

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Prucalopride Tablets 1 mg and 2 mg
Use of the Substance/mixture	Pharmaceuticals
Manufacturer	Lupin Limited Verna, (Goa) - 403722 Goa, India
Manufactured for	Lupin Pharmaceuticals, Inc. Naples, FL 34108 United States.

Section 2: Hazard(s) Identification

Health	May Cause hypersensitivity. Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Environment	No information available.

Section 3: Composition/Information on Ingredients

Name	CAS No.
Prucalopride Succinate	179474-85-2
Lactose monohydrate NF	63-42-3
Magnesium Stearate NF	557-04-0
Silicified microcrystalline cellulose NF	-
Opadry II Yellow 32K520105	-
Opadry II White 32K180001	-

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

Section 4: First-Aid Measures

Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
Skin Contact	In case of contact, remove contaminated clothing. Immediately flush the skin with copious amounts of water for at least 15 minutes. Use Soap. Obtain medical attention if a skin reaction occurs.
Inhalation	Move the individual to fresh air. If irritation or discomfort persists, seek medical attention. If not breathing, provide artificial respiration assistance.
Ingestion	In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately.

Section 5: Fire-Fighting Measures

Flammability	No unusual fire or explosion hazards were noted.
Hazardous Combustion Products	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, other pyrolysis products typical of burning organic material.
Extinguishing Media	Use carbon dioxide, dry chemical powder, or water spray.
Fire Fighting Procedure	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazard	Assume that this product is capable of sustaining combustion. Fine particles (such as dust and mists) may fuel fires/explosions.

Section 6: Accidental Release Measures

Health and Safety Precautions	Wear protective clothing and equipment consistent with the degree of hazard. Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Precautions for safe handling:	Normal room ventilation is expected to be adequate for routine handling of this product. Keep Prucalopride tablets and all medicines out of reach of children.
Storage :	Store at 20° to 25°C (68° to 77°F) in properly labeled containers. Store prucalopride tablets in the original container to protect from moisture.

Section 8: Exposure Controls/Personal Protection

Protective Measures	Handle in accordance with good industrial hygiene and safety practice.
Respiratory Protection	Choose respiratory protection appropriate to the task.
Skin Protection	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.
Eye Protection	Wear safety glasses or goggles if eye contact is possible.
Engineering Controls	Normal room ventilation is expected to be adequate for routine handling of this product.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Prucalopride Tablets

Prucalopride tablets containing 1 mg prucalopride are yellow colored, round shaped, film coated tablets, debossed with "J" on one side and "7" on the other side.

Prucalopride tablets containing 2 mg prucalopride are white colored, round shaped, film coated tablets, debossed with "J" on one side and "6" on the other side.

Tablet Strength	Package Configuration	NDC Code
1 mg	Bottles of 30	70748-389-01
2 mg	Bottles of 30	70748-390-01

Section 10: Stability and Reactivity

Stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Incompatible Material	As a precautionary measure, keep away from strong oxidizers.

Section 11: Toxicological Information

Acute Toxicity	: Knowledge about health hazard is incomplete.
Skin Corrosion/Skin Irritation	: Knowledge about health hazard is incomplete.
Respiratory/ Skin Sensitization	: Knowledge about health hazard is incomplete.
Mutagenicity	: Knowledge about mutagenicity is incomplete
Carcinogenicity	: Knowledge about carcinogenicity is incomplete.
Specific Target Organ Toxicity	: No data available.
Reproductive Toxicity	: No data available.

Section 12: Ecological Information

Environmental Overview	: Avoid release into the environment. The environmental characteristics of this product have not been fully evaluated.
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Section 13: Disposal Considerations

Waste Disposal	: Dispose of contents/ waste in accordance with local regulations.
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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 contact with the above product. Lupin reserves the right to revise this SDS.