

## References:

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### Patient Information About:

**CIPRO<sup>®</sup>**

**(ciprofloxacin hydrochloride) TABLETS**

**CIPRO<sup>®</sup>**

**(ciprofloxacin\*) ORAL SUSPENSION**

This section contains important patient information about CIPRO (ciprofloxacin hydrochloride) Tablets and CIPRO (ciprofloxacin\*) Oral Suspension and should be read completely before you begin treatment. This section does not take the place of discussion with your doctor or health care professional about your medical condition or your treatment. This section does not list all benefits and risks of CIPRO. If you have any concerns about your condition or your medicine, ask your doctor. Only your doctor can determine if CIPRO is right for you.

### What is CIPRO?

CIPRO is an antibiotic used to treat bladder, kidney, prostate, cervix, stomach, intestine, lung, sinus, bone, and skin infections caused by certain germs called bacteria. CIPRO kills many types of bacteria that can infect these areas of the body. CIPRO has been shown in a large number of clinical trials to be safe and effective for the treatment of bacterial infections.

Sometimes viruses rather than bacteria may infect the lungs and sinuses (for example the common cold). CIPRO, like all other antibiotics, does not kill viruses. You should contact your doctor if your condition is not improving while taking CIPRO.

CIPRO Tablets are white to slightly yellow in color and are available in 250 mg, 500 mg and 750 mg strengths. CIPRO Oral Suspension is white to slightly yellow in color and is available in concentrations of 250 mg per teaspoon (5%) and 500 mg per teaspoon (10%).

### **How and when should I take CIPRO?**

#### **CIPRO Tablets:**

Unless directed otherwise by your physician, CIPRO should be taken twice a day at approximately the same time, in the morning and in the evening. CIPRO can be taken with food or on an empty stomach. CIPRO should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone; however, CIPRO may be taken with a meal that contains these products.

You should take CIPRO for as long as your doctor prescribes it, even after you start to feel better. Stopping an antibiotic too early may result in failure to cure your infection. Do not take a double dose of CIPRO even if you miss a dose by mistake.

#### **CIPRO Oral Suspension:**

Take CIPRO Oral Suspension in the same way as above. In addition, remember to **shake the bottle vigorously each time before use for approximately 15 seconds** to make sure the suspension is mixed well. Be sure to swallow the required amount of suspension. Do not chew the microcapsules. Close the bottle completely after use. The product can be used for 14 days when stored in a refrigerator or at room temperature. After treatment has been completed, any remaining suspension should be discarded.

### **Who should not take CIPRO?**

You should not take CIPRO if you have ever had a severe reaction to any of the group of antibiotics known as “quinolones”. You should also not take CIPRO if you are also taking a medication called tizanidine (Zanaflex<sup>®</sup>), as excessive side effects from tizanidine are likely to occur.

CIPRO is not recommended during pregnancy or nursing, as the effects of CIPRO on the unborn child or nursing infant are unknown. If you are pregnant or plan to become pregnant while taking CIPRO talk to your doctor before taking this medication.

Due to possible side effects, CIPRO is not recommended for persons less than 18 years of age except for specific serious infections, such as complicated urinary tract infections.

### **What are the possible side effects of CIPRO?**

CIPRO is generally well tolerated. The most common side effects, which are usually mild, include nausea, diarrhea, vomiting, and abdominal pain/discomfort. If diarrhea persists, call your health care professional.

Rare cases of allergic reactions have been reported in patients receiving quinolones, including CIPRO, even after just one dose. If you develop hives, difficulty breathing, or other symptoms of a severe allergic reaction, seek emergency treatment right away. If you develop a skin rash, you should stop taking CIPRO and call your health care professional.

Sun sensitivity (photosensitivity), which can appear as skin eruption or severe sunburn, can occur in some patients taking quinolone antibiotics after exposure to sunlight or artificial ultraviolet light (UV) (e.g. tanning beds). CIPRO has been infrequently associated with photosensitivity. Avoid excessive exposure to sunlight or artificial UV light while taking CIPRO. Use a sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your physician.

