

^Patients excluded from the Per Protocol population were primarily those with no causative organism(s) at baseline or no organism present at $\geq 10^5$ CFU/mL at baseline, inclusion criteria violation, no valid test-of-cure urine culture within the TOC window, an organism resistant to study drug, premature discontinuation due to an adverse event, lost to follow-up, or non-compliance with dosage regimen (among other criteria).

* n/N = patients with baseline organism(s) eradicated and no new infections or superinfections/total number of patients

** n/N = patients with specified baseline organism eradicated/patients with specified baseline organism

***n/N = patients with clinical success /total number of patients

Of the 166 cUTI patients treated with CIPRO XR, 148 (89%) had the causative organism(s) eradicated, 8 (5%) had persistence, 5 (3%) patients developed superinfections and 5 (3%) developed new infections. Of the 177 cUTI patients treated in the control arm, 144 (81%) had the causative organism(s) eradicated, 16 (9%) patients had persistence, 3 (2%) developed superinfections and 14 (8%) developed new infections. Of the 40 patients with AUP treated with CIPRO XR, 35 (87.5%) had the causative organism(s) eradicated, 2 (5%) patients had persistence and 3 (7.5%) developed new infections. Of the 5 CIPRO XR AUP patients without eradication at TOC, 4 were considered clinical cures and did not receive alternative antibiotic therapy. Of the 52 patients with AUP treated in the control arm, 51 (98%) had the causative organism(s) eradicated. One patient (2%) had persistence.

References: 1. NCCLS, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically-Sixth Edition. Approved Standard NCCLS Document M7-A6, Vol. 23, No. 2, NCCLS, Wayne, PA, January, 2003.

2. NCCLS, Performance Standards for Antimicrobial Disk Susceptibility Tests-Eighth Edition.

Approved Standard NCCLS Document M2-A8, Vol. 23, No. 1, NCCLS, Wayne, PA, January, 2003.

PATIENT INFORMATION ABOUT

CIPRO[®] XR

(ciprofloxacin extended-release tablets)

This section contains important patient information about CIPRO XR 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 XR. CIPRO XR can be prescribed only by a licensed health care professional. Your doctor has prescribed CIPRO XR only for you.

CIPRO XR is intended only to treat urinary tract infections and acute uncomplicated pyelonephritis (also known as a kidney infection). It should not be used to treat other infections. Do not give it to other people even if they have a similar condition. Do not use it for a condition for which it was not prescribed. If you have any concerns about your condition or your medicine, ask your doctor. Only your doctor can determine if CIPRO XR is right for you.

What is CIPRO XR?

CIPRO XR is an antibiotic in the quinolone class that contains the active ingredient ciprofloxacin. CIPRO XR is specifically formulated to be taken just once daily to kill bacteria causing infection in the urinary tract. CIPRO XR has been shown in clinical trials to be effective in the treatment of urinary tract infections. You should contact your doctor if your condition is not improving while taking CIPRO XR.

CIPRO XR tablets are nearly white to slightly yellowish, film-coated, oblong-shaped tablets. CIPRO XR is available in 500 mg and 1000 mg tablet strengths.

How and when should I take CIPRO XR?

CIPRO XR should be taken once a day for three (3) to fourteen (14) days depending on your infection. Take CIPRO XR at approximately the same time each day with food or on an empty stomach. CIPRO XR should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone; however, CIPRO XR may be taken with a meal that contains these products. Should you forget to take it at the usual time, you may take your dose later in the day. Do not take more than one CIPRO XR tablet per day even if you missed a dose. Swallow the CIPRO XR tablet whole. **DO NOT SPLIT, CRUSH, OR CHEW THE TABLET.**

You should take CIPRO XR 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.

Who should not take CIPRO XR?

You should not take CIPRO XR 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[®]), as excessive side effects from tizanidine are likely to occur.

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

CIPRO XR is not recommended for persons less than 18 years of age.

What are the possible side effects of CIPRO XR?

CIPRO XR is generally well tolerated. The most common side effects, which are usually mild, include nausea, headache, dyspepsia, dizziness, vaginal yeast infection and diarrhea. If diarrhea persists, call your health care professional. Antibiotics of the quinolone class may also cause vomiting, rash, and abdominal pain/discomfort.

You should be careful about driving or operating machinery until you are sure CIPRO XR is not causing dizziness.

Rare cases of allergic reactions have been reported in patients receiving quinolones, including ciprofloxacin, 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 XR 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 XR has been infrequently associated with photosensitivity. Avoid excessive exposure to sunlight or artificial UV light while taking CIPRO XR. Use a sunscreen and wear protective clothing if out in the sun. If photosensitivity develops, contact your physician.

Pain, swelling, and tears of Achilles, shoulder, or hand tendons have been reported in patients receiving fluoroquinolones, including CIPRO XR. 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 XR, 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 XR. If you develop a watery and bloody stool with or without stomach cramps and fever, contact your physician as soon as possible.

Convulsions have been reported in patients receiving quinolone antibiotics including ciprofloxacin. If you have experienced convulsions in the past, be sure to let your physician know that 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.

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 XR can affect how other medicines work. Tell your doctor about all other prescriptions and nonprescription medicines or supplements you are taking. This is especially important if you are taking tizanidine (Zanaflex[®]) or theophylline or VIDEX[®] (didanosine) chewable/buffered tablets or pediatric powder. Other medications including warfarin, glyburide, and phenytoin may also interact with CIPRO XR. You should not take Cipro if you are also taking tizanidine.

Many antacids, multivitamins, and other dietary supplements containing magnesium, calcium, aluminum, iron or zinc can interfere with the absorption of CIPRO XR and may prevent it from working. You should take CIPRO XR either 2 hours before or 6 hours after taking these products.

Remember:

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

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

Keep CIPRO XR and all medications out of reach of children.

This information does not take the place of discussions with your doctor or health care professional about your medication or treatment.

Rx Only

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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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