

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	Mirabegron Extended-Release Tablets
Manufacturer	Lupin Limited Nagpur - 441108 Maharashtra, India Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221
Use of the Substance/mixture	Pharmaceuticals

Section 2: Hazard(s) Identification

Fire and Explosion	Expected to be non-combustible
Health	May cause an allergic skin reaction Suspected of damaging the unborn child.
Environment	Avoid release to the environment.

Section 3: Composition/Information on Ingredients

Name	CAS No.
Mirabegron IH	223673-61-8
Microcrystalline Cellulose	9004-34-6
Polyethylene Oxide NF	25322-68-3
Hydroxy propyl cellulose	9004-64-2
Polyethylene Glycol	25322-68-3

* 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	Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay.
Skin Contact	Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Inhalation	Remove to fresh air and keep at rest in a position comfortable for breathing. Obtain medical attention if breathing difficulty persists.
Note to physicians	Treat symptomatically.

Section 5: Fire-Fighting Measures

Suitable extinguishing media	Water spray, fog, CO2, dry chemical, or alcohol resistant foam
Advise for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Hazardous combustion products	Emits toxic fumes under fire conditions.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures	<p>Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.</p> <p>Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust.</p>
Environmental precautions	Environmental hazard - contain spillage. Do not release into the environment
Methods and material for containment and cleaning up	Small Liquid Spills: Absorb up with sand or other non-combustible absorbent material. Large quantities should not be discharged into the drain but removed with absorbing material. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.
Disposal Methods	Dispose of in accordance with local, state, and national regulations.

Section 7: Handling and Storage

Precautions for safe handling	<p>Avoid all personal contact, including inhalation.</p> <p>Wear protective clothing when risk of exposure occurs.</p> <p>Use in a well-ventilated area, Establish good housekeeping practices.</p> <p>Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.</p>
Advice on safe handling	Handle in accordance with good industrial hygiene and safety practices.
Conditions for safe storage, including any incompatibilities	
Storage conditions	<p>Store in original containers. Store in a dry, cool and well-ventilated place. Keep container closed when not in use. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.</p> <p>Keep containers securely sealed. Avoid reaction with oxidizing agents.</p> <p>Store at 25°C (77°F) with excursions permitted from 15° to 30°C (59° to 86°F). [see USP Controlled Room Temperature].</p>

Section 8: Exposure Controls/Personal Protection

Personal protection	Use appropriate personal protective equipment for protection.
Appropriate engineering controls	Engineering controls should be used as the primary means to control exposures. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure all national/local regulations are observed.
Individual protection measures, such as personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Wear chemically resistant protective gloves.
Eyes	Wear safety glasses or goggles if eye contact is possible. Chemical goggles and Face shield.
Skin	Wear suitable protective clothing. wear disposable coverall of low permeability and disposable shoe covers.
Respiratory protection	None required under normal product handling conditions. Use NIOSH-approved dust mask if dust has the potential to become airborne.

Section 9: Physical and Chemical Properties

Appearance Tablet

HOW SUPPLIED

Mirabegron extended-release tablets are supplied as oval, film-coated, extended-release tablets, available in bottles as follows:

Strength	25 mg	50 mg
Color	White	Pale-yellow
Debossed	M25, LU	M50, LU
Bottle of 30	NDC 68180-151-06	NDC 68180-152-06
Bottle of 90	NDC 68180-151-09	NDC 68180-152-09

Odour	Not available
pH	No data available
Odour threshold	Not available
Melting point/Freezing Point	144°C (291.2 °F)
Boiling point	No data available
Flash point	Not available
Evaporation rate	Not available
Flammability (solid, gas)	Not available
Flammability Limit in Air	Not available
Explosive properties	Not available
Explosive properties	Not available
Oxidising properties	Not available
Vapour pressure	No data available

Vapour density	Not available
Specific Gravity	Not available
Water solubility	Partly Miscible
Solubility in other solvent	Freely soluble in DMSO, soluble in methanol, sparingly soluble in ethanol
Partition coefficient	Not available
Auto-ignition temperature	Not available
Decomposition temperature	Not available
Upper flammability limit	Not available
Lower flammability limit	Not available

Section 10: Stability and Reactivity

Reactivity	Hazardous reactions will not occur under normal conditions.
Chemical stability	Stable under recommended handling and storage conditions
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Condition to avoid	Direct sunlight. Extremely high or low temperatures. Ignition sources. Incompatible materials
Incompatible Material	Strong oxidizers
Hazardous decomposition products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

Section 11: Toxicological Information

Acute toxicity :	Not classified
Skin Corrosion/Irritation:	Not classified
Serious Eye Damage/Irritation:	Not classified
Respiratory or Skin Sensitization:	May cause an allergic skin reaction.
Carcinogenicity:	Not classified
Reproductive Toxicity:	Suspected of damaging the unborn child.

Section 12: Ecological Information

General information	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Keep out of sewers and waterways.
Other Information	Avoid release to the environment.

Section 13: Disposal Considerations

Disposal of wastes: Disposal should be in accordance with applicable regional, national and local laws and regulations.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

Hierarchy of Controls seems to be common - the user should investigate:

Reduction

Reuse

Recycling

Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.

DO NOT allow wash water from cleaning or process equipment to enter drains.

Waste Materials: Avoid release to the environment.

Section 14: Transport Information

DOT:

Not regulated.

IMDG: -

International Maritime Dangerous Goods Code Not regulated.

IATA: -

International Air Transport Association Not regulated.

Section 15: Regulatory Information

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Section 16: Other Information

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.