

Doxycycline for Post-Exposure Prophylaxis of Anthrax

Emergency Use Instructions for Healthcare Providers

This fact sheet provides instructions for the use of doxycycline for post-exposure prophylaxis (PEP) during an emergency involving anthrax (referred to as Emergency Use Instructions (EUI) fact sheet). Doxycycline is FDA-approved for PEP of inhalation anthrax – to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis* (*B. anthracis*).¹ The Food and Drug Administration (FDA) has also issued an order permitting the emergency dispensing of oral formulations of doxycycline without a prescription during an anthrax emergency to individuals who may have been exposed to *B. anthracis*.²

What is inhalation anthrax?

Anthrax is a serious disease caused by the spore-forming bacterium *B. anthracis*. Inhalation anthrax is the most deadly form of the disease, with a historical mortality rate of approximately 90% for untreated cases. Inhalation anthrax occurs when an individual inhales aerosolized spores. It is not spread from person to person. Early symptoms include fever, chills, fatigue, cough or headache. Later symptoms include shortness of breath, chest pain, confusion or nausea. Symptoms usually occur within 7 days of inhaling anthrax spores, but can occur as soon as 24 hours after exposure or may take up to 6 to 7 weeks to appear (animal data show symptoms can occur more than 50 days after exposure).

Who should **NOT** take doxycycline?

Do not give doxycycline to anyone who is allergic to doxycycline or another antibiotic in the tetracycline class.

What is the usual dose of doxycycline for PEP of anthrax?

The full PEP regimen is 60 days. During an anthrax emergency, recipients may receive an initial 10-day supply to begin doxycycline therapy; public health officials will announce whether recipients need more doxycycline and how to get additional quantities of the drug.

- **Children weighing 76 lbs (35 kg) or more and Adults (≥ 18 years):** Take one tablet (100 mg) by mouth every 12 hours (one tablet in the morning and one tablet in the evening) each day with a full glass of water (with or without food or milk). For those who **cannot swallow tablets**, provide the [crushing and mixing directions](#) (which can also be found by searching “doxycycline crushing instructions” on www.cdc.gov). These instructions are appropriate **only** for 100 mg tablets.
- **Children weighing less than 76 lbs (35 kg):** Weight-based dosing (2.2 mg/kg) every 12 hours (one dose in the morning and one dose in the evening) each day. Provide the [crushing and mixing instructions](#) (which can also be found by searching “doxycycline crushing instructions” on www.cdc.gov). These instructions are appropriate **only** for 100 mg tablets.
- **Children weighing less than 30 lbs (14kg):** Children weighing less than 30 lbs (14 kg) should receive priority for doxycycline oral suspension, dosed by weight every 12 hours (one dose in the morning and one dose in the evening) each day. For convenience, the table below provides dosing by weight-range based on 2.2 mg/kg derived calculation.³ Doses in the table below are specific to doxycycline powder for oral suspension in the 25 mg/5 mL concentration only.
 - Follow the instructions provided with the oral suspension to mix the doxycycline powder with water before dispensing the drug to the recipient. Write the dose on the bottle and mark the dose with a line on the oral syringe.
 - Tell the recipient to shake the oral suspension very well (15 seconds) before each use.

| Weight in pounds (kilograms) | Dose in mL based on 25 mg/5 mL concentration (mg) | Number of 60-mL bottles (25 mg/5 mL concentration) needed for 10-day supply for one child |
|------------------------------|---|---|
| ≤ 5 lbs (≤ 2 kg) | 1 mL (5mg) | ONE (1) Bottle |
| 6–10 lbs (3–4 kg) | 2 mL (10 mg) | |
| 11–15 lbs (5–7 kg) | 3 mL (15 mg) | |
| 16–20 lbs (8–9 kg) | 4 mL (20 mg) | TWO (2) Bottles |
| 21–25 lbs (10–11 kg) | 5 mL (25 mg) | |
| 26–30 lbs (12–14 kg) | 6 mL (30 mg) | |

What are common side effects of doxycycline?

