

Plague Emergency: Ciprofloxacin to Treat Plague

Emergency Use Instructions for Recipients

During a plague emergency, you will be treated with a medicine called **ciprofloxacin** (sip-row-FLOX-a-sin) because you are sick from being exposed to **the germs that cause** plague. These germs can be **deadly**. Treatment with this medicine reduces your chance of getting very sick and dying.

What is plague?

Plague is a serious disease caused by a germ called *Yersinia pestis*. The symptoms of plague include: fever, weakness, chills, chest pain, abdominal pain, cough, difficulty breathing and coughing up bloody mucus. Symptoms can develop as soon as 1 day and up to 6 days after exposure to the plague germ. When this germ infects the lungs, it can be spread from person to person through the air, usually through coughing and close contact with a person who is sick. Without treatment for plague, you may die. **Early treatment with antibiotics may greatly reduce the risk of dying from plague.**

What is ciprofloxacin?

Ciprofloxacin is an antibiotic approved by the Food and Drug Administration (FDA) to treat plague. FDA is allowing certain uses of ciprofloxacin during a plague emergency. You may be given ciprofloxacin that has passed its expiration date. Be informed that FDA is allowing the use of certain lots of ciprofloxacin beyond the expiration date based on their scientific review. For more information, go to the FDA website at www.fda.gov (search for "ciprofloxacin expiration").

Who should **NOT** get ciprofloxacin?

You will not get ciprofloxacin if you have had a severe allergic reaction to ciprofloxacin or similar medicines known as quinolones. A severe reaction may include closing of the throat, trouble breathing or swelling of the lips, tongue or face. Ciprofloxacin needs to be avoided if you have a history of myasthenia gravis or are taking the muscle relaxant called Zanaflex (tizanidine). Talk to your doctor about other medicines available to treat plague.

How is ciprofloxacin given?

Ciprofloxacin can be given through a vein in your arm or by mouth as a pill or liquid. How you receive the medicine depends on several factors, including how sick you are. Your doctor will decide whether to give you ciprofloxacin by vein or by mouth.

What are common side effects of ciprofloxacin?

Common side effects of ciprofloxacin are mild nausea, vomiting, and/or diarrhea, a mild sunburn or a vaginal yeast infection. You can continue ciprofloxacin if you have these mild symptoms. If these symptoms become severe, talk to your doctor.

What are possible side effects when ciprofloxacin is given through a vein?

If you get ciprofloxacin through a vein in the arm, there may be a risk of pain and soreness at or near the site of injection. While this is unpleasant, it is not serious and can be treated with common pain relievers such as acetaminophen (like Tylenol). Some people may become lightheaded and dizzy. You could also get an infection from the needle stick, but this is rare.

What are possible serious side effects of ciprofloxacin?

Serious side effects from ciprofloxacin are rare. You should **STOP** taking ciprofloxacin and get medical help right away (go to the emergency room or call 911) if you develop:

- Closing of the throat or trouble breathing
- Swelling of the lips, tongue, or face
- Pain, swelling, or inflammation of joints or tendons
- Severe itching or rash, especially hives and wheals (red swollen bumps on the skin)
- Seizures, dizziness, tremors, or serious mood changes
- Very fast or irregular heart beat
- Severe stomach cramps with fever or bloody or watery diarrhea
- Pain, burning, tingling, numbness, or weakness of your arms, hands, legs, or feet
- Yellowing of eyes or skin, or dark brown or tea-colored urine (signs of liver failure)
- Unusual bleeding or bruising



What if I am taking other medicines?

- If you take **Zanaflex (tizanidine)**, a medicine for muscle spasms, it is important to talk with your doctor right away. A change in medicine for muscle spasms or medicine to treat plague would be necessary since tizanidine and ciprofloxacin should not be used together.
- Talk to your doctor if you take any of the following medicines: phenytoin for seizures, a blood thinner like warfarin, an anti-diabetic medicine like glyburide, clozapine for schizophrenia or theophylline for asthma. Ciprofloxacin may affect how much of these medicines you need.
- Ciprofloxacin taken by mouth might not work as well when taken with some medicines. Take it at least 2 hours before or 6 hours after taking:
 - Antacids
 - Carafate (sucralfate)
 - Videx (didanosine)
 - Multivitamins or supplements with magnesium, calcium, aluminum, iron or zinc
 - Phosphate binders

What else do I need to know about ciprofloxacin?

- It can worsen muscle weakness or breathing problems in myasthenia gravis. Talk to your doctor if you have a history of myasthenia gravis disorder.
- It can cause your skin to be more sensitive to the sun. Use sunscreen and cover exposed skin.
- Coffee, caffeinated sodas or energy drinks can make you feel jittery. Drink less caffeine if this occurs.
- Tell your doctor if you are or become pregnant or are breastfeeding.

How do I take ciprofloxacin at home?

If you are instructed to finish treatment with ciprofloxacin at home, it is important that you take ciprofloxacin exactly as you are told. If you do not take ciprofloxacin as instructed, you could get very sick or die from plague.

