LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material

Celecoxib Capsules
50 mg, 100 mg, 200 mg and 400 mg.

Manufacturer

Lupin Limited
Goa - 403722
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

Celecoxib is contraindicated:

- In patients with known hypersensitivity to celecoxib, aspirin, or other NSAIDs.
- In patients who have demonstrated allergic-type reactions to sulfonamides.
- In patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs. Severe anaphylactoid reactions to NSAIDs, some of them fatal, have been reported in such patients.
- For the treatment of peri-operative pain 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
---|---
Celecoxib | 169590-42-5

Section 4: First-Aid Measures

Section 4, First-aid measures

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.

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
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. Symptoms following acute NSAID overdoses are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. Gastrointestinal bleeding can occur. Hypertension, acute renal failure, respiratory depression and coma may occur, but are rare. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

Patients should be managed by symptomatic and supportive care following an NSAID overdose. There are no specific antidotes. 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. Emesis and/or activated charcoal (60 to 100 g in adults, 1 to 2 g/kg in children) and/or osmotic cathartic may be indicated in patients seen within 4 hours of ingestion with symptoms or following a large 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.
- **Storage**: 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

Physical Form

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.

They are supplied as follows:

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Size</th>
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<tbody>
<tr>
<td>NDC 68180-395-07</td>
<td>bottle of 60</td>
</tr>
</tbody>
</table>

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.

They are supplied as follows:

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<thead>
<tr>
<th>NDC Number</th>
<th>Size</th>
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<td>bottle of 500</td>
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<tr>
<td>NDC 68180-396-03</td>
<td>bottle of 1000</td>
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</table>

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.

They are supplied as follows:

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<td>bottle of 1000</td>
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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.

They are supplied as follows:

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<td>NDC 68180-398-01</td>
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Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.
### Section 11: Toxicological Information

#### Carcinogenesis, Mutagenesis, Impairment of Fertility

Celecoxib was not carcinogenic in rats given oral doses up to 200 mg/kg for males and 10 mg/kg for females (approximately 2-to 4 fold the human exposure as measured by the AUC$_{0-24}$ 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$_{0-24}$ 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 did not impair male and female fertility in rats at oral doses up to 600 mg/kg/day (approximately 11-fold human exposure at 200 mg twice daily based on the AUC$_{0-24}$).

### 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**

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**IMDG - Not Regulated**

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**Section 15: Regulatory Information**

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

**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 MSDS.