

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material Rivaroxaban
Identified uses of the substance or mixture Pharmaceutical
Manufacturer Made in India
Distributor Lupin Pharmaceuticals, Inc.
Naples FL, 34108
United States.

Section 2: Hazard(s) Identification

Health May cause damage to organs through prolonged or repeated exposure. 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 Data is available.

Precautionary statements Get medical advice/ attention if you feel unwell.

Section 3: Composition/Information on Ingredients

Ingredients	CAS No.	Ingredients	CAS No.
Rivaroxaban USP	366789-02-8	Croscarmellose Sodium NF	9004-32-4
Sodium Lauryl Sulphate NF	151-21-3	Purified Water IP/ BP/USP/LD	7732-18-5
Lactose Monohydrate NF	63-42-3	Magnesium Stearate NF	557-04-0
Hypromellose USP	9004-65-3	Opadry Yellow 03B22082 IH	117698-04-1
Microcrystalline Cellulose NF	9004-34-6	-	-

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

Section 4: First-Aid Measures

General advice Immediate medical attention is required.

Protection of first aiders First Aid responders should pay attention to self-protection and use the recommended personal protective equipment when the potential for exposure exists.

Inhaled After inhalation: fresh air. Consult a doctor if the person is feeling unwell.

Skin contact	In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower. Consult a physician.
Eye contact	After eye contact: rinse out with plenty of water. Remove contact lenses.
If swallowed	After swallowing: immediately make victim drink water (two glasses at most). Consult a physician. Please refer to the product information insert.

Section 5: Fire-Fighting Measures

Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special Firefighting Procedures	In the event of fire, wear a self-contained breathing apparatus.
Hazardous Combustion Products	No information is available.

Section 6: Accidental Release Measures

Personal Precautions	In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate. Evacuate personnel to safe areas. It should not be released into the environment.
Environmental Precautions	
Clean-up Methods	Sweep up into a suitable labeled container for disposal.

Section 7: Handling and Storage

Handling	Keep out of the reach of children. Keep away from heat and sources of ignition.
Storage	Avoid inhalation, ingestion, contact with skin and eyes. Store at 25°C (77°F) or room temperature; excursions permitted to 15°C to 30°C (59°F to 86°F).

Section 8: Exposure Controls/Personal Protection

Engineering Measures/Controls:	All personal protective equipment should be based on a risk assessment. Consult an environmental health Safety expert if necessary. If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Personal Protective Equipment:	Respiratory: Respiratory protection is generally not needed during routine conditions. Eye/Face: When handling very small quantities of the material eye protection may not be required. Skin/Body: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product.

Section 9: Physical and Chemical Properties

HOW SUPPLIED

Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg and 20 mg are available in the strengths and packages listed below:

2.5 mg tablets: Light yellow colored, round shaped, biconvex, film-coated tablets, debossed with "C4" on one side and "L" on the other side. The tablets are supplied in the packages listed:

NDC 68180-709-06 Bottle containing 30 tablets.

NDC 68180-709-09 Bottle containing 90 tablets.

10 mg tablets: Light pink colored, round shaped, biconvex, film-coated tablets, debossed with "LU" on one side and "R76" on the other side. The tablets are supplied in the packages listed:

NDC 68180-680-06 Bottle containing 30 tablets.

NDC 68180-680-09 Bottle containing 90 tablets.

15 mg tablets: Reddish brown colored, round shaped, biconvex, film-coated tablets, debossed with "LU" on one side and "R77" on the other side. The tablets are supplied in the packages listed:

NDC 68180-681-06 Bottle containing 30 tablets.

NDC 68180-681-09 Bottle containing 90 tablets.

20 mg tablets: White colored, round shaped, biconvex, film-coated tablets, debossed with "LU" on one side and "R78" on the other side. The tablets are supplied in the packages listed:

NDC 68180-682-06 Bottle containing 30 tablets.

NDC 68180-682-09 Bottle containing 90 tablets.

Odor	No information available
pH	No information available
Melting point/freezing point	230 °C
Initial boiling point and boiling range	No information available
Flash points	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability (liquids)	No information available
Upper explosion limit / Upper flammability limit	No information available
Lower explosion limit / Lower flammability limit	No information available
Vapor pressure	No information available
Relative vapor density	No information available
Relative density	No information available
Solubility & Water solubility	No information available
Partition coefficient	No information available
Auto-ignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Explosive properties	No information available

Section 10: Stability and Reactivity

Stability	The product is chemically stable under standard ambient conditions (room temperature).
Reactivity	None reasonably foreseeable.
Hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	To avoid thermal decomposition, do not overheat. Heat, flames, and sparks.
Hazardous decomposition products	None.

Section 11: Toxicological Information

Acute toxicity	
Acute oral toxicity	LD0 (Rat): > 500 mg/kg
Acute inhalation toxicity	No data available
Acute inhalation toxicity	No data available
Inhalation	No data available
Skin Contact	No data available
Ingestion	No data available
Eye Contact	No data available
Carcinogenicity	No data available
Reproduction toxicity	No data available.

Section 12: Ecological Information

Ecotoxicity	None Identified
Hazardous reactions	Product is considered stable.
Conditions to avoid	To avoid thermal decomposition, do not overheat, flames and sparks.
Hazardous decomposition products	None Known.

Section 13: Disposal Considerations

Dispose of contents/containers in accordance with 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.