

# LUPIN LIMITED

## SAFETY DATA SHEET

### Section 1: Identification

<b>Product Name</b>	<b>Dapagliflozin and Metformin HCL ER Tablets</b>
<b>Manufacturer</b>	<b>Lupin Limited</b> Nagpur 441 108 India
<b>Manufactured for</b>	<b>Lupin Pharmaceuticals, Inc.</b> Naples, FL 34108 United States Tel. 001-410-576-2000 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. May cause respiratory irritation. 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
Iso Propyl Alcohol	67-63-0
Lactose Monohydrate NF	63-42-3
Microcrystalline Cellulose NF	9004-34-6
Crospovidone NF	25249-54-1
Povidone USP	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 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
<b>Inhalation</b>	Move 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. Obtain medical attention if skin reaction occurs.
<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>	Should not be released into the environment.
<b>Clean-up Methods</b>	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

### Section 7: Handling and Storage

<b>Handling</b>	No special control measures are required for the normal handling of this product. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure. Keep away from sources of ignition.
<b>Storage</b>	Store at 20° to 25°C (68° to 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. 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 and metformin hydrochloride extended-release tablets have markings on one side, are plain on the reverse side.

Tablet Strength	Film-Coated Tablet Color/Shape	Tablet Markings	Package Size	NDC Code
5mg/500mg	Light orange to orange, biconvex, capsule shaped	"L108" debossed on one side and plain on other side	Bottle of 30	70748-101-06
			Bottle of 500	70748-101-02
5mg/1000mg	Purple to light purple, biconvex, oval shaped	"L109" debossed on one side and plain on other side	Bottle of 30	70748-102-06
			Bottle of 60	70748-102-07
			Bottle of 90	70748-102-09
			Bottle of 400	70748-102-18
10mg/500mg	Pink to light pink, biconvex, capsule shaped	"L110" debossed on one side and plain on other side	Bottle of 30	70748-103-06
			Bottle of 500	70748-103-02
10mg/1000mg	Yellow to dark yellow, biconvex, oval shaped	"L111" debossed on one side and plain on other side	Bottle of 30	70748-104-06
			Bottle of 400	70748-104-18

## Section 10: Stability and Reactivity

Stable under recommended storage conditions.

## Section 11: Toxicological Information

<b>Carcinogenic categories</b>	NO
<b>Mutagenicity</b>	NO
<b>Reproductivity:</b>	NO
<b>Respiratory or Skin Sensitization</b>	NO
	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.