

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Glucagon Injection
Manufacturer	Lupin Limited Nagpur - 441108 Maharashtra, India
Manufactured for	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States.
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible.
Health	Information on the absorption of this product via inhalation or skin contact is not available. Please refer to the product information insert.
Environment	No information is available about the potential of this product to produce adverse environmental effects. Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Name	CAS No.
Glucagon USP	16941-32-5
Lactose Monohydrate NF	10039-26-6
Hydrochloric Acid NF	7647-01-0
Water For Injection USP	7732-18-5
Nitrogen Gas NF	7727-37-9

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

Section 4: First-Aid Measures

General advice	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.
Eye contact	Immediately flush eye(s) with plenty of water. Get medical attention.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Immediately take off all contaminated clothing. Get medical attention if irritation develops and persists. Wash contaminated clothing before reuse.
Inhalation	Remove to fresh air. If breathing stops, provide artificial respiration. Get medical attention immediately.
Ingestion	Consult a physician.

Section 5: Fire-Fighting Measures

Flammability	Details not available.
Fire and Explosion Hazard	Hazardous decomposition products formed under fire conditions.
Extinguishing Media	Carbon dioxide, dry chemicals, or water.
Special Fire fighting procedure	No special provisions are required beyond normal firefighting equipment such as flame and chemical-resistant clothing and self-contained breathing apparatus.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipments.	Wear suitable protective clothing, gloves and eye/face protection. See Section 8 of the SDS for Personal Protective Equipment.
Environmental Precautions	Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Precautions for safe handling:	Keep the container tightly closed in a dry and well-ventilated place. Do not use glucagon for injection if the expiration date has passed. Do not freeze. Keep it in its original package and away from light.
Storage :	Store glucagon for injection at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature].
Special Precautions :	No special precautions are required for Hazard control.

Section 8: Exposure Controls/Personal Protection

Respiratory Protection	Use an approved respirator. Select the appropriate respirator for the physical characteristics of the material. Select a respirator with an appropriate protection factor. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product, and the safe working limits of the respirator.
Skin Protection	Chemical-resistant gloves and impermeable body covering to minimize skin contact.
Eye Protection	Wear goggles/face shield.
Engineering Controls	Engineering controls are normally not needed during the normal use of this product.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Glucagon Injection

Glucagon Emergency Kit for Low Blood Sugar contains 1 mg of Glucagon for Injection, USP (a white lyophilized cake or powder) in a single-dose vial, and 1 prefilled syringe containing 1 mL of diluent of Glucagon.

• NDC 70748-311-01

Appearance / Physical State	: Solid
Form	: Lyophilized Cake
Color	: White, Odorless
Odor	: Not Available
Odor Threshold	: Not Available
pH	: Not Available
Melting Point / Freezing Point	: Not Available
Initial Boiling Point / Boiling Point	: Not Available
Evaporation Rate	: Not Available
Flammability (Solid ,Gas)	: Not Available
Upper/Lower Flammability	: Not Available
Explosive Limit	: Not Available
Vapor Pressure	: Not Available
Vapor Density	: Not Available
Specific Gravity	: Not Available
Solubility	: Soluble in water.
Partition coefficient	: n-octanol / water : Not Available
Auto Ignition Temperature	: Not Available
Decomposition Temperature	: Not Available

Section 10: Stability and Reactivity

Reactivity	Not water reactive.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur
Condition to avoid	None known.
Incompatible Material	Strong oxidizing substances.
Hazardous decomposition products :	Hazardous decomposition products formed under fire conditions.

Section 11: Toxicological Information

Acute Toxicity	: Not expected to be active orally
Aspiration Hazard	: Not Applicable.
Skin Corrosion/Skin Irritation	: None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	: None anticipated from normal handling of this product.
Respiratory/ Skin Sensitization	: None anticipated from normal handling of this product. In clinical use, patients allergic to sulfonamides may show hypersensitivity to bumetanide.
Mutagenicity	: Negative in vitro genetic toxicity assays.
Carcinogenicity	: No carcinogenicity data is available for this product.
Specific Target Organ Toxicity	: No data available.
Reproductive Toxicity	: Based on available data, the classification criteria are not met.

Section 12: Ecological Information

Acute Toxicity	: No data is available
Persistence and biodegradability	: No data is available
Bioaccumulation	: No data is available.
Mobility in Soil	: Not determined for product

Section 13: Disposal Considerations

Waste Disposal	: Dispose of contents/ waste in accordance with local regulations.
Container Handling and Disposal:	Dispose of container and unused contents in accordance with federal, state and local 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 SDS.