Anthrax Emergency: How to Take Amoxicillin to Prevent Anthrax Fact Sheet for Recipients

During an anthrax emergency, you may be given a medicine called **amoxicillin** (sounds like **a-mox-i-SIL-in**) because you **may** have breathed in anthrax germs. These germs can be **deadly**. Taking certain medicines called antibiotics (like amoxicillin) reduces your chance of getting sick and dying. **People who may have breathed in anthrax germs should take antibiotics for 60 days**. If you started taking another medicine (like ciprofloxacin or doxycycline) to prevent anthrax, and are now being switched to amoxicillin, it is important that you take amoxicillin for as long as you are directed. To reduce your chance of getting sick, avoid stopping early. Public health officials will provide information on who should get this medicine. If you have questions, talk to a doctor or healthcare provider about taking amoxicillin.

What is anthrax?

Anthrax is a serious disease that can be deadly. You can get sick if you breathe in anthrax germs. **You cannot get anthrax from another person who has anthrax**.

- Early on, you could have any of the following symptoms: fever, chills, tiredness, cough or headache.
- Later, you could develop shortness of breath, chest discomfort, confusion or nausea. Symptoms usually start within 7 days of breathing in anthrax germs, but can start within 24 hours or take up to 7 weeks. See a doctor right away if you have symptoms. If you take amoxicillin as directed and begin to feel sick or show any of the symptoms mentioned above, get medical care right away.

What is amoxicillin?

Amoxicillin is a prescription antibiotic approved by the Food and Drug Administration (FDA) to treat various infections, and has been used safely for many years, including in children. It is currently not FDA-approved for anthrax. But scientific studies have shown that it may protect against anthrax disease. Therefore, FDA has authorized emergency use of amoxicillin to help prevent anthrax during this anthrax emergency. Amoxicillin gives another choice for children and certain adults who cannot tolerate or have side effects to other medicines (like ciprofloxacin and doxycycline) to prevent anthrax. If you were given amoxicillin that has an expired date on the container, please note that FDA is allowing the use of certain lots of amoxicillin beyond the expiration date on the container based on FDA's scientific review. For more information, go to the FDA website at www.fda.gov (search for "amoxicillin expiration").

Who should **NOT** take amoxicillin?

Do **NOT** take amoxicillin if you have had an allergic reaction to penicillin, amoxicillin or other penicillin-like drug (such as ampicillin, oxacillin, dicloxacillin, piperacillin, ticarcillin, or nafcillin). A severe reaction may include closing of the throat, trouble breathing, or swelling of the lips, tongue or face. Talk to your doctor or public health official about other medicines available to prevent anthrax.

How do I take amoxicillin or give amoxicillin to my child?

Amoxicillin is taken by mouth, either as a pill or liquid. Liquid forms will be prioritized for infants and very young children during an emergency.

For children who weigh 88 pounds (40 kg) or more and adults aged 18 years or older:

- > Take 2 pills (500 mg each) in the **morning** with a full glass of water (with or without food)
- Take 2 pills (500 mg each) at noon with a full glass of water (with or without food)
- Take 2 pills (500 mg each) in the **night** with a full glass of water (with or without food)

Doses should be taken three times (8 hours apart) each day for as long as directed.

If you or your child cannot swallow pills, follow the instructions in <u>How to Open Amoxicillin Capsules and Mix with Food for Those Who Cannot Swallow Pills</u> (which can also be found by searching "amoxicillin mixing instructions" on <u>www.cdc.gov</u>).

For children weighing less than 88 pounds (40 kg), the dose is determined based on the child's weight:

- Follow the instructions provided with liquid amoxicillin or amoxicillin pills. Give your child the right dose in the morning, noon, and night (8 hours apart) each day for as long as directed.
 - If your child is given pills and has trouble swallowing them, follow the instructions in <u>How to</u> Open Amoxicillin Capsules and Mix with Food for Those Who Cannot Swallow Pills.
 - If you received bottles of amoxicillin powder to mix at home, follow the instructions in the Amoxicillin Liquid Preparation Instructions.
- Do not skip doses. If you do miss a dose, do NOT take 2 doses at once. Take the next dose as scheduled.
- People with severe kidney problems may need a different dose. Discuss this with your doctor.
- If you get an upset stomach when you take the medicine, take it with food.
- Keep the pills dry in a cool, dry place (at or below 68°F or 20°C). Amoxicillin powder for oral suspension (400 mg/ 5 mL) should be stored at or below 25°C (77°F). Amoxicillin liquid should be stored in a tight container in the refrigerator (preferred) or at room temperature for up to 14 days.
- Keep amoxicillin away from children and pets. Call the poison control center if children or pets consume the medicine by accident (1-800-222-1222).

