

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Mesalamine Extended-Release Capsule 0.375 g</b>
<b>Manufacturer</b>	Catalent Pharma Solutions, LLC 1100 Enterprise Drive Winchester, KY 40391 Packaged at: Pharma Packaging Solutions 341 JD Yarnell Industrial Parkway Clinton, TN 37716
<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

#### Section 2, Hazard(s) identification

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Mesalamine extended-release capsules are contraindicated in patients with hypersensitivity to salicylates or aminosaliclates or to any of the components of mesalamine extended-release capsules.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

### Section 3: Composition/Information on Ingredients

#### Section 3, Composition/information on ingredients

<b>Ingredients</b>	<b>CAS</b>
Mesalamine	89-57-6

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

<b>Ingestion</b>	Rinse mouth. Call a doctor/physician if you feel unwell. Do NOT induce vomiting.
<b>Inhalation</b>	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a doctor/physician if you feel unwell.
<b>Skin Contact</b>	Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

**Eye Contact** Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/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** Mesalamine extended-release capsules are an aminosaliclylate, and symptoms of salicylate toxicity include hematemesis, tachypnea, hyperpnea, tinnitus, deafness, lethargy, seizures, confusion, or dyspnea. Severe intoxication may lead to electrolyte and blood pH imbalance and potentially to other organ (e.g., renal and liver) involvement. There is no specific antidote for mesalamine overdose; however, conventional therapy for salicylate toxicity may be beneficial in the event of acute overdose. This includes prevention of further gastrointestinal tract absorption by emesis and, if necessary, by gastric lavage. Fluid and electrolyte imbalance should be corrected by the administration of appropriate intravenous therapy. Adequate renal function should be maintained. Mesalamine extended-release capsules are a pH-dependent delayed-release product and this factor should be considered when treating a suspected overdose.

### **Section 5: Fire-Fighting Measures**

#### **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**

#### **Section 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.

### **Section 7: Handling and Storage**

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

## Section 8: Exposure Controls/Personal Protection

### 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

### Section 9, Physical and chemical properties

#### Physical Form

Mesalamine extended-release capsules are available as light blue opaque hard gelatin capsules containing 0.375 g mesalamine and with the letters "G" and "M" on either side of a black band imprinted on the capsule.

NDC 70748-214-16 Bottles of 120 capsules

## Section 10: Stability and Reactivity

### Section 10, Stability and reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

### Section 11, Toxicological information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Dietary mesalamine was not carcinogenic in rats at doses as high as 480 mg/kg/day, or in mice at 2000 mg/kg/day. These doses are about 2.6 and 5.4 times the recommended human dose of granulated mesalamine capsules of 1.5 g/day (30 mg/kg if 50 kg body weight assumed or 1110 mg/m<sup>2</sup>), respectively, based on body surface area. Mesalamine was negative in the Ames test, the mouse lymphoma cell (L5178Y/TK+/-) forward mutation test, the sister chromatid exchange assay in the Chinese hamster bone marrow test, and the mouse bone marrow micronucleus test. Mesalamine at oral doses up to 320 mg/kg (about 1.7 times the recommended human dose based on body surface area) was found to have no effect on fertility or reproductive performance in rats.

## Section 12: Ecological Information

### Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

### Section 13: Disposal Considerations

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

## Section 14: Transport Information

### 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

### Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

## Section 16: Other Information

### 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.

**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.