

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material Minocycline hydrochloride extended-release Tablets
45 mg, 90 mg and 135 mg

Manufacturer Lupin Limited
Pithampur (M.P.) – 454 775
INDIA

Distributor Lupin Pharmaceuticals, Inc.
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS	Quantity
Minocycline hydrochloride	13614-98-7	45 mg, 90 mg and 135 mg

3. HAZARD 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.

4. FIRST AID MEASURE

Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Inhalation	Move individual to fresh air. Obtain medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance.
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Eye Contact	Flush eyes with plenty of water. Get medical attention.

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.
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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.
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5. FIRE FIGHTING MEASURE

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Water spray, carbon dioxide, dry chemical powder or appropriate foam.
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.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labeled container for recovery or disposal.

7. HANDLING AND STORAGE

Handling	No special control measures required for the normal handling of this product. 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 25°C (77°F); excursions are permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form Minocycline hydrochloride extended-release tablets are supplied as aqueous film coated tablets containing minocycline hydrochloride equivalent to 45 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 equivalent to 45 mg minocycline, supplied as follows:

NDC	68180-379-06	Bottle of 30
NDC	68180-379-01	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 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 equivalent to 135 mg minocycline, supplied as follows:

NDC 68180-381-06 Bottle of 30
NDC 68180-381-01 Bottle of 100

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of minocycline. A structurally related compound, oxytetracycline, was found to produce adrenal and pituitary tumors in rats.

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.

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 deleterious effect on spermatogenesis.

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

12. ECOLOGICAL INFORMATION

No relevant studies identified.

13. DISPOSAL CONSIDERATION

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

14. TRANSPORT INFORMATION

IATA/CAO - 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

15. REGULATORY INFORMATION

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

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 MSDS.