How long do I take amoxicillin for?

If you started with a different antibiotic to prevent anthrax (such as doxycycline or ciprofloxacin) and now switching to amoxicillin, you will need to take amoxicillin until you complete a **total of 60 days** of antibiotics. If you are also receiving anthrax vaccine (BioThrax®), it is important to take amoxicillin for as long your healthcare provider tells you. Healthy adults 18 to 65 years of age can stop taking antibiotics 42 days after the first dose of the anthrax vaccine or 2 weeks after the last dose, whichever happens later. Older adults, pregnant women, and people with certain conditions should take antibiotics for 60 days.

What are common side effects of amoxicillin?

During the first few days of taking amoxicillin you might have an upset stomach, diarrhea, nausea, or vomiting. Vaginal yeast infections may also occur while taking amoxicillin. **KEEP** taking the medicine if you have if these symptoms, but let your doctor know if they continue or become very bad.

What are possible serious side effects of amoxicillin?

Serious side effects from amoxicillin are rare. **STOP** taking the medicine and get medical care right away (go to the emergency room or call 911) if you have:

- Closing of the throat or trouble breathing
- Swelling of the face, lips, tongue, or throat
- Severe itching or rash, especially hives or wheals (red, swollen bumps on the skin)
- Severe stomach cramps with fever or bloody or watery diarrhea
- Seizures, dizziness, tremors, or serious mood changes
- Yellowing of eyes or skin or dark brown or tea-colored urine
- Unusual bleeding or bruising
- Excessive tiredness or lack of energy

This is not a complete list of all side effects that may occur. If you have questions about side effects, contact your healthcare provider.

What are the risks if I am pregnant or breastfeeding?

Taking amoxicillin for a short time is not likely to cause problems for an unborn baby. It is unknown what the effects are on pregnant women taking amoxicillin for a long time, but it is expected to have similar effects as taking amoxicillin for a short time. Taking amoxicillin should reduce your risk of getting anthrax, which can be deadly. Amoxicillin passes into breast milk, but you can continue to breastfeed while taking the medicine.

What if I am taking other medicines?

- Be sure to tell your doctor about any prescription and over-the-counter medications you use, especially if you are taking any of the following medications:
 - Probenecid (also called Probalan)

- ➤ Blood thinners such as heparin, Coumadin (warfarin), Xarelto (rivaroxaban), Pradaxa (dabigatran), Eliquis (apixaban)
- Methotrexate (also called Rasuvo, Trexall, or Otrexup)
- > Any type of antibiotic

What else do I need to know about amoxicillin?

- Brown, yellow, or gray tooth discoloration has previously occurred in some patients, especially children, taking amoxicillin, but is rare and can be prevented by brushing or dental cleaning.
- Birth control pills may not work as well while you take amoxicillin. Use another form of birth control until you finish taking all of your amoxicillin.
- Tell your doctor if you are or become pregnant or are breastfeeding.
- If you receive anthrax vaccine (BioThrax®), your healthcare provider will tell you how long you need to take amoxicillin.

What other antibiotics can I take instead of amoxicillin?

Public health officials will tell you if other antibiotics (such as doxycycline, ciprofloxacin, or levofloxacin) are available. The risks and benefits of other available antibiotics will be explained in separate instructions.

Risk-Benefit Statement

Although amoxicillin has some potential and serious side effects, the expected benefit of amoxicillin in helping to prevent disease and death associated with anthrax exposure outweighs these risks.

How do I report side effects or medication errors?

Tell your doctor right away and report side effects or medication errors to FDA MedWatch at www.fda.gov/medwatch or 1-800-FDA-1088.

