

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

<b>Material</b>	<b>Celecoxib Capsules</b> 50 mg, 100 mg, 200 mg and 400 mg.
<b>Manufacturer</b>	<b>Lupin Limited</b> Goa - 403722 India
<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>	Celecoxib is contraindicated in the following patients: <ul style="list-style-type: none"><li>• Known hypersensitivity (e.g., anaphylactic reactions and serious skin reactions) to celecoxib, any components of the drug product.</li><li>• 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.</li><li>• In the setting of CABG surgery.</li><li>• In patients who have demonstrated allergic-type reactions to sulfonamides.</li></ul>
<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>
Celecoxib	169590-42-5

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

<b>Ingestion</b>	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.
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**Inhalation**

Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.

**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****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 overdoses 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.

No overdoses of celecoxib were reported during clinical trials. Doses up to 2400 mg/day for up to 10 days in 12 patients did not result in serious toxicity. No information is available regarding the removal of celecoxib by hemodialysis, but based on its high degree of plasma protein binding (>97%) dialysis is unlikely to be useful in overdose.

Manage patients with symptomatic and supportive care following an NSAID overdose. 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 overdose (5 to 10 times the recommended dosage). Forced diuresis, alkalinization of urine, hemodialysis, or hemoperfusion may not be useful due to high protein binding.

For additional information about overdose 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**

Extinguish fires with CO<sub>2</sub>, extinguishing powder, foam, or water.

**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**

Formation of toxic gases is possible during heating or fire.

## Section 6: Accidental Release Measures

### Section 6, Accidental release measures

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labeled container for recovery or disposal.

## Section 7: Handling and Storage

### Section 7, Handling and storage

<b>Handling</b>	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
<b>Storage</b>	Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 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

<b>Physical Form</b>	Celecoxib Capsules, 50 mg are available as size “3” capsules having red opaque cap, imprinted with ‘LU’ in black ink and white opaque body imprinted with ‘N41’ in black ink, containing white to off-white powder.				
	<table><tr><td><b><u>NDC Number</u></b></td><td><b><u>Size</u></b></td></tr><tr><td>NDC 68180-395-07</td><td>bottle of 60</td></tr></table>	<b><u>NDC Number</u></b>	<b><u>Size</u></b>	NDC 68180-395-07	bottle of 60
<b><u>NDC Number</u></b>	<b><u>Size</u></b>				
NDC 68180-395-07	bottle of 60				
	Celecoxib Capsules, 100 mg are available as size “3” capsules having blue opaque cap, imprinted with ‘LU’ in black ink and white opaque body imprinted with ‘N42’ in black ink, containing white to off-white powder.				

**NDC Number**

NDC 68180-396-01  
NDC 68180-396-02  
NDC 68180-396-03

**Size**

bottle of 100  
bottle of 500  
bottle of 1000

Celecoxib Capsules, 200 mg are size "0" capsules having gold opaque cap, imprinted with 'LU' in black ink and white opaque body imprinted with 'N43' in black ink, containing white to off-white powder.

**NDC Number**

NDC 68180-397-01  
NDC 68180-397-02  
NDC 68180-397-03

**Size**

bottle of 100  
bottle of 500  
bottle of 1000

Celecoxib Capsules, 400 mg are size "00EL" capsules having green opaque cap, imprinted with 'LU' in black ink and white opaque body imprinted with 'N44' in black ink, containing white to off-white powder.

**NDC Number**

NDC 68180-398-07  
NDC 68180-398-01

**Size**

bottle of 60  
bottle of 100

## 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

Celecoxib was not carcinogenic in Sprague-Dawley rats given oral doses up to 200 mg/kg for males and 10 mg/kg for females (approximately

2-to 4- times the human exposure as measured by the AUC<sub>0-24</sub> at 200 mg twice daily) or in mice given oral doses up to 25 mg/kg for males and 50 mg/kg for females (approximately equal to human exposure as measured by the AUC<sub>0-24</sub> at 200 mg twice daily) for two years.

Celecoxib was not mutagenic in an Ames test and a mutation assay in Chinese hamster ovary (CHO) cells, nor clastogenic in a chromosome aberration assay in CHO cells and an *in vivo* micronucleus test in rat bone marrow.

Celecoxib had no effect on male or female fertility or male reproductive function in rats at oral doses up to 600 mg/kg/day (approximately 11-times human exposure at 200 mg twice daily based on the AUC<sub>0-24</sub>). At ≥50 mg/kg/day (approximately 6-times human exposure based on the AUC<sub>0-24</sub> at 200 mg twice daily) there was increased preimplantation loss.

## Section 12: Ecological Information

### Section 12: Ecological Information

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

### 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.