Safety Data Sheet
Doxycycline Hyclate Tablets, USP
Strength: 100 mg
Pack Size: 50's, 100's, 500's and 1000's Tablets per bottle and Cartons of 100 Tablets (10 x 10 Unit Dose)

Revision No.: 00

EMERGENCY OVERVIEW

Each Doxycycline Hyclate Tablets, USP intended for oral administration contains Doxycycline Hyclate and excipients generally considered to be non- toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

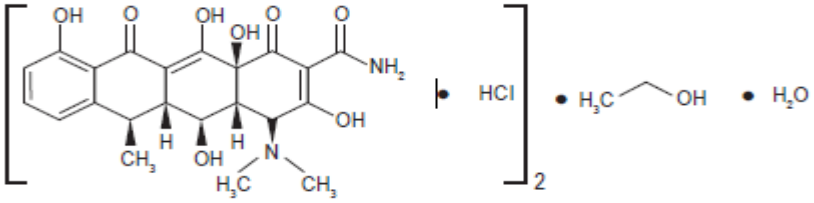
Section 1. Identification

Identification of the product

Product Name: Doxycycline Hyclate Tablets, USP

Formula: Hyclate$(C_{22}H_{24}N_2O_8 \bullet HCl)_2 \bullet C_2H_6O \bullet H_2O$

Chemical Name: 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacene-carboxamide monohydrate



Doxycycline Hyclate

Manufacturer / supplier identification

Company: **Cadila Healthcare Ltd., Matoda, India**

Address: Cadila Healthcare Limited, Plot No- 1A/1 & 2, Pharmez Special Economic Zone, Sarkhej- Bavla N.H. No. 8A, Near Village Matoda, Tal. Sanand, Dist. Ahmedabad-382 213, India

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Recommended use / Therapeutic Category	Doxycycline Hyclate tablets are indicated for the treatment of the following infections: • Rocky Mountain spotted fever, typhus fever and the typhus group, Q fever, rickettsia pox, and tick fevers caused by Rickettsiae. • Respiratory tract infections caused by Mycoplasma pneumoniae. • Lymphogranuloma venereum caused by Chlamydia trachomatis. • Psittacosis (ornithosis) caused by Chlamydophila psittaci. • Trachoma caused by Chlamydia trachomatis, although the infectious agent is not always eliminated, as judged by immunofluorescence. • Inclusion conjunctivitis caused by Chlamydia trachomatis. • Uncomplicated urethral, endocervical, or rectal infections in adults caused by Chlamydia trachomatis. • Nongonococcal urethritis caused by Ureaplasma urealyticum. • Relapsing fever due to Borrelia recurrentis.
Restriction on Use / Contraindications:	This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines
Section 2. Hazard(s) Identification	
Dose and Administration	The usual dosage and frequency of administration of doxycycline differs from that of the other tetracyclines. Exceeding the recommended dosage may result in an increased incidence of side effects. Adults: The usual dose of oral doxycycline is 200 mg on the first day of treatment (administered 100 mg every 12 hours) followed by a maintenance dose of 100 mg/day. In the management of more severe infections (particularly chronic infections of the urinary tract), 100 mg every 12 hours is recommended. Pediatric Patients: For all pediatric patients weighing less than 45 kg with severe or life-threatening infections (e.g., anthrax, Rocky Mountain spotted fever), the recommended dosage is 2.2 mg/kg of body weight administered every 12 hours. Children weighing 45 kg or more should receive the adult dose.

Adverse Effects	Due to oral doxycycline's virtually complete absorption, side effects of the lower bowel, particularly diarrhea, have been infrequent. The following adverse reactions have been observed in patients receiving tetracyclines: Gastrointestinal: anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis, inflammatory lesions (with monilial overgrowth) in the anogenital region, and pancreatitis. Hepatotoxicity has been reported rarely. These reactions have been caused by both the oral and parenteral administration of tetracyclines. Superficial discoloration of the adult permanent dentition, reversible upon drug discontinuation and professional dental cleaning has been reported. Permanent tooth discoloration and enamel hypoplasia may occur with drugs of the tetracycline class when used during tooth development. Rare instances of esophagitis and esophageal ulcerations have been reported in patients receiving capsule and tablet forms of the drugs in the tetracycline class. Most of these patients took medications immediately before going to bed. Skin: toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, skin hyperpigmentation, maculo-papular and erythematous rashes. Exfoliative dermatitis has been reported but is uncommon. Photosensitivity is discussed above. Renal toxicity: Rise in BUN has been reported and is apparently dose related.
Over Dose Effect	In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Dialysis does not alter serum half-life and thus would not be of benefit in treating cases of overdosage.
Contraindications	This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines
Pregnancy Comments	There are no adequate and well-controlled studies on the use of doxycycline in pregnant women. The vast majority of reported experience with doxycycline during human pregnancy is short-term, first trimester exposure. There are no human data available to assess the effects of long-term therapy of doxycycline in pregnant women, such as that proposed for treatment of anthrax exposure. An expert review of published data on experiences with doxycycline use during pregnancy by TERIS – the Teratogen Information System – concluded that therapeutic doses during

	pregnancy are unlikely to pose a substantial teratogenic risk (the quantity and quality of data were assessed as limited to fair), but the data are insufficient to state that there is no risk.1 A case-control study (18,515 mothers of infants with congenital anomalies and 32,804 mothers of infants with no congenital anomalies) shows a weak but marginally statistically significant association with total malformations and use of doxycycline anytime during pregnancy. Sixty-three (0.19%) of the controls and fifty-six (0.30%) of the cases were treated with doxycycline. This association was not seen when the analysis was confined to maternal treatment during the period of organogenesis (i.e., in the second and third months of gestation) with the exception of a marginal relationship with neural tube defect based on only two exposed cases. A small prospective study of 81 pregnancies describes 43 pregnant women treated for 10 days with doxycycline during early first trimester. All mothers reported their exposed infants were normal at 1 year of age.3
Pregnancy Category	Not available

