

Flesh-Kincaid: 10.4

Please consider formulating a Patient Information Sheet similar to the example below.

Patient Information Sheet on Home Storage of Doxycycline for Emergency Use for Potential Anthrax Exposure.

This Sheet contains the minimum information necessary to inform you of the significant known and potential risks and benefits of the emergency use of doxycycline to prevent anthrax after a person breathes in anthrax spores. In general, home storage of antibiotics is not recommended. However, we recognize that some individuals may wish to consider home storage of appropriate antibiotics for use during an emergency involving anthrax to reduce their dependency upon Federal, State, and local public health mitigation strategies for delivering antimicrobial drugs to exposed populations, we want to make sure they have information provided below.

What is this supply of doxycycline for?

*This 10-day supply of doxycycline is prescribed for you by your doctor since you have no known allergies to doxycycline or antibiotics called tetracyclines. Your 10-day supply of doxycycline is for home storage for **Emergency Use** to be opened and used only when doxycycline therapy is clearly determined to be necessary by the public health officials or your health care provider due to potential exposure to anthrax spores.*

Inappropriate use of doxycycline may lead to increasing antibiotic resistance (the ability of bacteria to resist the effects of an antibiotic) to more common diseases such as urinary tract infections or pneumonia. Antibiotic-resistant bacteria can quickly spread to family members, schoolmates, and co-workers. When infections (including anthrax) become resistant to antibiotics, they are more difficult to prevent and treat.

Therefore, reserve doxycycline for use only when exposed to anthrax spores and instructed to begin taking it by your doctor or public health officials. Inadvertent (use in a person who has not been exposed to anthrax spores) or inappropriate use (use for treatment of an illness such as a common cold, flu, or other illness where doxycycline would not be appropriate) must be avoided. In such cases, the risks associated with doxycycline use outweigh the benefits. The risks and benefits of doxycycline are described below.

What is anthrax?

Anthrax is a serious infectious disease caused by ***Bacillus anthracis***, a spore-forming bacterium. A spore is a cell, like a seed that is dormant (asleep) but may come to life with the right conditions. Anthrax spores can cause anthrax if they get into a person's lungs (inhalation anthrax), skin (cutaneous anthrax), or stomach (gastrointestinal anthrax) and come to life. People who are exposed to spores inhaled into the lungs are at greatest risk of serious anthrax. Anthrax can be fatal.

How Do You Get It?

Anthrax is not known to spread from one person to another.

Anthrax from animals. People can become infected with anthrax spores by handling products from infected animals or by breathing in the spores from infected animal products (like wool, for example). People also can develop gastrointestinal anthrax by eating undercooked meat from anthrax infected animals.

Anthrax as a weapon. Anthrax spores also can be used as a weapon. This happened in the United States in 2001. Anthrax spores were deliberately spread through the postal system by sending letters with spore containing powder which caused 22 cases of anthrax.

What are the symptoms of anthrax?

Symptoms (warning signs) can occur within 7 days of coming in contact with anthrax spores. However, for inhalation (breathed into the lungs) anthrax, symptoms can take up to 42 days to appear.

- Fever (temperature greater than 100 degrees F). The fever may be accompanied by chills or night sweats.
- Flu-like symptoms.
- Cough, usually non-productive cough (without sputum or phlegm), chest discomfort, shortness of breath, fatigue, or muscle aches.
- Sore throat, followed by difficulty swallowing, enlarged lymph nodes (swollen glands), headache, nausea, loss of appetite, abdominal distress (stomach pain), vomiting, or diarrhea
- A sore, especially on your face, arms or hands, that starts as a raised bump and develops into a painless ulcer with a black area in the center.

If you suspect you have been exposed to anthrax and begin to show symptoms of anthrax, seek medical care immediately. Only people who are exposed to anthrax should take doxycycline from this prescription. Inappropriate use of antibiotics can cause antibiotics to be less effective against more common diseases and can be harmful to you and your community. It is critical that you follow instructions from public health officials and your health care provider.

What are the benefits of doxycycline?

Doxycycline is an antibiotic used to treat bacterial infections in many different parts of the body. However, it does not treat viral infections, such as the common cold or flu. Doxycycline does not treat all bacterial infections.

Doxycycline is approved by the Food and Drug Administration for anthrax of all types [inhaled (lung), skin (cutaneous), and stomach (gastrointestinal)]. Doxycycline reduces the risk of developing severe anthrax when used in people who have been exposed to anthrax spores but have not yet become sick.

In most cases early treatment with antibiotics such as doxycycline can cure cutaneous (skin) anthrax. Even if untreated, eight out of every ten people who only develop cutaneous anthrax survive (do not die). Gastrointestinal (stomach) anthrax is more serious because between one-fourth and more than half of cases lead to death. Inhalation (lung) anthrax is much more severe. In 2001, about half of the people that developed inhalation anthrax died even with being admitted to the hospital and receiving and antibiotic treatment.

