Doxycycline Information Sheet for Health Care Professionals First Responder Voluntary Option to Purchase Anthrax Post-exposure Prophylaxis Antibiotics

Dear Health Care Professional:

Doxycycline is approved by the Food and Drug Administration to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*, including post-exposure prophylaxis (PEP) of inhalational anthrax. First responders can personally purchase a 10-day supply of doxycycline, under a prescription written by you or one of your staff, and to be stored for their own immediate use following a declared emergency. The Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response and the Department of Homeland Security, Office of Health Affairs, encourage those who are authorized to prescribe in their state(s) of practice, to provide these prescriptions to first responders, if deemed medically appropriate. Our recommendations for pre-event availability of antibacterial drugs do not extend beyond the immediate need of first responders at this time.

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. Important information about the current availability of doxycycline can be found at the following site: http://emergency.cdc.gov/HAN/han00349.asp?s_cid=fb_hpot120.

Why is advanced purchase of antibiotic prophylaxis potentially beneficial for first responders and the community?

First responders have the ability to purchase a 10-day supply of antibiotics if prescribed, to be kept for emergency use purposes only. First responders will likely be immediately called upon to perform a variety of tasks within the community during a response to an anthrax attack. Quick access to antibiotic prophylaxis will allow first responders to carry on with their duties without delay. The remaining 50-day supply will need to be obtained from federal stockpiles, in keeping with the plans for the rest of the community.

What are the symptoms of anthrax?

First symptoms are cold-like or flu-like symptoms (e.g., sore throat, mild fever, myalgias). Later symptoms are cough, chest discomfort, shortness of breath, and fatigue. Symptoms usually occur within 7 days of inhaling anthrax germs, but can take up to 6 weeks to appear.

Who cannot take doxycycline?

Doxycycline must not be given to anyone who is allergic to doxycycline, or any other tetracycline.

What is the usual dose of doxycycline for adults?

• The full PEP regimen for inhalational anthrax is 100 mg twice daily for 60 days. Adults (≥ 18 years of age) should take one tablet (100 mg) by mouth in the morning and one tablet in the evening.

What are important patient instructions when providing the prescription?

A fact sheet for doxycycline has been developed and can be provided to the first responder with the prescription.

Doxycycline should be taken on an empty stomach with a full glass of water.

Patients taking antacids, sucralfate (Carafate), didanosine (Videx), or other products containing magnesium, calcium, aluminum, iron, or zinc should take doxycycline at least 2 hours before or 2 hours after taking any of these products.

Doxycycline tablets should be kept dry, and stored at room temperature (between 68°F–77°F or 20°C-25°C).

Doxycycline bottles should be closed tightly and kept away from children and pets. Poison Control Center should be contacted if doxycycline is taken by accident (1-800-222-1222).

Patients should properly dispose of doxycycline when it expires. Information is available at http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicineSafeDisposalofMedicines/ucm186187.htm.

Tell patients to <u>STOP</u> taking doxycycline and get medical help immediately if they get any of the following possible serious side effects:

- Serious allergic/hypersensitivity reactions, which sometimes can be fatal (anaphylaxis and/or rashes)
- Severe abdominal pain with high fever or bloody diarrhea (antibiotic-associated diarrhea and pseudomembranous colitis)
- Yellowing of the eyes or skin or dark-colored urine (liver failure)
- Dysphagia (esophageal ulcers). Tell patients to drink a glass of water after taking doxycycline.
- Unusual bleeding or bruising
- Severe headaches, dizziness, or double vision

But tell patients to keep taking doxycycline if they develop:

- Mild nausea or vomiting, upset stomach, loose stools
- Vaginal yeast infection

What are other possible serious side effects of doxycycline?

- Doxycycline can be used as PEP of inhalational anthrax during pregnancy, but if taken during the last half of pregnancy or when nursing, children may later have teeth problems (permanent discoloration and poor enamel formation).
- Photosensitivity
- Antibiotics may cause birth control pills to not work as well. Recommend use of an additional form of birth control while taking doxycycline.

Reporting adverse events or medication errors:

You should report adverse events or medication errors to MedWatch at www.fda.gov/medwatch, by submitting a MedWatch Form 3500 (available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) or by calling 1-800-FDA-1088.

Contacts:

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