Doxycycline for Post-Exposure Prophylaxis of Anthrax
Emergency Use Instructions for Health Care Providers

The Food and Drug Administration (FDA) has 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 *Bacillus anthracis* (*B. anthracis*), the pathogen that causes anthrax.[1] Doxycycline is FDA-approved for treatment and post-exposure prophylaxis (PEP) of inhalation anthrax - to reduce the incidence or progression of disease following exposure to aerosolized *B. anthracis*.[2] This fact sheet provides instructions for the use of doxycycline during an emergency involving anthrax (referred to as Emergency Use Instructions (EUI) fact sheet). For more information on EUI, visit www.cdc.gov.

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 are fever, chills, fatigue, cough or headache. Later symptoms are 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 greater 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 the rest of the drug. If you have been asked to dispense doxycycline that has an expired date on the container, please be informed that based on scientific review, FDA is allowing the use of certain lots of doxycycline beyond the labeled expiration date during an anthrax emergency. For more information, go to the FDA website at www.fda.gov (search for "doxycycline expiration").

- **Children weighing 76 lbs (35 kg) or more and Adults (≥ 18 years)** should 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 available at www.cdc.gov (search for "doxycycline crushing instructions").
- **Children weighing less than 76 lbs (35 kg)** should take crushed doxycycline mixed with food or drink, dosed by weight every 12 hours (one dose in the morning and one dose in the evening) each day. Provide the crushing and mixing instructions available at www.cdc.gov (search for "doxycycline crushing instructions"). These instructions are appropriate for **tablet** formulations, but **not** for capsules.
- **Children weighing less than 30 lbs (14kg)** should receive priority for using doxycycline oral suspension, dosed by weight (see table below; dose is specific to doxycycline oral suspension in 25 mg/5 mL concentration only) every 12 hours (one dose in the morning and one dose in the evening) each day.

Doxycycline powder for oral suspension (25 mg/5 mL concentration):

- 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)	Number of 60 mL bottles (25 mg/5 mL concentration) needed for 10-day supply for one patient
0–5 lbs (0–2 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)	

---

[1] FDA's issued 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.

[2] For more information about the benefits and risks of doxycycline, please see the FDA-approved package insert for doxycycline available at www.dailymed.nlm.nih.gov and search for doxycycline.

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.

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.
- If a recipient is taking doxycycline with concurrent blood thinners (increased blood thinning) or seizure drugs (decreased doxycycline concentration), consider changing the dose of these drugs or recommending alternative drugs.

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).

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 current, or potential future, 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 effects, the expected benefit of doxycycline to help prevent disease and death associated with anthrax exposure outweigh these risks.

Available Alternatives
During an anthrax emergency, you will be informed of any alternative drugs that are available, such as ciprofloxacin and amoxicillin. The risks and benefits of alternative drugs will be explained in their own fact sheets. For more information, visit www.cdc.gov.

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.

Space Reserved for State/Local Public Health Information