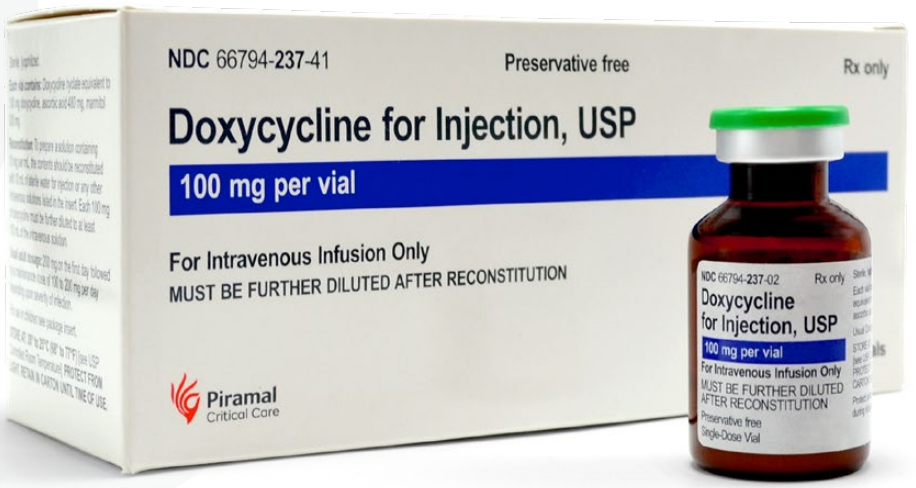
Piramal Critical Care is a world leader in inhaled anesthetics, intrathecal therapy, and generic injectables, with a strong presence in more than 100 countries.

Backed by 25 years of quality, dependability, and growth, we are proud to offer a comprehensive U.S. product portfolio and bring you high-quality critical care drugs at affordable prices.

Doxycycline for Injection, USP

For Intravenous Infusion Only



Available through the wholesaler or distributor of your choice:

10 single-dose vials per carton, saleable unit NDC # 66794-237-41

WHOLESALER/DISTRIBUTOR	CATALOG NUMBER
ABC	10280814
Cardinal	5850680
McKesson	2822054
Morris and Dickson	292946

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Indication and Important Safety Information you should know about Doxycycline for Injection, USP

DESCRIPTION:
Doxycycline for Injection, USP is a sterile, lyophilized powder prepared from a solution of doxycycline hyclate, ascorbic acid and mannitol in Water for Injection. Doxycycline hyclate is a broad spectrum antibiotic derived from oxytetracycline. For INTRAVENOUS use only after reconstitution.

Qualitative and Quantitative Composition: Each 100 mg vial contains: Doxycycline hyclate equivalent to 100 mg doxycycline; ascorbic acid 480 mg; mannitol 300 mg. pH of the reconstituted solution (10 mg/mL) is between 1.8 and 3.3.

Pharmaceutical Form: Powder for solution for injection.

Therapeutic Indications: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Doxycycline for Injection, USP and other antibacterial drugs.

Doxycycline for Injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. Doxycycline for Injection, USP is indicated in infections caused by the following microorganisms:

• Rickettsiae, *Mycoplasma pneumoniae*, *Borrelia recurrentis*, Haemophilus ducreyi (chancroid)., Yersinia pestis and Francisella tularensis, Bartonella bacilliformis. Bacteroides species, Vibrio cholera, Campylobacter fetus, Brucella species (in conjunction with streptomycin).Doxycycline is indicated for treatment of infections caused by the following gram-negative microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug: Escherichia coli., Enterobacter aerogenes Shigella species, Acinetobacter species, Haemophilus influenzae (respiratory infections), Klebsiella species (respiratory and urinary infections).

Gram-positive microorganisms when bacteriologic testing indicates appropriate susceptibility to the drug: *Streptococcus* species: Anthrax due to *Bacillus anthracis*, including inhalational anthrax (post-exposure). Doxycycline is an alternative drug in the treatment of infections due to: *Neisseria gonorrhoeae* and *N. meningitidis.*, *Treponema pallidum* and *Treponema pertenue* (syphilis and yaws), *Listeria monocytogenes, Clostridium* species, *Fusobacterium fusiforme* (Vincent's infection), *Actinomyces* species. In acute intestinal amebiasis or trachoma.