Inform recipients that mild gastrointestinal side effects such as nausea, vomiting, and/or diarrhea, a mild sunburn or a vaginal yeast infection may be experienced but to continue taking doxycycline. If these side effects become severe, over-the-counter or prescription drugs can help to relieve the symptoms.

¹ See the FDA-approved package insert for doxycycline at www.dailymed.nlm.nih.gov and search for doxycycline.

² FDA’s emergency dispensing order applies to all FDA-approved oral dosage forms of doxycycline products for the post-exposure prophylaxis of inhalation anthrax during an emergency involving *B. anthracis*. For details, see www.fda.gov.

³Weight-range dosing table is provided as exact dose calculation (based on 2.2 mg/kg) may not be feasible during an emergency.



What are possible serious side effects of doxycycline?

Tell recipients to **STOP** the doxycycline and get medical help immediately if they develop any of the following:

- Serious allergic/hypersensitivity reactions (anaphylactic and/or severe rashes)
- Severe stomach cramps with high fever or bloody diarrhea (antibiotic-associated diarrhea and pseudomembranous colitis)
- Liver problems (anorexia, jaundice, dark brown or tea-colored urine, pruritus or tender abdomen)
- Pain when swallowing (esophageal ulcers)
- Unusual bleeding or bruising
- Severe headaches, dizziness or double vision

What should recipients avoid while taking doxycycline?

- If a recipient is taking multivitamins, supplements or antacids that contain aluminum, calcium, magnesium, or iron, or drugs containing bismuth subsalicylate, instruct the recipient to take doxycycline at least 2 hours before or 2 hours after taking any of these products.
- Doxycycline can interact with certain drugs like blood thinners (increased blood thinning) or seizure drugs (decreased doxycycline concentration). If a recipient is taking these or other drugs with known interaction with doxycycline, consider changing the dose of these drugs or recommending alternative drugs. For more information on doxycycline drug interactions, please see package insert.

What additional information should be provided to recipients taking doxycycline?

- Tell recipients to take with food or milk if they have gastrointestinal upset with doxycycline. Co-administration of doxycycline with food or milk does not significantly reduce doxycycline absorption.
- Doxycycline is recommended as antimicrobial PEP for anthrax during pregnancy and while breastfeeding, but if taken during the last half of pregnancy or possibly when nursing, infants may have permanent tooth discoloration (yellow-gray-brown) and poor enamel formation. This may also occur in children under 8 years old who take doxycycline.
- Slowed bone growth may occur in children who take doxycycline.
- Doxycycline can cause sun sensitivity. Instruct recipients to use sunscreen and cover exposed skin.
- The effectiveness of birth control pills may be reduced with doxycycline use. Recommend a second form of birth control while taking doxycycline.
- Instruct recipients to keep doxycycline tablets dry and to store them at room temperature (between 68–77°F or 20–25°C).
- If you have been asked to dispense doxycycline with an expired date on the container, please note that FDA is allowing for the use of certain lots of doxycycline beyond the labeled expiration date during an anthrax emergency based on scientific review. For more information, go to the FDA website at www.fda.gov (search for “doxycycline expiration”).
- The Countermeasures Injury Compensation Program (CICP) is a federal program created to help pay for related costs of medical care and other specific expenses for eligible people seriously injured by the administration or use of certain medical countermeasures. Medical countermeasures may include vaccines, medications, devices or other items used to prevent, diagnose or treat the public during a public health emergency or security threat. For more information about CICP, visit www.hrsa.gov/cicp or call: 1-855-266-2427.

Risk-Benefit Statement

Although doxycycline has some potential and serious adverse events, the expected benefit of doxycycline to help prevent disease and death associated with anthrax exposure outweighs these risks.

Available Alternatives

During an anthrax emergency, you will be informed of any alternative antibiotics that are available, such as ciprofloxacin, levofloxacin or amoxicillin. The risks and benefits of available alternative antibiotics will be explained in their own fact sheets.

Reporting Adverse Event or Medication Errors

Report adverse events or medication errors to MedWatch (www.fda.gov/medwatch) by completing a MedWatch Form 3500 or by calling 1-800-FDA-1088.

Give recipients "Anthrax Emergency: How to Take Doxycycline to Prevent Anthrax" instructions.

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