If it is confirmed that you have been exposed to anthrax, you will need to continue doxycycline beyond the 10-day supply. Be certain to check with public health officials or your health care provider to find out if additional doses of doxycycline are needed. Other medications in addition to doxycycline may be necessary. **It is very important that you consult with your doctor or public health officials and follow their instructions when beginning your medication.**

What are the risks from doxycycline?

This list is NOT a complete list of side effects reported with doxycycline. Do not take doxycycline if you are allergic to doxycycline or antibiotics known as tetracyclines, or if otherwise instructed by your doctor.

Some possible uncommon but serious side effects of doxycycline include:

- a life-threatening allergic reaction (symptoms are trouble breathing; closing of the throat; swelling of the lips, tongue, or face; hives)
- blood problems (symptoms are unusual bleeding or bruising)
- liver damage (symptoms are yellowing of the skin or eyes, dark urine, nausea, vomiting, loss of appetite, abdominal pain)
- irritation of the esophagus

Other more common, but less serious, side effects include:

- nausea, vomiting, diarrhea
- increased sensitivity of the skin to sunlight
- vaginal yeast infection in females

Other precautions:

- It is very important to tell the doctor the names of **ALL** medicines that you are currently taking even pills bought at the store such as vitamins and antacids. Be sure to tell the doctor if you are allergic to any medicine.
- Doxycycline can make skin very sensitive to the sun which increases the chance of getting severe sunburn. Avoid the sun as much as possible. When outside, wear a long sleeve shirt and hat and always apply sunscreen (30 SPF).
- Birth control pills may not work as well when taking doxycycline. Be sure to use condoms or another form of birth control until you are finished with the entire course of treatment. If you are pregnant or breastfeeding, tell your doctor.
- In women, doxycycline can cause vaginal itching and discharge commonly known as a yeast infection. Tell your doctor if this happens.
- Tell the doctor if you have ever had problems with your liver or kidneys, or if you have frequent heartburn.

If you experience any side effects with doxycycline, consult your doctor before stopping the medication. If you have been exposed to anthrax, the risk of developing serious disease outweighs the risk of side effects from doxycycline and the medication may need to continue. If you stop this medication too soon, you may become ill.

When and how to take doxycycline?

Doxycycline therapy from this prescription should be started **only** when exposure (contact) to anthrax spores is suspected or confirmed by public health officials or your doctor and you are at risk for anthrax disease.

The risks of taking the medicine must be weighed against the good it might do. If a person is exposed to anthrax, the risk of side effects caused by doxycycline may be acceptable because of the seriousness of the disease. However, if a person has not been exposed to anthrax, these risks may outweigh the benefits.

Before taking doxycycline provided by this prescription, be certain that you have been told to do so by public health officials or your doctor because of an exposure to anthrax spores which places you at risk for developing anthrax disease.

Adult dose: Take 1 doxycycline pill (100 mg) every 12 hours with food and at least one full glass of water. Avoid taking antacids (like Tums or Maalox), cholestyramine (Questran), colestipol (Colestid), dairy products (like milk or yogurt) or vitamins 3 hours before or after taking doxycycline.

If you miss a dose, start again taking 1 pill every 12 hours. Do not take 2 pills to make up for the missed dose. Finish all your pills, even if you feel okay, unless your doctor tells you to stop. If you stop this medication too soon, you may become ill. You may need to continue doxycycline beyond the 10-day supply. Be certain to check with public health officials or your health care provider if additional doses of doxycycline and/ or other medications are needed.

**** Special Note for use of doxycycline in Pregnant Women and Breastfeeding Mothers:** There is little known information about side effects from the use of doxycycline during pregnancy and in mothers who are breastfeeding. If the mother of an unborn baby takes doxycycline, staining of the baby's teeth or poor bone development can result. Babies whose mothers are breastfeeding while taking doxycycline may be at higher risk for staining of teeth and diarrhea. There is a remote chance of severe liver disease in some pregnant women.

Children's dose: For children weighing more than 88 pounds and able to swallow pills, give same dose as adult dose [1 pill (100 mg) every 12 hours]. For children weighing less than 88 pounds or those who are unable to swallow pills, follow the directions in the Home Preparation Crushing Instruction Sheet given by your doctor or public health officials. If you have questions about giving the correct dose to a young child, ask your physician or pharmacist **before** giving doxycycline.

**** Special Note for use of doxycycline in Children:** Doxycycline may cause permanent discoloration of the teeth in children younger than 8 years old. This means that their teeth can become grayish in color and this color does not go away. This medicine can also cause bone growth delay in premature infants but this side effect goes away after the medicine is finished.

How to store doxycycline?

Store in a safe, dry place, and at room temperature (68-77F). Keep out of reach of children and pets. Throw away any unused doxycycline when it is out of date or when it is no longer needed. Do not take any doxycycline after the expiration date printed on the bottle.

How can I learn more?

For more information on anthrax and doxycycline therapy, refer to Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) websites.

<http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html>

<http://www.bt.cdc.gov/agent/anthrax/>