

USPS National Postal Model Doxycycline EUA FACT SHEET FOR RECIPIENTS: HOUSEHOLD ANTIBIOTIC KITS AND INDIVIDUAL ANTIBIOTIC KITS

BACKGROUND

This fact sheet provides background about the National Postal Model (NPM) that would be used to respond to a large-scale airborne anthrax attack, including information about Household Antibiotic Kits (kits for eligible United States Postal Service [USPS] participants and household members) and Individual Antibiotic Kits (kits stored at the workplace only for eligible USPS participants). The first part gives background information and important details to be considered while completing the USPS NPM Health Assessment Form. The second part gives detailed instructions about what the USPS participant and their household members should do if they are instructed to take the antibiotics in the kits because of an actual anthrax attack.

The National Postal Model is a system to distribute medications door-to-door in certain emergency situations. This program was developed by security and public health officials and the USPS. USPS employee volunteers (referred to as “USPS participants”) who are participating in a venue-specific adaptation of the National Postal Model are capable of rapidly distributing antibiotics to people exposed to the anthrax bacteria germ to prevent inhalational anthrax disease in people. The U.S. Department of Health and Human Services (HHS) is coordinating the packaging and dispensing of the Household Antibiotic Kits and Individual Antibiotic Kits.

What if I do not want to be a part of the USPS National Postal Model?

The National Postal Model is a volunteer program. There is no penalty for deciding not to participate. If you decide not to participate, you and your household members may receive antibiotics through other ways the government would distribute them to the public to prevent anthrax disease in an anthrax emergency.

IMPORTANT INFORMATION

Read this fact sheet so you will be ready to use your Household Antibiotic Kit or Individual Antibiotic Kit if you are told by a public health official to use it. The HHS Secretary has declared an emergency and the Food and Drug Administration (FDA) Commissioner has issued an Emergency Use Authorization (EUA) to authorize the pre-event storage and post-event use of Household Antibiotic Kits and Individual Antibiotic Kits. The emergency was declared because the Secretary of Homeland Security has determined that there is a significant potential for a domestic emergency involving a heightened risk of attack with anthrax. These actions allowed the Food and Drug Administration (FDA) Commissioner to authorize the distribution and potential use during an emergency of Household Antibiotic Kits and Individual Antibiotic Kits for USPS employee volunteers participating in the National Postal Model and their household members to prevent inhalational anthrax disease.

Doxycycline is a prescription medicine approved by the FDA to prevent and treat infections caused by certain bacteria (germs), including the life-threatening bacterial germ that causes anthrax disease. However, a special legal permission called an FDA Emergency Use Authorization is needed to allow for emergency use instructions, home preparation instructions, and other information to be provided to you. The specific emergency use instructions in this fact sheet are new and so have not been studied in the past. Some persons may have to prepare doxycycline dosages at home from the Household Antibiotic Kit. The home preparation instructions are also new and so have not been evaluated for use in a home setting. You will receive more information and instructions for use at the time of exposure to anthrax. The Emergency Use Authorization may be revoked if the criteria for issuing it are no longer met or other circumstances make revocation appropriate to protect public health or safety.

NOTE: This emergency declaration and Emergency Use Authorization do not mean that an actual anthrax emergency has happened or that there is currently an exposure that can make you sick. If an

actual anthrax emergency happens in your area, you will be instructed by a public official to start taking the doxycycline in the Household Antibiotic Kit or Individual Antibiotic Kit. Do not use the Household Antibiotic Kit or Individual Antibiotic Kit unless you have been told to start using it by a public official. Taking doxycycline at that time can help keep you from getting sick if you have been exposed to certain bacteria germs, such as the one that causes anthrax.

If you have been exposed to the anthrax bacteria germ, are taking doxycycline as directed, and begin to have the symptoms of anthrax described below, get medical care right away. Do not delay getting medical care.

FACTS ABOUT ANTHRAX AND DOXYCYCLINE

What is anthrax?

Anthrax is a serious disease caused by the bacterial germ *Bacillus anthracis*. This bacterial germ forms spores. A spore is a cell that is asleep (inactive) but may become active under the right conditions. Anthrax spores can cause anthrax disease if they get into your lungs, skin, or stomach and become active. People who breathe in (inhale) anthrax spores are at risk of getting serious inhalational anthrax disease. Taking antibiotics soon after exposure to anthrax germs may prevent getting anthrax disease. Anthrax disease can cause death even if you are treated. Anthrax disease affects children and adults in much the same way. However, children may be more likely than adults to suffer bad effects from some of the antibiotics used to prevent the disease.

What are the symptoms of breathing in (inhalational) anthrax?

