# LUPIN LIMITED
## SAFETY DATA SHEET

## Section 1: Identification

**Section 1, Identification**

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| **Material** | **Famotidine for Oral Suspension USP**<br>**40 mg/5 mL** |
| **Manufacturer** | **Lupin Limited**<br>Goa – 403 722<br>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

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

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| **Fire and Explosion** | Expected to be non-combustible. |
| **Health** | Famotidine for oral suspension is contraindicated in patients with a history of serious hypersensitivity reactions (e.g., anaphylaxis) to famotidine or other histamine-2 ($H_2$) receptor antagonists. |
| **Environment** | 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**

| **Ingredients** | **CAS** |
|---|---|
| Famotidine USP | 76824-35-6 |

## Section 4: First-Aid Measures

**Section 4, First-aid measures**

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| **Ingestion** | If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention. |
| **Inhalation** | Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance. |

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| **Skin Contact** | Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs. |
| **Eye Contact** | Flush eyes with plenty of water. Get medical attention. |

**NOTES TO HEALTH PROFESSIONALS**

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| **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** | The types of adverse reactions in overdosage of famotidine are similar to the adverse reactions encountered with use of recommended dosages.<br><br>In the event of overdosage, treatment should be symptomatic and supportive. Unabsorbed material should be removed from the gastrointestinal tract, the patient should be monitored, and supportive therapy should be employed.<br><br>Due to low binding to plasma proteins, famotidine is eliminated by hemodialysis. There is limited experience on the usefulness of hemodialysis as a treatment for famotidine overdosage. |

## Section 5: Fire-Fighting Measures

**Section 5, Fire-fighting measures**

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| **Fire and Explosion Hazards** | Assume that this product is capable of sustaining combustion, |
| **Extinguishing Media** | Water. Carbon dioxide ($CO_2$). Dry chemical powder. |
| **Special Firefighting Procedures** | Wear self-contained breathing apparatus and protective clothing. |
| **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**

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| **Personal Precautions** | Wear suitable protective clothing, gloves and eye/face protection. |
| **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**

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|---|---|
| **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 famotidine for oral suspension dry powder and constituted suspension at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Protect from freezing. Discard unused constituted suspension after 30 days.

Dispense in a USP tight, light-resistant container.

## 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**

Famotidine for Oral Suspension USP is a white to off-white granular powder forming an off-white suspension with characteristic odor on constitution, containing 40 mg of famotidine per 5 mL.

The suspension is a cherry-banana-mint flavored.

50 mL NDC # 68180-150-01 Bottle containing 400 mg famotidine.

Prior to dispensing, constitute famotidine for oral suspension.

## 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**

Carcinogenic potential of famotidine was assessed in a 106-week oral carcinogenicity study in rats and a 92-week oral carcinogenicity study in mice. In the 106-week study in rats and the 92-week study in mice at oral doses of up to 2000 mg/kg/day (approximately 243 and 122 times, respectively, based on body surface area, the recommended human dose of 80 mg per day for the treatment of erosive esophagitis), there was no evidence of carcinogenic potential for famotidine.

Famotidine was negative in the microbial mutagen test (Ames test) using *Salmonella typhimurium* and *Escherichia coli* with or without rat liver enzyme activation at concentrations up to 10,000 mcg/plate.

In *in vivo* studies in mice, with a micronucleus test and a chromosomal aberration test, no evidence of a mutagenic effect was observed.

In studies with rats given oral doses of up to 2000 mg/kg/day (approximately 243 times, based on body surface area, the recommended human dose of 80 mg per day) fertility and reproductive performance were not affected.

## 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**

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|---|---|---|
| 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**

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|---|---|---|
| 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.