A federal program called the Countermeasures Injury Compensation Program (CICP) may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by some medicines or vaccines. To learn more about this program, visit www.hrsa.gov/cicp or call 1-855-266-2427 (toll-free).

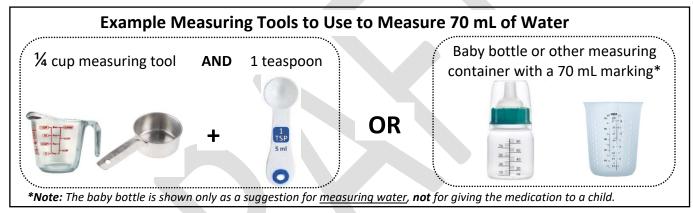
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At-Home Mixing Instructions for Amoxicillin Oral Suspension 100 mL Bottle with 400 mg/5 mL dose concentration

These instructions show you how to prepare any 100 mL bottle of 400 mg/5 mL amoxicillin powder regardless of the manufacturer's name on the bottle. The label on your amoxicillin powder bottle may tell you to measure a different amount of water than what is recommended in these instructions. This small difference will not affect how well the medicine works.

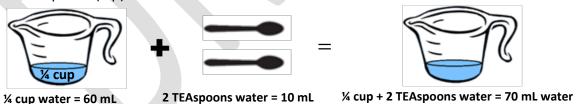
Step 1. Gather the supplies you need.

- Bottle of Amoxicillin Powder for Oral Suspension:
- → Make sure the bottle you have says '400 mg / 5 mL' on the label. If it has a different number listed, do not use these instructions and talk to your healthcare provider about how much to take.
- Drinkable water (70 mL of distilled or bottled water)
- Measuring tools to accurately measure and pour 70 mL of water:
 - o Common household kitchen tools like one-quarter (¼) cup and a 1 teaspoon, **OR** a measuring container with a marking for 70 milliliters (mL). Clean before use.
 - A bowl or cup with a spout to hold and help pour the measured water into the amoxicillin powder bottle OR a funnel to pour the measured water into the powder bottle



Step 2. Measure out 70 mL of drinkable water and pour the water into a container.

• Option A: If using <u>a measuring cup and teaspoon to measure the water</u>, measure one-quarter (1/4) cup and 2 teaspoons (tsp) of water. You now have 70 mL of water.



OR

 Option B: If using <u>a baby bottle or measuring container with a 70 mL marking</u>, fill the baby bottle or container with 70 mL of water.

Step 3. Add water in two parts into the amoxicillin powder bottle and mix.

- 1. To help loosen the power, turn the amoxicillin powder bottle upside down and back to upright. Lightly tap the sides and bottom of the bottle to help prevent the powder from sticking to the sides when water is added. Open the cap and remove the inner seal, if present.
- 2. Add about half (about 35 mL) of the measured water (from **Step 2**) to the amoxicillin powder bottle.
- 3. Screw the cap back completely on the amoxicillin bottle and shake vigorously for about 15 seconds.
- 4. Remove the cap of the amoxicillin bottle and add the rest of the water. Screw the cap back completely on the amoxicillin bottle and shake vigorously again (about 15 seconds). Make sure all the powder gets mixed with the water. There should be no visible dry powder.
 - If the powder sticks to the sides or is not completely mixed, tap the bottle firmly using the palm of your hand until no clumps are visible. **Do not** put a utensil into the bottle to stir since this will not help to mix it and may accidentally cause some of the medicine to be removed. Shake the bottle before giving each dose.

You now have liquid amoxicillin (reconstituted) in the bottle ready for use.

Step 4. Write the expiration date and store the reconstituted amoxicillin bottle.

- 1. Figure out the expiration date by counting 14 days from the day you mixed the powder with water (reconstituted) and write that date on the bottle. For example, if you mixed the amoxicillin powder with water on January 1, write January 15 on the bottle.
 - **Do not use** any medicine remaining in the bottle after the expiration date. Start a new bottle and follow the mixing instructions above. Throw away the expired bottle.
- 2. Store the mixed bottle in a refrigerator and out of the reach of children. Keep the bottle tightly closed.