The first symptoms of breathing in (inhalational) anthrax are cold-like or flu-like symptoms and can include a sore throat, mild fever, and muscle aches. Later symptoms include cough, chest discomfort, shortness of breath, tiredness, and muscle aches. (*Caution:* Do not assume that just because a person has cold or flu symptoms that they have breathed in, i.e., inhalational, anthrax.)

If I get anthrax, will I make others sick with anthrax?

No, anthrax is not a disease where there is person-to-person spread like the flu.

What is doxycycline?

Doxycycline is an antibiotic medicine that is used to treat infections caused by certain bacterial germs, including life-threatening germs such as anthrax.

Who should not take doxycycline?

Do not take doxycycline if you:

- Are allergic to doxycycline
- Are allergic to any antibiotic known as a tetracycline. Ask your doctor if you are not sure. A partial list of tetracycline drugs includes:
 - Chlortetracycline (Aureomycin)
 - Demeclocycline (Declomycin)
 - Doxycycline (Adoxa, Atridox, Bio-Tab, Doryx, Doxychel, Doxy, Monodox, Periostat, Vibra-Tabs, Vibramycin)
 - Minocycline (Arestin, Dynacin, Minocin, Vectrin)
 - Oxytetracycline (Terak, Terra-Cortril, Terramycin, Urobiotic-250)
 - Tetracycline (Achromycin V, Bistracycline, Sumycin, Tetrex, Topicycline, Helidac)

How do I report side effects or problems with using the medicine in the Household Antibiotic Kit or Individual Antibiotic Kit?

For life-threatening emergencies, call 911. If you take doxycycline and if you experience any adverse event or a medication error, contact your personal physician or emergency department. You or your personal physician should report side effects or medication errors by any of these methods:

- Reporting to MedWatch via the MedWatch website at: www.fda.gov/medwatch; www.fda.gov/medwatch;
- Submitting a MedWatch Form 3500 with the report (one is included with the information in your Household Antibiotic Kit or Individual Antibiotic Kit); it is also available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf); or
- Reporting to MedWatch using the “800” number: 1-800-FDA-1088.

When you report side effects or errors to your personal physician and via MedWatch, state that you have used a “doxycycline hyclate tablet emergency kit” received under the “USPS-NPM EUA” (United States Postal Service National Postal Model Emergency Use Authorization) by including in the description of the event the abbreviations “USPS-NPM EUA” or the words “USPS-NPM Emergency Use Authorization.” In addition, report adverse effects to a designated National Disaster Medical System (NDMS) clinician at 800-*place holder*.

What if I do not take the antibiotic in the kit when told to do so?

It is your choice to take the preventative antibiotic or not. Note that Postal workers will not be allowed to be a part of the USPS National Postal Model if they do not take the antibiotic following an anthrax event. If you do not take the antibiotic in the Household Antibiotic Kit or Individual Antibiotic Kit, you may develop or die from severe anthrax disease if you are exposed to the anthrax germ.

Are there other medicines for preventing or treating anthrax?

Other FDA-approved antibiotic medicines approved by the FDA to prevent or treat anthrax that are not a part of the Household Antibiotic Kit or Individual Antibiotic Kit include: ciprofloxacin, levofloxacin, and penicillin G procaine. These antibiotic medicines require a prescription from your doctor and are not part of the EUA. Each of these other medicines, like all medicines, can have side effects. Ciprofloxacin and levofloxacin can cause adverse effects including: tendon rupture, convulsions, hallucinations (seeing things that are not there), depression, abnormal heartbeats, and a severe type of diarrhea. Penicillins can cause a number of adverse effects including serious allergic reactions, skin rashes, and a severe type of diarrhea.

BioThrax (Anthrax Vaccine Adsorbed) may be given to protect adults ages 18 to 65 years old who may come in contact with animal products, such as hides, hair, or bones from areas where anthrax germs are found, and that may be contaminated with anthrax germ (*Bacillus anthracis*) spores. The vaccine may also be given to people such as veterinarians and laboratory workers whose job may involve touching animals or other materials that may be infected. It is not clear if BioThrax works or is safe for people after they have been contaminated with anthrax germ (*Bacillus anthracis*) spores. Side effects of BioThrax are muscle or joint aches, headache, tiredness, chills, rashes, and low fever. BioThrax is not covered in this Emergency Use Authorization because the vaccine does not provide protection for several weeks. If you have questions about these other medicines, talk with your doctor.

What if I use other medicines?