You should be careful about driving or operating machinery until you are sure CIPRO is not causing dizziness. Convulsions have been reported in patients receiving quinolone antibiotics including ciprofloxacin. Be sure to let your physician know if you have a history of convulsions. Quinolones,

including ciprofloxacin, have been rarely associated with other central nervous system events including confusion, tremors, hallucinations, and depression.

Pain, swelling, and tears of Achilles, shoulder, or hand tendons have been reported in patients receiving fluoroquinolones, including CIPRO. The risk for tendon effects is higher if you are over 65 years of age, and especially if you are taking corticosteroids. If you develop pain, swelling, or rupture of a tendon you should stop taking CIPRO, refrain from exercise and strenuous use of the affected area, and contact your health care provider.

Diarrhea that usually ends after treatment is a common problem caused by antibiotics. A more serious form of diarrhea can occur during or up to 2 months after the use of antibiotics. This has been reported with all antibiotics including with CIPRO. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.

CIPRO has been associated with an increased rate of side effects with joints and surrounding structures (like tendons) in pediatric patients (less than 18 years of age). Parents should inform their child's physician if the child has a history of joint-related problems before taking this drug. Parents of pediatric patients should also notify their child's physician of any joint related problems that occur during or following CIPRO therapy.

If you notice any side effects not mentioned in this section, or if you have any concerns about side effects you may be experiencing, please inform your health care professional.

### **What about other medications I am taking?**

CIPRO can affect how other medicines work. Tell your doctor about all other prescription and non-prescription medicines or supplements you are taking. This is especially important if you are taking tizanidine (Zanaflex<sup>®</sup>) or theophylline. You should not take Cipro if you are also taking tizanidine. Other medications including warfarin, glyburide, and phenytoin may also interact with CIPRO.

Many antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc can interfere with the absorption of CIPRO and may prevent it from working. Other medications such as sulcrafate and Videx<sup>®</sup> (didanosine) chewable/buffered tablets or pediatric powder may also stop CIPRO from working. You should take CIPRO either 2 hours before or 6 hours after taking these products.

### **What if I have been prescribed CIPRO for possible anthrax exposure?**

CIPRO has been approved to reduce the chance of developing anthrax infection following exposure to the anthrax bacteria. In general, CIPRO is not recommended for children; however, it is approved for use in patients younger than 18 years old for anthrax exposure. If you are pregnant, or plan to become pregnant while taking CIPRO, you and your doctor should discuss if the benefits of taking CIPRO for anthrax outweigh the risks.

CIPRO is generally well tolerated. Side effects that may occur during treatment to prevent anthrax might be acceptable due to the seriousness of the disease. You and your doctor should discuss the risks of not taking your medicine against the risks of experiencing side effects.

CIPRO can cause dizziness, confusion, or other similar side effects in some people. Therefore, it is important to know how CIPRO affects you before driving a car or performing other activities that require you to be alert and coordinated such as operating machinery.

Your doctor has prescribed CIPRO only for you. Do not give it to other people. Do not use it for a condition for which it was not prescribed. You should take your CIPRO for as long as your doctor prescribes it; stopping CIPRO too early may result in failure to prevent anthrax.

**Remember:**

Do not give CIPRO to anyone other than the person for whom it was prescribed.

Take your dose of CIPRO in the morning and in the evening.

Complete the course of CIPRO even if you are feeling better.

Keep CIPRO and all medications out of reach of children.

\* Does not comply with USP with regard to “loss on drying” and “residue on ignition”.

Manufactured by:



**Bayer HealthCare**

Bayer Pharmaceuticals Corporation  
400 Morgan Lane  
West Haven, CT 06516

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Schering Corporation  
Kenilworth, NJ 07033

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