Safety Data Sheet
DOXYCYCLINE HYCLATE CAPSULES USP
Strength: 50 mg and 100 mg
Pack Size: 50's for 50 mg and 50's and 500's for 100mg per bottle

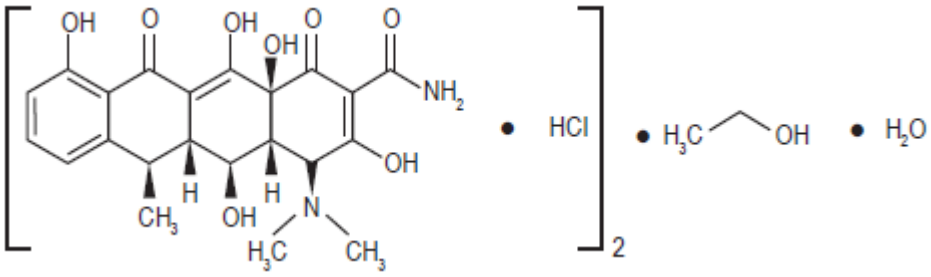
Revision No.: 00

EMERGENCY OVERVIEW
Each Doxycycline Hyclate Capsules 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 Capsules USP
Formula:	$(C_{22}H_{24}N_2O_8\ HCl)_2\ C_2H_6O\ H2O$
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.



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
Contact for information:	Tel: +91-79-26868100 Fax: +91-79-26868533
Emergency Telephone No.	Tel: +91-79-26868101
Recommended use / Therapeutic Category	Doxycycline Hyclate is an antibacterial drug which is used to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.
Restriction on Use / Contraindications:	Doxycycline hyclate may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, doxycycline hyclate should be discontinued and appropriate therapy be instituted.

Section 2. Hazard(s) Identification	
Dose and Administration	For 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. For Paediatric patients weighing less than 45 kg with severe or life-threatening infections the recommended dosage is 2.2 mg/kg of body weight administered every 12 hours and for children weighing 45 kg or more should receive the adult dose. The therapeutic antibacterial serum activity will usually persist for 24 hours following recommended dosage. When used in streptococcal infections, therapy should be continued for 10 days. If gastric irritation occurs, it is recommended that doxycycline be given with food or milk. The absorption of doxycycline is not markedly influenced by simultaneous ingestion of food or milk. Uncomplicated gonococcal infections in adults 100 mg, by mouth, twice a day for 7 days. As an alternate single visit dose, administer 300 mg stat followed in one hour by a second 300 mg dose. The dose may be administered with food, including milk or carbonated beverage, as required. Uncomplicated urethral, endocervical, or rectal infection in adults caused by Chlamydia trachomatis: 100 mg, by mouth twice a day for 7 days. Nongonococcal urethritis (NGU) caused by C. trachomatis or U. urealyticum: 100 mg by mouth, twice a day for 7 days. Syphilis – early: Patients who are allergic to penicillin should be treated with doxycycline 100 mg, by mouth, twice a day for 2 weeks. Syphilis of more than one year's duration: Patients who are allergic to penicillin should be treated with doxycycline 100 mg, by mouth, twice a day for 4 weeks. Acute epididymo-orchitis caused by N. gonorrhoeae and C. trachomatis: 100 mg, by mouth, twice a day for at least 10 days. For prophylaxis of malaria: For adults, the recommended dose is 100 mg daily. For children over 8 years of age, the recommended dose is 2 mg/kg given once daily up to the adult dose. **Inhalational anthrax (post-exposure)** ADULTS: 100 mg of doxycycline, by mouth, twice a day for 60 days. CHILDREN: weighing less than 45 kg; 2.2 mg/kg of body weight by mouth, twice a day for 60 days. Children weighing 45 kg or more should receive the adult dose.

Adverse Effects	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. Skin: toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema multiforme, skin hyperpigmentation, maculopapular and erythematous rashes. Renal toxicity: Rise in BUN has been reported and is apparently dose related. Immune: Hypersensitivity reactions including urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, serum sickness, pericarditis, exacerbation of systemic lupus erythematosus, drug reaction with eosinophilia and systemic symptoms (DRESS), and Jarisch-Herxheimer reaction has been reported. Blood: Hemolytic anemia, thrombocytopenia, neutropenia, and eosinophilia have been reported. Other: Bulging fontanels in infants and intracranial hypertension in adults.
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. The use of drugs of the tetracycline class during tooth development may cause permanent discoloration of the teeth. This adverse reaction is more common during long-term use of the drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Clostridium difficile associated diarrhea (CDAD) has been reported with use of doxycycline hyclate, and may range in severity from mild diarrhea to fatal colitis. Severe skin reactions, such as exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in patients receiving doxycycline. If severe skin reactions occur, doxycycline should be

	discontinued immediately and appropriate therapy should be instituted. Intracranial hypertension (IH) has been associated with the use of tetracyclines including Vibramycin. Clinical manifestations of IH include headache, blurred vision, diplopia, and vision loss; papilledema can be found on fundoscopy. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in prematures given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued. The antianabolic action of the tetracyclines may cause an increase in BUN. Studies to date indicate that this does not occur with the use of doxycycline in patients with impaired renal function. Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines.
Pregnancy Comments	Use of Doxycycline Hyclate can cause Teratogenic Effects. The use of drugs of the tetracycline class during last half of pregnancy, infancy and childhood to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown). Evidence of embryotoxicity has also been noted in animals treated early in pregnancy. **Lactation** Tetracyclines are excreted in human milk; however, the extent of absorption of tetracyclines, including doxycycline, by the breastfed infant is not known. Short-term use by lactating women is not necessarily contraindicated.
Pregnancy Category	D

Section 3. Composition / information on ingredients

Component	**Exposure Limit**	**CAS No.**
Principle Component:		
Doxycycline Hyclate USP	Not Found	24390-14-5
Inactive ingredients:		
Anhydrous Lactose	Not Found	63-42-3
Micro Crystalline Cellulose	Not Found	9004-34-6
Croscarmellose Sodium	Not Found	74811-65-7
Magnesium Stearate	Not Found	557-04-0

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	In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures.
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°C to 25°C (68°F to 77°F). **Precautions for safe handling**: Dispense in tight, light-resistant containers **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 Capsules USP, 50 mg** are Yellowish powder filled in size "3" hard gelatin capsule with light blue opaque cap imprinted with "CHL" in white ink and white opaque body imprinted with "D75" in black ink. Description of **Doxycycline Hyclate Capsules USP, 100 mg** Yellowish powder filled in size "1" hard gelatin capsule with light blue opaque cap imprinted with "CHL" in white ink and light blue opaque body imprinted with "D76" in black ink.		
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	
	It is soluble in water (50 mg/ml), yielding a clear, yellow-green solution. Mild warming may be required to fully dissolve the material.
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. Approved by USFDA & the ANDA Number is 207774.
Section 16. Other information	
	None

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