Doxycycline and other medicines may affect each other, causing side effects. Doxycycline may affect the way other medicines work and other medicines may affect how doxycycline works. The doses of some medicines may need to be changed while you take doxycycline. You should prepare a list of the medications that you or your household members take, including prescription and non-prescription medicines, vitamins, and herbal supplements. It is especially important to discuss with the medical screener if anyone takes:

- medicine to thin your blood known as warfarin (Coumadin, Jantoven). People who take a blood thinner (anticoagulant therapy) may need a different dose when taking doxycycline.
- seizure medicine such as phenobarbital, phenytoin (Dilantin), fosphenytoin (Cerebyx), or carbamazepine (Carbatrol, Eptol, Equetro, Tegretol, or Teril)
- isotretinoin (Accutane) or acitretin (Soriatane)
- methotrexate

- oral contraceptives (birth control pills may not work as well when you take doxycycline; use condoms or another form of birth control to prevent pregnancy until you finish taking doxycycline.)
- lithium
- ciprofloxacin, levofloxacin, or other quinolone antibiotics

How can I learn more?

The Department of Health and Human Services, in collaboration with USPS and the public health authority, will make you aware of any important new information found during the time of emergency use of the Household Antibiotic Kit or Individual Antibiotic Kit.

WHAT SHOULD I CONSIDER ABOUT DOXYCYCLINE AFTER I RECEIVE MY HOUSEHOLD ANTIBIOTIC KIT OR INDIVIDUAL ANTIBIOTIC KIT?

Upon receiving a Household Antibiotic Kit or Individual Antibiotic Kit:

As soon as you receive a Household Antibiotic Kit or Individual Antibiotic Kit, review the list of drugs directly above. If you currently are taking any of them, ask your regular health care provider whether you should continue to take it/them during an emergency for which public health authorities instruct you to take the doxycycline in your kit. Also ask your health care provider if there are additional measures you should take if you are recommended to continue with your ongoing medications as well as the doxycycline.

Upon a change in health status after receiving a Household Antibiotic Kit or Individual Antibiotic Kit:

If, after you receive a kit, you experience any of the following changes in health status, ask your regular health care provider whether you should take the doxycycline in your Household Antibiotic Kit or Individual Antibiotic Kit during an emergency for which public health authorities instruct you to do so:

- develop a serious liver or kidney problem
- develop an allergy to doxycycline or tetracycline
- become pregnant
- are breast feeding.

Upon starting a medication on the list above:

If, after you receive a Household Antibiotic Kit or Individual Antibiotic Kit, you begin taking any of the drugs listed above, ask your regular health care provider whether you should continue to take it/them during an emergency for which public health authorities instruct you to take the doxycycline in your kit.

How should I store doxycycline?

- Store doxycycline between 68°F and 77°F (20°-25°C).
- Keep doxycycline in the container it comes in.
- Keep doxycycline dry.
- Keep the container closed tightly.
- Keep doxycycline and all medicines out of the reach of children.
- A good storage place in many homes is on an upper shelf in a bedroom closet that is kept off-limits to children.

How should I dispose of the doxycycline when it reaches its expiration date, when I change jobs or move, when I no longer want to be a part of the USPS National Postal Model, or when the emergency ends?

You should contact *Place Holder* to get information on how to return your Household Antibiotic Kit or Individual Antibiotic Kit for proper disposal.

DURING AN ANTHRAX EMERGENCY: USE OF HOUSEHOLD ANTIBIOTIC KITS OR INDIVIDUAL ANTIBIOTIC KITS

The following information should be reviewed prior to taking the medicine during an emergency caused by anthrax exposure. If an actual anthrax emergency happens in your area, you will be instructed by a public health official to start taking the doxycycline in the Household Antibiotic Kit or Individual Antibiotic Kit.

***** Do not use your kit unless you have been told to start by a public health official. *****

This kit contains only enough medicine for 10 days. This is not a full course of preventive therapy. You need to take a full course of medication, which is usually 60 days. It is important to complete the full course of medication to help protect you from getting anthrax disease. Public officials will announce where you can get the rest of the medicine that you and your household members will need to complete your preventive therapy.

You have received a Household Antibiotic Kit or Individual Antibiotic Kit containing a 10-day supply of doxycycline in the event you are exposed to the anthrax germ, which can be deadly. You do not have to take this drug, but taking doxycycline (when told to start taking it by a public health official) to treat anthrax will reduce your risk of getting sick and dying. If possible, you may want to discuss with a health care professional the benefits and risks described in this fact sheet, or any available alternatives.

The full course of treatment is usually 60 days. Public officials will announce where you can get the rest of the medicine.

What is anthrax?

Anthrax is a serious disease caused by the germ *Bacillus anthracis*. People who breathe in (inhale) anthrax germs are at risk of serious illness, **including death**. However, you can't get anthrax from another person.

