LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Meloxicam Capsules** **5 mg and 10 mg**
Manufacturer	**Lupin Limited** Aurangabad – 431 210 India
Distributor	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

Fire and Explosion	Expected to be non-combustible.
Health	Meloxicam capsules are contraindicated in the following patients: • Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to meloxicam or any components of the drug product. • History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs. Severe, sometimes fatal, anaphylactic reactions to NSAIDs have been reported in such patients. • In the setting of coronary artery bypass graft (CABG) surgery.
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**
Meloxicam USP	71125-38-7

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Immediately give large quantities of water to drink. Never give anything by mouth to a victim who is unconscious or is having convulsions. Call a physician immediately.

Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
Skin Contact	Wash off immediately with plenty of water. Continue to rinse for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists.
Eye Contact	In case of eye contact, remove contact lens and rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. 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	Symptoms following acute NSAID overdosages have been typically limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which have been generally reversible with supportive care. Gastrointestinal bleeding has occurred. Hypertension, acute renal failure, respiratory depression, and coma have occurred, but were rare. There is limited experience with meloxicam overdose. In four reported cases of meloxicam overdose, patients took 6 to 11 times the highest available dose of meloxicam tablets (15 mg); all recovered. Cholestyramine is known to accelerate the clearance of meloxicam. Manage patients with symptomatic and supportive care following an NSAID overdosage. There are no specific antidotes. Consider emesis and/or activated charcoal (60 to 100 grams in adults, 1 to 2 grams per kg of body weight in pediatric patients) and/or osmotic cathartic in symptomatic patients seen within four hours of ingestion or in patients with a large overdosage (5 to 10 times the recommended dosage). Accelerated removal of meloxicam by 4 g oral doses of cholestyramine given three times a day was demonstrated in a previous clinical trial. Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding. For additional information about overdosage treatment contact a poison control center (1-800-222-1222).

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 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

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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 at 25 °C (77 °F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Store in the original container and keep the bottle tightly closed to protect from moisture. Dispense in a tight container if package is subdivided.

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

Meloxicam capsules are supplied as:

- 5 mg - yellow opaque cap and yellow opaque body (imprinted “M76” on the body and “LU” on the cap in black ink)

NDC (68180-188-06)	Bottles of 30 capsules
NDC (68180-188-09)	Bottles of 90 capsules
NDC (68180-188-02)	Bottles of 500 capsules

- 10 mg - green opaque cap and green opaque body (imprinted “M78” on the body and “LU” on the cap in black ink)

NDC (68180-189-06)	Bottles of 30 capsules
NDC (68180-189-09)	Bottles of 90 capsules
NDC (68180-189-02)	Bottles of 500 capsules

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

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

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no increase in tumor incidence in long-term carcinogenicity studies in rats (104 weeks) and mice (99 weeks) administered meloxicam at oral doses up to 0.8 mg/kg/day in rats and up to 8.0 mg/kg/day in mice (up to 0.8- and 3.9-times, respectively, the maximum recommended daily dose (MRDD) of 10 mg of meloxicam capsules based on body surface area (BSA) comparison).

Meloxicam was not mutagenic in an Ames assay, or clastogenic in a chromosome aberration assay with human lymphocytes and an in vivo micronucleus test in mouse bone marrow.

In previous studies of meloxicam, there was no impairment of male or female fertility in rats at oral doses up to 9 mg/kg/day in males and 5 mg/kg/day in females (up to 8.7 and 4.8-times, respectively, the MRDD based on BSA comparison).

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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

Section 14: Transport Information

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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.