Dosage and Administration: NOTE: Rapid administration is to be avoided. Parenteral therapy is indicated only when oral therapy is not indicated. Oral therapy should be instituted as soon as possible. If intravenous therapy is given over prolonged periods, thrombophlebitis may result. **Adults:** The usual dosage of doxycycline for injection is 200 mg on the first day of treatment administered in one or two infusions. Subsequent daily dosage is 100 to 200 mg depending upon the severity of infection, with 200 mg administered in one or two infusions. **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.

General: The duration of infusion may vary with the dose (100 to 200 mg/day), but is usually one to four hours. A recommended minimum infusion time for 100 mg of a 0.5 mg/mL solution is one hour. Therapy to be continued for at least 24 to 48 hours after symptoms and fever have subsided. The therapeutic antibacterial serum activity will usually persist for 24 hours following recommended dosage. IV solutions not to be injected intramuscularly or subcutaneously. Avoid the inadvertent introduction of the intravenous solution into the adjacent soft tissue. **[For additional information, please refer to the full prescribing information]**

CONTRAINDICATIONS:
This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS:
The use of drugs of the tetracycline class during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-graybrown). Enamel hypoplasia has also been reported. Use doxycycline in pediatric patients when the potential benefits outweigh the risks in severe or life-threatening conditions (e.g., anthrax, Rocky Mountain spotted fever), particularly when there are no alternative therapies. **[For additional information regarding, please refer to the full prescribing information]**

Drug Interactions
Adjustment of anticoagulant dosage when on Doxycycline. Avoid with penicillin.

Barbiturates, carbamazepine, and phenytoin decrease the half-life of doxycycline. The concurrent use of tetracycline and Penthrane® (methoxyflurane) has been reported to result in fatal renal toxicity.

Concurrent use of drug may render oral contraceptives less effective.

Usage in Pregnancy: Doxycycline for Injection has not been studied in pregnant patients. **Usage in Children:** The use of Doxycycline for Injection in children under 8 years is not recommended because safe conditions for its use have not been established. **Lactation:** Tetracyclines are present in the milk of lactating women who are taking a drug in this class.

ADVERSE REACTIONS:
Anorexia, nausea, vomiting, diarrhea, glossitis, dysphagia, enterocolitis and inflammatory lesions (with monilial overgrowth) in the anogenital region, and pancreatitis. Hepatotoxicity, Superficial discoloration of the adult permanent dentition. Maculopapular and erythematous rashes, Exfoliative dermatitis, Photosensitivity. Renal Toxicity [Rise in BUN]. Hypersensitivity reactions including urticaria, angioneurotic edema, anaphylaxis, anaphylactoid purpura, pericarditis and exacerbation of systemic lupus erythematosus, drug reaction with eosinophilia and systemic symptoms (DRESS).Bulging fontanels in infants and intracranial hypertension in adults, Hemolytic anemia, thrombocytopenia, neutropenia and eosinophilia. Discoloration of thyroid glands. No abnormalities of thyroid function studies are known to occur. **[For additional information, please refer to the full prescribing information]**

PREPARATION OF SOLUTION:
To prepare a solution containing 10 mg/mL, the contents of the vial should be reconstituted with 10 mL (for the 100 mg/vial container) of Sterile Water for Injection or any of the 10 intravenous infusion solutions listed in detail in complete prescribing information. Dilutions should result in desired concentrations of 0.1 to 1 mg/mL. Concentrations lower than 0.1 mg/mL or higher than 1 mg/mL are not recommended.

Stability
Doxycycline is stable for 48 hours in solution when diluted with Sodium Chloride Injection, USP, or 5% Dextrose Injection, USP, to concentrations between 1 mg/mL and 0.1 mg/mL and stored at 25°C.. Reconstituted solutions (1 to 0.1 mg/mL) may be stored up to 72 hours prior to start of infusion if refrigerated and protected from sunlight and artificial light. To be completed within 12 hours or discarded. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. **[For additional information, please refer to the full prescribing information].**

HOW SUPPLIED:
Doxycycline for Injection, USP, sterile powder, supplied as follows:

Unit of Sale	Strength	Each
NDC 66794-237-41 10 Single-Dose Vials per carton	Doxycycline hyclate equivalent to 100 mg doxycycline per vial	NDC 66794-237-02 20 mL Single-Dose Vial

Store at 20° to 25°C (68° to 77°F) [see USP]

- **Full prescribing information of Doxycycline for Injection, USP can be seen at https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=6a5780a9-4548-427c-972a-ef49fdcbc84d**
- **Adverse events should be reported to Piramal Critical Care at http://pcc-chex.force.com/SiteComplaintForm.**
- **You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.**

Piramal Critical Care

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