

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

|                         |   |
|-------------------------|---|
| <b>Product Name</b>     | <b>Dapagliflozin Tablets</b>  |
| <b>Manufacturer</b>     | <b>Lupin Limited</b><br>MADE IN INDIA   |
| <b>Manufactured for</b> | <b>Lupin Pharmaceuticals, Inc.</b><br>Naples, FL 34108<br>United States<br>Tel. 001-410-576-2000<br>Fax. 001-410-576-2221 |

### Section 2: Hazard(s) Identification

|                             |  |
|-----------------------------|--|
| <b>Fire &amp; Explosion</b> | Expected to be non-combustible.  |
| <b>Health</b>               | Please read the product information leaflet before use.<br>May cause respiratory irritation.<br>History of serious hypersensitivity reaction to dapagliflozin or any of the excipients in dapagliflozin tablets. |

### Section 3: Composition/Information on Ingredients

| <b>Ingredients</b>                       | <b>CAS</b>  |
|--|-------------|
| Dapagliflozin                            | 461432-26-8 |
| Lactose anhydrous Ph. Eur.               | 63-42-3     |
| Silicified Microcrystalline Cellulose IH | 9004-34-6   |
| Crospovidone Ph. Eur                     | 9003-39-8   |
| Povidone Ph. Eur                         | 9003-39-8   |
| Purified Water                           | 7732-18-5   |
| Colloidal Silicon Dioxide                | 7631-86-9   |
| Magnesium Stearate                       | 557-04-0    |

\* The exact percentage composition of this mixture has been withheld as a trade secret.

## Section 4: First-Aid Measures

|                     |  |
|---------------------|--|
| <b>Ingestion</b>    | If swallowed, do not induce vomiting. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness. Seek medical advice. |
| <b>Inhalation</b>   | Move the individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.                          |
| <b>Skin Contact</b> | Wash all exposed areas of skin with plenty of soap and water. Seek medical advice.   |
| <b>Eye Contact</b>  | Flush eyes with plenty of water. Get medical attention.  |

## Section 5: Fire-Fighting Measures

|  |   |
|--|---|
| <b>Extinguishing Media</b>             | Use extinguishing media suitable for the surrounding area.                                      |
| <b>Special Firefighting Procedures</b> | Wear breathing apparatus plus protective gloves in the event of a fire.                         |
| <b>Hazardous Combustion Products</b>   | Hazardous combustion or decomposition products are expected when the product is exposed to fire |

## Section 6: Accidental Release Measures

|   |  |
|---|--|
| <b>Personal Precautions</b>                                 | Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.  |
| <b>Environmental Precautions</b><br><b>Clean-up Methods</b> | Should not be released into the environment.<br>Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal. |

## Section 7: Handling and Storage

|                 |   |
|-----------------|---|
| <b>Handling</b> | Store in original containers. Keep containers securely sealed. Store in a cool, dry area protected from environmental extremes. Store away from incompatible materials and food containers. |
| <b>Storage</b>  | Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).  |

## Section 8: Exposure Controls/Personal Protection

|   |   |
|---|---|
| <b>Personal protection</b>              | Avoid all unnecessary exposure.<br>Wear appropriate clothing to avoid skin contact. Wash your hands and arms thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice |
| <b>Appropriate engineering controls</b> | Work must be done with effective mechanical ventilation   |

## Section 9: Physical and Chemical Properties

### HOW SUPPLIED

Dapagliflozin tablets have markings on one side and are available in the strengths and packages listed in Table

| Tablet Strength | Film-Coated Tablet Color/Shape   | Tablet Markings                                    | Package Size  | NDC Code     |
|-----------------|----------------------------------|--|---------------|--------------|
| 5 mg            | yellow, biconvex, round          | "L40" engraved on one side and plain on other side | Bottles of 30 | 70748-105-06 |
| 10 mg           | yellow, biconvex, diamond-shaped | "L41" engraved on one side and plain on other side | Bottles of 30 | 70748-106-06 |

## Section 10: Stability and Reactivity

Stable under recommended storage conditions

### Storage and Handling

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

## Section 11: Toxicological Information

|                                  |    |
|----------------------------------|----|
| <b>Carcinogenic categories</b>   | NO |
| <b>Mutagenicity</b>              | NO |
| <b>Reproductivity:</b>           | NO |
| <b>Acute Toxicity</b>            | NO |
| <b>Skin Irritation/Corrosion</b> | NO |

## Section 12: Ecological Information

No relevant studies identified.

## Section 13: Disposal Considerations

Follow all federal, state, and local environmental regulations.

## 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

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.