LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	**Minocycline Hydrochloride Extended-Release Tablets, USP 45 mg, 55 mg, 90 mg, and 135 mg**
Manufacturer	**Lupin Limited** **MADE IN 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

Section 2: Hazard(s) Identification

Section 2, Hazard(s) identification

Fire and Explosion	Expected to be non-combustible.
Health	This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	**CAS**
Minocycline Hydrochloride USP	13614-98-7

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Flush out mouth with water, consult a physician immediately.
Inhalation	In case of inhalation remove to fresh air and seek medical aid.
Skin Contact	Remove immediately contaminated clothes, wash affected skin with plenty of water.

Eye Contact	In case of contact with eyes rinse thoroughly with plenty of water and get medical advice.

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 patient's vital signs, blood gases, serum electrolytes, etc.
OVERDOSAGE	In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Minocycline is not removed in significant quantities by hemodialysis or peritoneal dialysis.

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, 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

Section 6, Accidental release measures

Personal Precautions	Avoid excessive contact and contact with eyes. Wear safety goggles or shield.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

Section 7: Handling and Storage

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Handling	Keep out of reach of children. Protect from light, moisture, and excessive heat. Dispense in tight, light-resistant container with child-resistant closure.

Storage	Store at 25ºC (77ºF); excursions are permitted to 15º to 30ºC (59º to 86ºF) [see USP Controlled Room Temperature].

Section 8: Exposure Controls/Personal Protection

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

Section 9, Physical and chemical properties

Physical Form

Minocycline hydrochloride extended-release tablets USP are supplied as aqueous film coated tablets containing minocycline hydrochloride USP equivalent to 45 mg, 55 mg, 90 mg, or 135 mg minocycline.

The 45 mg extended-release tablets are pink colored, round shaped, biconvex, film-coated tablets debossed with “F21” on one side and “LU” on the other side. Each tablet contains minocycline hydrochloride USP equivalent to 45 mg minocycline, supplied as follows:
NDC 68180-379-06 Bottle of 30
NDC 68180-379-01 Bottle of 100

The 55 mg extended-release tablets are green colored, round shaped, biconvex, film-coated tablets debossed with “F26” on one side and “LU” on the other side. Each tablet contains minocycline hydrochloride equivalent to 55 mg minocycline, supplied as follows:
NDC 68180-460-06 Bottle of 30
NDC 68180-460-01 Bottle of 100

The 90 mg extended-release tablets are pale yellow colored, round shaped, biconvex, film-coated tablets debossed with “F22” on one side and “LU” on the other side. Each tablet contains minocycline hydrochloride USP equivalent to 90 mg minocycline, supplied as follows:
NDC 68180-380-06 Bottle of 30
NDC 68180-380-01 Bottle of 100

The 135 mg extended-release tablets are brown colored, capsule shaped, biconvex, film-coated tablets debossed with “F23” on one side and “LU” on the other side. Each tablet contains minocycline hydrochloride USP equivalent to 135 mg minocycline, supplied as follows:
NDC 68180-381-06 Bottle of 30
NDC 68180-381-01 Bottle of 100

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis – In a carcinogenicity study in which minocycline hydrochloride was orally administered to male and female rats once daily for up to 104 weeks at dosages up to 200 mg/kg/day, minocycline hydrochloride was associated in both genders with follicular cell tumors of the thyroid gland, including increased incidences of adenomas, carcinomas and the combined incidence of adenomas and carcinomas in males, and adenomas and the combined incidence of adenomas and carcinomas in females. In a carcinogenicity study in which minocycline hydrochloride was orally administered to male and female mice once daily for up to 104 weeks at dosages up to 150 mg/kg/day, exposure to minocycline hydrochloride did not result in a significantly increased incidence of neoplasms in either males or females.

Mutagenesis - Minocycline was not mutagenic *in vitro* in a bacterial reverse mutation assay (Ames test) or CHO/HGPRT mammalian cell assay in the presence or absence of metabolic activation. Minocycline was not clastogenic *in vitro* using human peripheral blood lymphocytes or *in vivo* in a mouse micronucleus test.

Impairment of Fertility - Male and female reproductive performance in rats was unaffected by oral doses of minocycline of up to 300 mg/kg/day (which resulted in up to approximately 40 times the level of systemic exposure to minocycline observed in patients as a result of use of minocycline hydrochloride extended-release tablets). However, oral administration of 100 or 300 mg/kg/day of minocycline to male rats (resulting in approximately 15 to 40 times the level of systemic exposure to minocycline observed in patients as a result of use of minocycline hydrochloride extended-release tablets) adversely affected spermatogenesis. Effects observed at 300 mg/kg/day included a reduced number of sperm cells per gram of epididymis, an apparent reduction in the percentage of sperm that were motile, and (at 100 and 300 mg/kg/day) increased numbers of morphologically abnormal sperm cells. Morphological abnormalities observed in sperm samples included absent heads, misshapen heads, and abnormal flagella.

Limited human studies suggest that minocycline may have a eleterious effect on spermatogenesis.

Minocycline hydrochloride extended-release tablets should not be used by individuals of either gender who are attempting to conceive a child.

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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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

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This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

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.