If you have been prescribed ciprofloxacin tablets:

- Follow instructions provided on the ciprofloxacin label.
- Take your **morning** dose with a full glass of water (with or without food) **and**
- Take your **evening** dose with a full glass of water (with or without food)

**The morning and evening doses should be taken 12 hours apart each day for as long as directed.

** Do not split, crush, or chew the pills.

If you have been prescribed ciprofloxacin liquid suspension:

- Follow instructions provided on the liquid ciprofloxacin label.
- Take the same amount in the morning and in the evening.

**The morning and evening doses should be taken 12 hours apart each day for as long as directed.

** Shake the liquid very well for about 15 seconds before each use.

- Do not skip doses. However, if you miss a dose, **do NOT take 2 doses at once**. Take the next dose as scheduled.
- Do not take ciprofloxacin with milk, yogurt, or calcium-fortified juices.
- Keep the pills dry. Store ciprofloxacin pills and liquid at room temperature (between 68–77°F or 20–25°C). The liquid can be stored for up to 14 days at room temperature.
- Keep ciprofloxacin away from children and pets. Call the poison control center if children or pets ingest the medicine by accident (1-800-222-1222).

Risk-Benefit Statement

Although ciprofloxacin has some potential and serious side effects, the expected benefit of ciprofloxacin in helping to treat disease and prevent death associated with plague outweigh these risks.



Are there other antibiotics besides ciprofloxacin?

Your doctor or healthcare provider will tell you if other antibiotics (such as streptomycin, gentamicin, doxycycline, levofloxacin or moxifloxacin) are available. The risks and benefits of other available antibiotics will be explained in separate instructions. For more information, visit www.cdc.gov.

How do I report side effects or medication errors?

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

What can I do if I think I have been injured by taking ciprofloxacin?

On rare occasions, ciprofloxacin can cause serious problems. 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 Ciprofloxacin Oral Suspension

These instructions show you how to prepare ciprofloxacin suspension. You can follow these instructions for mixing a bottle of ciprofloxacin 5% (250 mg/5 mL) or 10% (500 mg/5mL)* from any manufacturer.

*Note: Although these mixing instructions can be used for both 5% and 10% ciprofloxacin oral suspension, **please be aware that the dosing for these two strengths is different.** Dosing tables (1 and 2) for both strengths are provided in Step 4 of the instructions below.

Step 1. Gather the supplies you need.

- Ciprofloxacin dry powder
- Liquid for mixing with ciprofloxacin (this liquid is included in the ciprofloxacin kit). **Do NOT add water** to mix the ciprofloxacin suspension.

Step 2. Mix the liquid with the ciprofloxacin dry powder.

1. Take the caps off both bottles.
2. Pour the contents of the smaller bottle into the larger bottle.
3. Screw the cap completely back on the larger bottle. Shake the larger bottle vigorously for about 15 seconds.

In the larger bottle, you now have well-mixed (reconstituted) ciprofloxacin liquid ready for use.



4. Throw the empty smaller bottle away.

Step 3. Write the expiration date and store the reconstituted ciprofloxacin bottle.

1. Figure out the expiration date by counting 14 days from the day you mixed the powder with the liquid and write that date on the bottle. For example, if you mixed the ciprofloxacin suspension 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 at room temperature out of the reach of children and pets. Keep the bottle tightly closed.

Step 4. Give the correct dose.

1. **Shake** the bottle very well before each dose.
2. Using the table that corresponds to your bottle below, follow the row of your child's weight to find the correct dose (mL). This is one dose.
 - If you have received ciprofloxacin **5% (250 mg/5 mL)**, find your correct dose in **Table 1**.

Table 1: Dosage using Ciprofloxacin Bottle 5% (250 mg/5mL)

| Weight* | Amount of liquid ciprofloxacin to measure* |
|------------------|--|
| 7 pounds or less | 1 mL |
| 8 to 14 pounds | 2 mL |
| 15 to 22 pounds | 3 mL |
| 23 to 29 pounds | 4 mL |
| 30 to 36 pounds | 5 mL |

*If your child weighs more than 36 pounds, ask a healthcare provider how much to give

**Weight range dosing based on 15 mg/kg derived dose calculation

- If you have received ciprofloxacin **10% (500 mg/5 mL)**, find your correct dose in **Table 2**.

Table 2: Dosage using Ciprofloxacin Bottle 10% (500 mg/5mL)

| Weight* | Amount of liquid ciprofloxacin to measure* |
|------------------|---|
| 7 pounds or less | 0.5 mL |
| 8 to 14 pounds | 1 mL |
| 15 to 22 pounds | 1.5 mL |
| 23 to 29 pounds | 2 mL |
| 30 to 36 pounds | 2.5 mL |

*If your child weighs more than 36 pounds, ask a healthcare provider how much to give

**Weight range dosing based on 15 mg/kg derived dose calculation

3. Use the oral dosing syringe provided with your medicine to give the dose to your child. Give this amount once **every 12 hours** (once in the morning AND once at night) each day for as long as directed.