# SAFETY DATA SHEET

**Doxycycline Hyclate Tablets, USP Eq. 75 mg base and Eq. 150 mg base**

**EMERGENCY OVERVIEW**

DOXYCYCLINE HYCLATE TABLETS, USP contain an active drug substance doxycycline hyclate, USP and pharmaceutical excipients generally considered safe, non-toxic and non-hazardous. The quantities of the excipients used in the product are well within the IID (Inactive Ingredient Database) limits prescribed by USFDA for oral tablets.

WARNING: Accidental ingestion of large amounts may be harmful.

## Section 1. Identification of the substance

**Identification of the product**

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|---|---|---|
| **Product name** | : | Doxycycline Hyclate Tablets, USP |
| **Potencies** | : | Eq. 75 mg base and Eq. 150 mg base |
| **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-naphthacenecarboxamide monohydrochloride, compound with ethyl alcohol (2:1), monohydrate. |
| **Therapeutic Category** | : | Antibiotics |
| **Product Use** | : | • Rickettsial infections<br>• Sexually transmitted infections<br>• Respiratory tract infections<br>• Specific bacterial infections<br>• Ophthalmic infections<br>• Anthrax, including inhalational anthrax (post-exposure)<br>• Alternative treatment for selected infections when penicillin is contraindicated<br>• Adjunctive therapy for acute intestinal amebiasis and severe acne<br>• Prophylaxis of malaria |
| **Marketed by** | : | **Ajanta Pharma USA Inc**.<br>Bridgewater, NJ 08807.<br>Made in India |
| **Contact Information** | : | 855-664-7744 |

## Section 2. Health hazards information

**Potential Health Effects** : **Inhalation:** Not expected to be hazardous in final pharmaceutical form.
**Eye Contact**: Not expected to be hazardous in final pharmaceutical form.
**Skin Contact:** Not expected to be hazardous in final pharmaceutical form.
**Ingestion:** Health injuries are not known or expected under normal use. Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.

**Effects of Overexposure** : The potential for exposure is reduced in finished pharmaceutical form.

## Section 3. Composition / information on ingredients

| **Active ingredient** | **Exposure Limit** | **CAS No.** |
|---|---|---|
| Doxycyline hyclate, USP | TWA-8 Hr: 250µg/$m^3$ | 24390-14-5 |

**Inactive ingredients:** Each film-coated tablets contains the following inactive ingredients in the tablet formulation: silicified microcrystalline cellulose, sodium lauryl sulfate and magnesium stearate. Film-coating contains: hypromellose, titanium dioxide, polyethylene glycol, FD&C Blue #2 (75 mg Tablet), FD&C Yellow #6 (75 mg Tablet), FD&C Blue #2 (150 mg Tablet) and yellow iron oxide (150 mg Tablet).

## Section 4. First aid measures

This product in the final dosage form (tablets) does not pose a problem of exposure to active moieties, and does not cause inhalation, skin and eye irritation problem. The lose powder exposure hazards are during the manufacturing process.

**Eye Contact** : Immediately flush eyes with water for at least 15 minutes. Get medical attention.

**Skin Contact** : Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

**Ingestion** : Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. DO NOT induce vomiting unless directed to do so by medical personnel.

**Inhalation** : Remove to fresh air. If not breathing, give artificial respiration or oxygen by trained personnel. Get immediate medical attention immediately.

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| **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. |
| **Over dosage** | : | There is no specific treatment for overdose with doxycycline hyclate, USP. General supportive care of the patient is indicated, including monitoring of vital signs and observation of clinical status, should an overdose occur. If indicated, elimination of unabsorbed drug should be achieved by emesis or gastric lavage; usual precautions should be observed to maintain the airway. Because doxycycline hyclate, USP is highly bound to plasma proteins, hemodialysis should not be considered. |

## Section 5. Fire-fighting measures

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| **Flash Point** | : | Not Available. |
| **Extinguishing Media** | : | Water spray, carbon dioxide, extinguishing powder, foam or water. |
| **General Fire Hazards/ Hazardous Combustible Products** | : | Hazardous combustion or decomposition products are expected when the product is exposed to fire. |
| **Special Fire Fighting Procedures** | : | Wear self-contained breathing apparatus pressure-demand (NIOSH approved or equivalent), and full protective gear to prevent contact with skin and eyes. |

## Section 6. Accidental release measures

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| **Personal Precautions** | : | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. |
| **Environmental Protections** | : | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. |
| **Clean-up Methods** | : | Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains. |
| **Additional Consideration for Large Spills** | : | Non-essential personnel should be evacuated from affected area. Report emergency situations |

immediately. Clean up operations should only be undertaken by trained personnel.