- First symptoms are cold-like or flu-like symptoms, e.g., a sore throat, mild fever, muscle aches.
- Later symptoms are cough, chest discomfort, shortness of breath, tiredness, muscle aches.

Symptoms usually occur within 7 days of inhaling anthrax germs, but can take up to 42 days to appear. See a doctor immediately if you have symptoms.

What is doxycycline?

Doxycycline is a prescription drug approved by the Food and Drug Administration (FDA) to prevent anthrax. Federal authorities have specially authorized certain uses of doxycycline, including use with associated with kits and emergency information, for this emergency situation. If you take doxycycline as directed and begin to feel sick anyway, **get medical care right away**.

How do I take doxycycline?

- Adults and those 8 years and older and children 89 lbs (40 kg) or more – take one pill (100 mg) in the morning and one pill in the evening on an empty stomach with a full glass of water.
- If you get an upset stomach or indigestion, take it with some food or milk. Be sure to drink lots of fluids.
- Children under 89 lbs (40 kg) and adults who can't swallow a pill – **Follow the directions provided to you on crushing and mixing doxycycline.**
- If you miss a dose, take only the next scheduled dose – **Do not take two doses at one time.**
- Doxycycline may not work as well when taken with some medicines. Take it 2 hours before or 2 hours after taking: antacids; multivitamins or supplements with calcium, iron, magnesium, or sodium bicarbonate; Sucralfate (Carafate); Colestipol (Colestid); cholestyramine; Didanosine; Bismuth subsalicylate (Helidac) (Pepto Bismol) (Kaopectate); or any other products to treat indigestion, nausea, or diarrhea.
- Doxycycline may affect dosing of certain blood thinners or seizure medicines; call your doctor if you are on these medications.
- Keep the pills dry; store them between 68–77°F (20–25°C).
- Keep containers out of the reach of children and pets; call the poison control center if accidental ingestion occurs (1-800-222-1222).

Who should **NOT** take doxycycline?

Do not take doxycycline if you have had a severe allergic reaction to doxycycline or another tetracycline drug. If you or other household members have begun taking new drugs since you received your kit and have not already consulted your regular health care

provider, ask the provider—or report to one of the local public health agency medication dispensing centers—to determine whether to continue to take those medications and whether there are additional health measures you should follow.

STOP taking the medicine if you get any of these serious, but rare, side effects; get medical help right away (go to the Emergency Room or call 911):

- swelling of the tongue, hands, or feet
- closing of the throat
- trouble breathing
- severe itching or rash, especially hives and welts
- severe stomach cramps with high fever or bloody diarrhea
- yellowing of the eyes or skin or dark-colored urine
- pain when swallowing
- unusual bleeding or bruising
- severe headaches, dizziness, or double vision

Keep taking the medicine if you have:

- mild nausea or vomiting, upset stomach, loose stools
- vaginal yeast infection

Are there other possible severe side effects?

- Serious liver problems (liver failure)
- Sensitivity to the sun
- Discolored teeth, poor tooth enamel in children under the age of 8 or when taken by their mothers during the last half of pregnancy or while nursing
- Slowed bone growth in children
- Birth control pills stop working. Use another form of birth control until you finish taking all of your doxycycline

What is unknown about the emergency use of doxycycline?

The benefit of providing you with emergency access to an initial supply of doxycycline is expected to outweigh the risks. However, it is unknown how well these emergency instructions will be used, how these kits will be stored and used, or how many individuals will receive the full, 60-day course of post-exposure prophylaxis (PEP).

How do I report side effects or errors?

Tell your doctor right away. You or your personal physician may report side effects or medication errors by:

- Reporting to MedWatch via the MedWatch website at: www.fda.gov/medwatch;
- Submitting a MedWatch Form 3500 with the report (one is included with the information in your kit); it is also available at http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf); or
- Reporting to MedWatch using the “800” number: 1-800-FDA-1088.

When you report side effects or errors to your personal physician and via MedWatch, state that you have used a “doxycycline hyclate tablet emergency kit” received under the “USPS-NPM EUA” (United States Postal Service National Postal Model Emergency Use Authorization) by including in the description of the event the abbreviations “USPS-NPM EUA” or the words “USPS-NPM Emergency Use Authorization.” Adverse events and medication errors must be documented and reported promptly (within 15 days) to MedWatch.

Reports of adverse effects should also be made to the designated NDMS clinician at: **800-Place Holder**.

CONTACTS: If you have any questions, please contact XXXXX (*placeholder for HHS/OPEO/NDMS specific contact information*). The Department of Health and Human Services (HHS), in collaboration with USPS and the public health authority, will make you aware of any important new information found during the time of emergency use of the Household Antibiotic Kit or Individual Antibiotic Kit.