Section 3. Composition / information on ingredients

Component	Exposure Limit	CAS No.
Principle Component:		
Doxycycline Hyclate	Not Found	24390-14 -5
Inactive ingredients:		
Microcrystalline cellulose	Not Found	9004-34-6
Anhydrous Lactose	Not Found	63-42-3
Pre gelatinized Starch	Not Found	9005-25-8
Croscarmellose Sodium	Not Found	74811-65-7
Colloidal Silicon dioxide	Not Found	7631-86-9
Magnesium Stearate	Not Found	557-04-0
OPADRY 03F570018 Beige	Not Found	NA

Section 4. First -aid measures

General	• **After inhalation:** Move to fresh air in case of accidental inhalation. assure fresh air breathing. • **After skin contact:** Rinse skin with water/shower • **After eye contact:** Rinse with water while holding the eyes wide open. Contact lenses should be removed.

	• **After swallowing:** Rinse mouth out with water • **Information for doctor:** • **Most important symptoms and effects, both acute and delayed-** No further relevant information available. • **Indication of any immediate medical attention and special treatment needed-** No further relevant information available.
Overdose Treatment	No additional information available
Section 5. Fire -fighting measures	
	Extinguishing media · **Suitable extinguishing agents:** Use extinguishing media appropriate for surrounding fire. Extinguishing blanket. Carbon dioxide. Dry powder **Special hazards arising from the substance or mixture** Stable under normal conditions. · **Advice for firefighters** Small amounts: Use normal individual fire protective equipment. Large amounts: Not · **Protective equipment:** Hand protection : Gloves Skin and body protection : Lab coat Respiratory protection : Quarter mask (DIN EN 140)
Specific hazards arising from the chemical	No additional information available
Special protective equipment and precautions for firefighters	Use normal individual fire protective equipment
General fire hazards	No unusual fire or explosion hazards noted
Section 6. Accidental Release Measures	
Personal precautions, protective equipment and emergency procedures	Avoid raising dust. Wear suitable protective clothing, gloves and eye or face protection.
Environmental precautions:	No additional information available
Methods and material for containment and cleaning up:	Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Ensure waste is collected and contained. Clean thoroughly. Poorly soluble in water. Clean

	with the help of detergents.
Section 7. Handling and Storage	
Storage:	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture. Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure **Precautions for safe handling**: Keep it dry & in a cool, well ventilated place away from heat. Store in original container **Information about fire - and explosion protection:** No special measures required.
Section 8. Exposure controls / personal protection	
Respiratory Protection	Quarter mask (DIN EN 140)
Skin protection	For prolonged or repeated skin contact use suitable protective gloves.
Eye/face protection	If contact is likely, safety glasses with side shields are recommended.
Protective Clothing	Protective clothing is not normally necessary, however it is good practice to use apron.
Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	General ventilation normally adequate.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations	Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.
Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Section 9. Physical and chemical properties

Appearance	Description of **Doxycycline Hyclate Tablets USP, 100 mg** is Light yellow to beige colored round bevel edged, biconvex tablets debossed with "D77" on one side and plain on other side.		
Solubility	Not available	**Odour**	Not available.
Boiling point	Not available.	**Melting Point**	Not available.
Evaporation rate	Not available.	**Vapour density**	Not available.
Reactivity in water	Not available.	**Vapour pressure**	Not available.
% Volatile by volume	Not available.	**Specific gravity**	Not available.

Section 10. Stability and Reactivity

Conditions to avoid	Contact with incompatible materials.
Stable	**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Hazardous reactions	No dangerous reaction known under conditions of normal use.

Decomposition products	When heated to decomposition, emits dangerous fumes.
Incompatible materials	Strong Oxidizing agent
Section 11. Toxicological information	
General	Handling of formulated product is not expected to cause any toxicological affects. The data pertains to the ingredient in formulations, rather than this specie formulation.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Other	Not Available
Symptoms related to the physical, chemical and Toxicological characteristics	Not available
Information on toxicological effects	
Acute toxicity	Not available
Further information	Not available
Section 12. Ecological information	
	Poorly soluble in water. No data available on ecotoxicity.
Section 13. Disposal Consideration	
	Dispose the waste in accordance with all applicable Federal, State and local laws.
Section 14. Transport Information	
	The product is not hazardous when shipping via air (IATA), ground (DOT), or sea (IMDG). In accordance with ADR / RID / IMDG / IATA / ADN
Section 15. Regulatory Information	
	Generic Medicine. Under Approval by USFDA & the ANDA Number is 207773
Section 16. Other information	
	None

Date of issue: 25/01/19 **Supersedes edition:** New Edition