor level ignition hazard.

**Explosion hazard** Not expected for the product although the packaging is combustible

**Reactivity** Product is not explosive

### Advice for firefighters

**Precautionary measures fire** 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.



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## Section 6: Accidental Release Measures

### Personal precautions, protective equipment and emergency procedure

<b>General measures</b>	Keep upwind-Mark the danger area-Consider evacuation-Seal off low-lying area-Close doors and windows of adjacent- premises
<b>For non- emergency personnel</b>	No additional information available
<b>For emergency responders</b>	No additional information available
<b>Environmental precaution</b>	Keep upwind-mark the danger area-consider evacuation-seal off low-lying areas-close door and windows of adjacent premises.
<b>Methods and material for containment and cleaning up</b>	
<b>Methods of cleaning up</b>	Wipe up with a damp cloth and place in container for disposal. Clean spill area thoroughly.
<b>Other information</b>	Wash clothing and equipment after handling.
<b>Reference to other section</b>	
No additional information available	

## Section 7: Handling and Storage

<b>Storage conditions</b>	Store the tablets at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture. Replace cap securely after opening.
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## Section 8: Exposure Controls/Personal Protection

### Control parameters

No additional information available

### Exposure controls

<b>Appropriate engineering controls</b>	Engineering controls should be use as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits.
<b>Hand protection</b>	Gloves.
<b>Eye protection</b>	Protective goggles
<b>Skin and body protection</b>	Protective clothing.
<b>Respiratory protection</b>	Gas mask with filter type A.



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## Section 9: Physical and Chemical Properties

Description	Rufinamide tablets USP, 200 mg (containing 200 mg rufinamide) are pink, oval, biconvex tablets, debossed with 'H' on one side with score line and 'R' and '7' separated by score line on the other side. They are available in
	Bottles of 30 Tablets      NDC 31722-598-30 Bottles of 120 Tablets     NDC 31722-598-12
	Rufinamide tablets, 400 mg (containing 400 mg rufinamide) are pink, oval, biconvex tablets, debossed with 'H' on one side with score line and 'R' and '8' separated by score line on the other side. They are available in
	Bottles of 30 Tablets      NDC 31722-599-30 Bottles of 120 Tablets     NDC 31722-599-12

## Section 10: Stability and Reactivity

<b>Reactivity</b>	Product is not explosive
<b>Chemical stability</b>	Stable under normal conditions of use.
<b>Possibility of hazardous reaction</b>	No additional information available
<b>Conditions to avoid</b>	No additional information available
<b>Incompatible materials</b>	As a precautionary measure. Keep away from strong oxidizers.
<b>Hazardous decomposition products</b>	No additional information available

## Section 11: Toxicological Information

### Information on toxicological effects

<b>Acute toxicity</b>	Not classified
<b>Skin corrosion/irritation</b>	Not classified
<b>Serious eye damage/irritation</b>	Not classified
<b>Respiratory or skin sensitisation</b>	Not classified
<b>Germ cell mutagenicity</b>	Not classified
<b>Carcinogenicity</b>	Not classified
<b>Reproductive toxicity</b>	Not classified
<b>Specific target organ toxicity (single</b>	Not classified



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exposure)	
Specific target organ toxicity (repeated exposure)	Not classified
Aspiration hazard	Not classified

## Section 12: Ecological Information

### Toxicity

**Ecology – air** Not dangerous for the ozone layer (1999/45/EC).

### **Rufinamide (106308-44-5)**

#### Persistence and degradability

**Persistence and degradability** % biodegradation.

#### Bio accumulative potential

**Bio accumulative potential** The substance has low potential for bioaccumulation.

#### Mobility in soil

**Ecology - soil** The substance has moderate mobility in groundwater. The substance has moderate mobility in soil.

## Section 13: Disposal Considerations

### **Waste treatment methods**

**Additional information** Wash clothing and equipment after handling

**Ecology- waste materials** Take up liquid spill into absorbent material-  
Scoop absorbed substance into closing containers.

## Section 14: Transport Information

No dangerous good in sense of transport regulation.

## Section 15: Regulatory Information

### **Safety, health and environmental regulations/legislation specific for the substance or mixture**

**EU-Regulations** No annex XVII restrictions  
Contains no REACH candidate substances

**National regulations** No additional information available

**Chemical safety assessment** No additional information available



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## Section 16: Other Information

### Section 16, Other information

**Issue Date : 15-04-2021**

**Version : 00**

### Further information

**Revision date: New issue**

**Revision note: New issue**

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