Step 5. Give the correct dose.

- 1. **Shake** the bottle very well before each dose.
- 2. Find your child's weight in the table below. Select the correct dose for the measuring device you are using (teaspoon or milliliter).

Amoxicillin Dose using Oral Suspension Strength 400 mg/5 mL

Weight (lbs)*	Dose for teaspoon (tsp)	Dose for milliliter (mL)	
	measuring device	measuring device	
< 8 lbs	1/4 tsp	1.25 mL	
8 – 11 lbs	1/3 tsp	1.7 mL	
12 – 17 lbs	1/2 tsp	2.5 mL	
18 – 26 lbs	3/4 tsp	3.75 mL	
27 – 35 lbs	1 tsp	5 mL	
> 35 lbs	See Method 2: How to Prepare Amoxicillin with Food		

^{*}Weight-range dosing is provided since exact dose calculations (based on 25 mg/kg) may not be feasible during an emergency.

3. Give the dose using a teaspoon (tsp) measuring device or an oral dosing syringe or medicine cup with milliliters (mL) marked.

Be sure to give the dose three times (8 hours apart) each day as long as instructed.

In an Emergency: How to Open Amoxicillin Capsules and Mix with Food for Those Who Cannot Swallow Pills

During a public health emergency, you might need to prepare emergency doses of amoxicillin for children and adults who cannot swallow pills. These instructions show you how to remove the powder inside the amoxicillin 500 mg capsules and mix the powder with food.

Give the **right amount** of medicine **every 8 hours** (morning, noon, and night) **each day** for as long as directed. **Children younger than 1 year of age should be given amoxicillin <u>oral suspension</u> (see At-Home Mixing Instructions for Amoxicillin Oral Suspension**) **instead of using the instructions below** because measuring the right amount of medicine needed from a capsule is not feasible for this age group. Follow the directions depending on your child's weight.

Step A: Get the following supplies:

- The amoxicillin capsules (500 mg each) required for your child's dose. For children weighing 44 lbs or less, you will need 1 amoxicillin capsule. For children weighing 45 lbs or more, you will need 2 amoxicillin capsules.
- 1 metal spoon
- 1 tablespoon
- 2 small glass or metal bowls
- Food for mixing with the amoxicillin. Sweet foods with a thick, pudding-like consistency such as chocolate pudding, sweet yogurt, or baby food will cover the taste of the medicine best.

Step B: Determine the amount of amoxicillin powder needed

- 1. Find **your child's weight** on the chart below. Weight is better, but if you don't know how much your child weighs, find your child's age on the chart and follow instructions for the weight that is listed to the left of your child's age.
- 2. Follow the row of your child's weight across to the column titled "Amount of Powder from Capsule Needed for Dose". This column will tell you how much amoxicillin powder to use for your child's dose.

Child's Weight	Child's Age	Number of Capsules Needed	Dose of Amoxicillin	Amount of Powder from Capsule Needed for Dose
15 – 22 lbs	*	1 capsule	250 mg	Give half (1/2) the powder from 1 capsule
23 – 44 lbs	1 – 5 ½ years	1 capsule	500 mg	Give all the powder from 1 capsule
45 – 66 lbs	6 – 9 ½ years	2 capsules	750 mg	Give all the powder from 1 capsule and half (1/2) the powder from another capsule
67 lbs or more	10 years or older	2 capsules	1,000 mg	Give all the powder from 2 capsules

^{*}Children less than 1 year of age should receive amoxicillin suspension

Step C: Open the first capsule required for your child's dose

- 1. Take one amoxicillin capsule and hold it over one of the bowls (**Bowl A**). Hold each end of the capsule between the thumb and index finger.
- 2. Carefully pull the capsule open by twisting the ends of the capsule in opposite directions while pulling apart firmly.
 - a. Be careful not to apply too much pressure to the capsule (this may cause the capsule to break into several pieces). If the capsule breaks into pieces, throw the capsule and contents of the bowl away and start over (clean the bowl and dry it thoroughly before using it again).
- 3. After twisting the capsule open, pour the powder from the capsule into the bowl, tapping each end of the capsule until all the powder has been removed.
- 4. Using the back of a metal spoon, crush the powder until it is smooth and there are no big pieces remaining (this may take about 1–2 minutes). You now have 1 crushed amoxicillin capsule in Bowl A.