## Section 7. Handling and storage

**Handling** : No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin and clothing. Use adequate ventilation. Minimize dust generation and accumulation.

**Storage** : Store at 20ºC to 25ºC (68ºF to 77ºF); excursions permitted to 15ºC to 30ºC (59ºF to 86ºF) [See USP Controlled Room Temperature]. Protect from light and moisture.

## Section 8. Exposure controls/personal protection

**Exposure Limits** : OEL TWA-8 Hr: 250µg/$m^3$

**Engineering Controls** : For consumer use, no unusual precaution are necessary for handling packets. In laboratory, medical or industrial setting use appropriate ventilation.

**Respiratory Protection** : For consumer use, no unusual precaution are necessary. However, for handling packets, in laboratory, medical or industrial setting use NIOSH/MSHA approved respirators for protection if necessary.

**Personal Protection** : For consumer use, no unusual precaution are necessary. However, for handling packets in laboratory, medical or industrial setting use gloves as recommended.

**Recommended Facilities** : None

## Section 9. Physical and chemical properties

**Appearance** : **Doxycycline Hyclate Tablets, USP 75 mg** are blue colored, round-shaped, biconvex, film-coated tablets with 'DY' debossed on one side of the tablet and '2' debossed on the other. (NDC 27241-153-02)

**Doxycycline Hyclate Tablets, USP 150 mg** are yellowish-green to green colored, capsule shaped, biconvex, film-coated tablets. Each side of the functionally scored tablet has two parallel score lines for splitting into 3 equal portions with 'D' or 'Y' or '1' debossed on either portion of one side of the tablet, and no debossing on the other. (NDC 27241-154-02)

**Other Information** : Doxycycline hyclate, USP is a yellow crystalline powder soluble in water and in solutions of alkali hydroxides and carbonates.

## Section 10. Stability and reactivity

**Stability** : Stable
**Incompatibility** : Strong oxidizers. Strong bases. Strong acids.
**Hazardous Decomposition** : Thermal decomposition generates: Carbon oxides (CO, $CO_2$).
**Conditions to Avoid** : Direct sunlight. Extremely high or low temperatures. Avoid creating or spreading dust.

## Section 11. Toxicological information

**Acute toxicity** : Mouse Oral LD50 1900 mg/kg (hydrochloride)

**Eye Contact** : May cause minor eye irritation.

**Short Term Exposure** : May cause allergic reactions in susceptible individuals. Accidental ingestion may cause effects similar to those seen in clinical use.

**Long Term Exposure** : Repeat-dose studies in animals have shown a potential to cause adverse effects on liver.

**Known Clinical Effects** May cause permanent discoloration of teeth if used during tooth development. May cause effects similar to those generally seen in clinical use of tetracyclines including gastrointestinal irritation, nausea, vomiting, and diarrhea. Photosensitivity has been reported in some individuals taking tetracyclines.

## Section 12. Ecological information

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| **Eco toxicity of drug substance** | **:** | Avoid release into the environment. Runoff from fire control or dilution water may cause pollution. |
| **In the finished product form** | **:** | There is no potential for air borne contamination since the drug substance is in consolidated form as tablets. |

## Section 13. Disposal Consideration

**Waste Disposal Considerations:** Dispose the material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: If pharmacy service available, return unused tablets to pharmacy for disposal. Discard away from children's reach.

## Section 14. Transport information

This product is not subject to the regulations for the safe transport of hazardous chemicals

**DOT:** Not regulated for transport of dangerous goods.
**IATA**: Not regulated for transport of dangerous goods.
**IMDG**: Not regulated for transport of dangerous goods.

## Section 15. Regulatory information

**DEA:** Not available
**FDA:** Doxycycline Hyclate Tablets, USP is an approved prescription medication.

## Section 16. Disclaimer

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.

Ajanta shall not be held liable for any damage resulting from handling or from contact with the above product.

**Date:** Mar 31, 2022

## SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION