

MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE AND THE COMPANY

Material Doxycycline Capsules USP
50 mg, 75 mg and 100 mg

Manufacturer Lupin Limited
Goa 403 722
INDIA.

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

Ingredients	CAS	Quantity
Doxycycline USP	17086-28-1	50 mg, 75 mg and 100 mg

3. HAZARDOUS IDENTIFICATION

Fire and Explosion Assume that this product is capable of sustaining combustion.

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 MEASURES

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

OVERDOSAGE In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Dialysis does not alter serum half-life, and it would not be of benefit in treating cases of overdosage.

5. FIRE-FIGHTING MEASURES

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 precautions are necessary when handling packed product. In case of accident, avoid breathing dust from crushed tablets. Avoid contact with skin and eyes. Wash hands after use.

Storage

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP controlled room temperature]. Protect from light.

Dispense in a tight, light-resistant container as defined in the USP/NF.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

9. PHYSICAL & CHEMICAL PROPERTIES**Physical Form**

Doxycycline capsules USP, 50 mg are brown opaque cap and yellow opaque body imprinted with "LU" on cap in white ink and "M71" on the body in black ink filled with light yellow to grey colored blend.

Each capsule contains doxycycline monohydrate USP equivalent to 50 mg doxycycline.

Doxycycline capsules USP, 50 mg is available in:
Bottle of 100 capsules NDC 68180-650-01

Doxycycline capsules USP, 75 mg are brown opaque cap and light yellow opaque body imprinted with "LU" on cap in white ink and "M72" on the body in black ink filled with light yellow to grey colored blend.

Each capsule contains doxycycline monohydrate USP equivalent to 75 mg doxycycline.

Doxycycline capsules USP, 75 mg is available in:
Bottle of 100 capsules NDC 68180-651-01

Doxycycline capsules USP, 100 mg are brown opaque cap and yellow opaque body imprinted with "LU" on cap in white ink and "M73" on the body in black ink filled with light yellow to grey colored blend.

Each capsule contains doxycycline monohydrate USP equivalent to 100 mg doxycycline.

Doxycycline capsules USP, 100 mg is available in:
Bottle of 50 capsules NDC 68180-652-08
Bottle of 250 capsules NDC 68180-652-29

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to evaluate the carcinogenic potential of doxycycline have not been conducted. However, there has been evidence of oncogenic activity in rats in studies with related antibacterial, oxytetracycline (adrenal and pituitary tumors) and minocycline (thyroid tumors). Likewise, although mutagenicity studies of doxycycline have not been conducted, positive results in *in vitro* mammalian cell assays have been reported for related antibacterial (tetracycline, oxytetracycline). Doxycycline administered orally at dosage levels as high as 250 mg/kg/day had no apparent effect on the fertility of female rats. Effect on male fertility has not been studied.

12. ECOLOGICAL INFORMATION

No information available

13. DISPOSAL CONSIDERATION

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

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

MSDS : 105/00
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15. REGULATORY INFORMATION

No information available.

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.