Step D: Prepare the powder required for your child's dose

1. Look at the titles on the four boxes below. **Find the box that matches the amount of amoxicillin powder needed for your child's dose** determined in Step B. Using the powder you just crushed in Bowl A, follow the directions in the appropriate box below that corresponds to the dose needed.

IF YOUR CHILD WEIGHS 15–22 LBS, EACH DOSE IS ONE-HALF (½) CAPSULE (250 MG):

- You will need only half the powder from this capsule in Bowl A. Using the spoon, gather all of the crushed powder into the middle of Bowl A.
- Separate out half of the powder to one side of the bowl and the other half of the powder to the other side of the bowl.
- Use the spoon to scoop up half of the amoxicillin powder and put it into another bowl (Bowl B). You now have a 250 mg dose in each bowl.
- You now have the amount of amoxicillin required for your child's dose (250 mg) in Bowl A. Using the powder in Bowl A, proceed to Step E. Save the powder in Bowl B for Step F.

IF YOUR CHILD WEIGHS 23–44 LBS, EACH DOSE IS 1 CAPSULE (500 MG):

- Bowl A contains 1 capsule, which is the amount required for your child's dose.
- You now have the amount of amoxicillin required for your child's dose (500 mg) in Bowl A. Using the powder in Bowl A, proceed to Step E.

IF YOUR CHILD WEIGHS 45–66 LBS, EACH DOSE IS ONE AND ONE-HALF (1 AND ½) CAPSULES (750 MG):

- You will need only half the powder from this capsule in Bowl A. Using the spoon, gather all of the crushed powder into the middle of Bowl A.
- Separate out half of the powder to one side of the bowl and the other half of the powder to the other side of the bowl
- Use the spoon to scoop up half of the amoxicillin powder and put it into another bowl (Bowl B). You now have a 250 mg dose in each bowl. Set Bowl B aside.
- Take Bowl A. You need to add one more capsule to Bowl A to get your child's dose. Using another amoxicillin capsule, repeat Step C to open another capsule and add it to Bowl A. Make sure to repeat all parts of Step C, including crushing the capsule with a spoon. Once you have completed this, you now have 1 and ½ crushed capsules in Bowl A.
- You now have the amount of amoxicillin required for your child's dose (750 mg) in Bowl A. Using the powder in Bowl A, proceed to Step E. Save the powder in Bowl B for Step F.

IF YOUR CHILD WEIGHS 67 LBS OR MORE, EACH DOSE IS 2 CAPSULES (1,000 MG):

- Bowl A contains 1 capsule, so you need to add one more capsule to this bowl to get your child's required dose.
- Using another amoxicillin capsule, repeat Step C to open another capsule and add it to Bowl A. Make sure to repeat all parts of Step C, including crushing the capsule with a spoon. Once you have completed this, you now have 2 crushed capsules in Bowl A.
- You now have the amount of amoxicillin required for your child's dose (1,000 mg) in Bowl A. Using the powder in Bowl A, proceed to Step E.

Step E: Mix the amoxicillin powder with food and give to your child

1. Add 2–3 tablespoons of a thick, sweet food to the amoxicillin powder in Bowl A and mix well before feeding the mixture to your child. Be sure your child eats all the mixture to receive the correct dose.

Step F: Store the powder remaining in Bowl B**

- **This step is only applicable if your child's dose was $\frac{1}{2}$ capsule or 1 and $\frac{1}{2}$ capsule
- 1. Cover the powder remaining in Bowl B with plastic wrap or aluminum foil and label it with your child's name, "250 mg", and the date and time of the next dose. If your child's dose is one-half (½) capsule, then this amount will be enough for your child's entire next dose. If your child's dose is one and one-half (1 and ½) capsules, then you will need to add one more capsule (500 mg) to the saved powder to make your child's next dose (750 mg).
- 2. Store the bowl at room temperature, out of the reach of children and pets. You can keep the powder stored this way to use for the next dose. If it is not used for the next dose, throw it away.