LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Material	**Varenicline Tartrate Tablets**
Manufacturer	**Lupin Limited** Pithampur (M.P.) – 454 775 INDIA.
Distributor	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	Varenicline tablets is contraindicated in patients with a known history of serious hypersensitivity reactions or skin reactions to varenicline tablets.
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

Composition/information on ingredient:

Ingredients	CAS No.	Ingredients	CAS No.
Varenicline Tartrate Premix IH	375815-87-5	Opadry White 00A580043 IH	889676-18-0
Anhydrous Dibasic Calcium Phosphate USP	7757-93-9	Isopropyl Alcohol USP	67-63-0
Croscarmellose sodium NF	74811-65-7	Methylene Chloride NF	75-09-2
Magnesium Stearate NF	557-04-0	-	-

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

Section 4: First-Aid Measures

Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Skin Contact	Remove contaminated clothing. Flush exposed area with large amounts of water. Use soap. Seek Medical attention.
Eye Contact	Flush eyes with plenty of water. Get medical attention immediately.
NOTES TO HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patients vital signs, blood gases, serum electrolytes etc.

Section 5: Fire-Fighting Measures

Fire and Explosion Hazards	No data available.
Extinguishing Media	Extinguish fires with Carbon dioxide, dry chemical powder, foam, or water.
Special Firefighting Procedures	Self-contained breathing apparatus and full protective equipment are recommended for firefighters.
Hazardous Combustion Products	Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard. Minimize exposure.
Environmental Precautions	Place waste in appropriately labelled for large spills, take precautions to avoid environmental release.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal. Clean up area thoroughly.

Section 7: Handling and Storage

Handling	Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment. Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage	Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Keep this and all medications out of reach of children.

Section 8: Exposure Controls/Personal Protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Physical State	Film-coated tablets
Odor	No data available
Molecular Formula	Mixture
Solvent Solubility	No data available
Water Solubility	No data available
pH	No data available
Melting/Freezing Point (°C)	No data available
Boiling Point (°C)	No data available
Decomposition Temperature (°C)	No data available
Evaporation Rate (Gram/s)	No data available
Vapor Pressure (kPa)	No data available
Vapor Density (g/ml)	No data available
Relative Density	No data available
Viscosity	No data available
Flammability:	
Autoignition Temperature (Solid) (°C)	No data available
Flammability (Solids)	No data available
Flash Point (Liquid) (°C)	No data available
Upper Explosive Limits (Liquid) (% by Vol.)	No data available
Lower Explosive Limits (Liquid) (% by Vol.)	No data available

Section 10: Stability and Reactivity

The product is stable and non-reactive under normal condition of use, storage and transport.

Section 11: Toxicological Information

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Lifetime carcinogenicity studies were performed in CD-1 mice and Sprague-Dawley rats. There was no evidence of a carcinogenic effect in mice administered varenicline by oral gavage for 2 years at doses up to
20 mg/kg/day (47 times the maximum recommended human daily (MRHD) exposure based on AUC). Rats were administered varenicline
(1, 5, and 15 mg/kg/day) by oral gavage for 2 years. In male rats (n = 65 per sex per dose group), incidences of hibernoma (tumor of the brown fat) were increased at the mid dose (1 tumor, 5 mg/kg/day, 23 times the MRHD exposure based on AUC) and maximum dose (2 tumors, 15 mg/kg/day,
67 times the MRHD exposure based on AUC). The clinical relevance of this finding to humans has not been established. There was no evidence of carcinogenicity in female rats.

Varenicline was not genotoxic, with or without metabolic activation, in the following assays: Ames bacterial mutation assay; mammalian CHO/HGPRT assay; and tests for cytogenetic aberrations in vivo in rat bone marrow and in vitro in human lymphocytes.

There was no evidence of impairment of fertility in either male or female Sprague-Dawley rats administered varenicline succinate up to 15 mg/kg/day (67 and 36 times, respectively, the MRHD exposure based on AUC at 1 mg twice daily).
Maternal toxicity, characterized by a decrease in body weight gain, was observed at 15 mg/kg/day. However, a decrease in fertility was noted in the offspring of pregnant rats who were administered varenicline succinate at an oral dose of 15 mg/kg/day. This decrease in fertility in the offspring of treated female rats was not evident at an oral dose of 3 mg/kg/day (9 times the MRHD exposure based on AUC at 1 mg twice daily).

Section 12: Ecological Information

No relevant studies identified.
This mixture contains material that is toxic to aquatic life. Releases to the environment should be avoided.

Section 13: Disposal Considerations

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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

California Proposition 65 Not listed.

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.