

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

#### Section 1, Identification

|                     |  |
|---------------------|--|
| <b>Material</b>     | <b>Clobazam Tablets</b> <br><b>10mg and 20mg</b>  |
| <b>Manufacturer</b> | <b>Lupin Limited</b><br>Nagpur 441 108<br>India  |
| <b>Distributor</b>  | 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

|                           |   |
|---------------------------|---|
| <b>Fire and Explosion</b> | Expected to be non-combustible.   |
| <b>Health</b>             | Clobazam is contraindicated in patients with a history of hypersensitivity to the drug or its ingredients. Hypersensitivity reactions have included serious dermatological reactions. |
| <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> |
|--------------------|------------|
| Clobazam           | 22316-47-8 |

### Section 4: First-Aid Measures

#### Section 4, First-aid measures

|                   |   |
|-------------------|---|
| <b>Ingestion</b>  | Flush out mouth with water, consult a physician immediately.    |
| <b>Inhalation</b> | In case of inhalation remove to fresh air and seek medical aid. |

**Skin Contact**

Remove immediately contaminated clothes, wash affected skin with plenty of water.

**Eye Contact**

In case of contact with eyes rinse thoroughly with plenty of water and get medical advice.

**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****Signs and Symptoms of Overdosage**

Overdose and intoxication with benzodiazepines, including clobazam, may lead to CNS depression, associated with drowsiness, confusion and lethargy, possibly progressing to ataxia, respiratory depression, hypotension, and, rarely, coma or death. The risk of a fatal outcome is increased in cases of combined poisoning with other CNS depressants, including alcohol.

**Management of Overdosage**

The management of clobazam overdose may include gastric lavage and/or administration of activated charcoal, intravenous fluid replenishment, early control of airway and general supportive measures, in addition to monitoring level of consciousness and vital signs. Hypotension can be treated by replenishment with plasma substitutes and, if necessary, with sympathomimetic agents.

The efficacy of supplementary administration of physostigmine (a cholinergic agent) or of flumazenil (a benzodiazepine antagonist) in clobazam overdose has not been assessed. The administration of flumazenil in cases of benzodiazepine overdose can lead to withdrawal and adverse reactions. Its use in patients with epilepsy is typically not recommended.

## 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**

Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.

**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

|                                  |   |
|----------------------------------|---|
| <b>Personal Precautions</b>      | Avoid excessive contact and contact with eyes. Wear safety goggles or shield.                                     |
| <b>Environmental Precautions</b> | For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.          |
| <b>Clean-up Methods</b>          | This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids. |

## Section 7: Handling and Storage

### Section 7, Handling and storage

|                 |   |
|-----------------|---|
| <b>Handling</b> | No special control measures required for the normal handling of this product.       |
| <b>Storage</b>  | Store tablets at 20°C to 25°C (68°F to 77°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> | <p>Clobazam Tablets, 10 mg: White to off-white, oval tablets with functional score on one side with 'L' and '7' debossed either side of scoreline and plain on other side<br/>NDC 68180-157-06: 10 mg scored tablet, Bottles of 30,<br/>NDC 68180-157-07: 10 mg scored tablet, Bottles of 60,<br/>NDC 68180-157-09: 10 mg scored tablet, Bottles of 90,<br/>NDC 68180-157-01: 10 mg scored tablet, Bottles of 100 and<br/>NDC 68180-157-02: 10 mg scored tablet, Bottles of 500</p> <p>Clobazam Tablets, 20 mg: White to off-white, oval tablets with functional score on one side with 'L' and '8' debossed either side of scoreline and plain on other side<br/>NDC 68180-158-06: 20 mg scored tablet, Bottles of 30,<br/>NDC 68180-158-07: 20 mg scored tablet, Bottles of 60,<br/>NDC 68180-158-09: 20 mg scored tablet, Bottles of 90,<br/>NDC 68180-158-01: 20 mg scored tablet, Bottles of 100 and<br/>NDC 68180-158-02: 20 mg scored tablet, Bottles of 500</p> |
|----------------------|---|

## 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

The carcinogenic potential of clobazam has not been adequately assessed.

In a limited study in rats, oral administration of clobazam (4, 20, and 100 mg/kg/day) for 2 years resulted in an increased incidence of thyroid follicular cell adenomas in males at the high dose.

Clobazam and the major active metabolite, N-desmethyloclobazam, were negative for genotoxicity, based on data from a battery of *in vitro* (bacteria reverse mutation, mammalian clastogenicity) and *in vivo* (mouse micronucleus) assays.

In a study in which clobazam (50, 350, or 750 mg/kg/day) was orally administered to male and female rats prior to and during mating and continuing in females to gestation day 6, increases in abnormal sperm and pre-implantation loss were observed at the highest dose tested. The no effect level for fertility and early embryonic development in rats was associated with plasma exposures (AUC) for clobazam and its major active metabolite, N-desmethyloclobazam, less than those in humans at the maximum recommended human dose of 40 mg/day.

## 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.