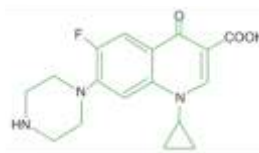


Rx CIPROFLOXACIN

(Ciprofloxacin is an antibiotic that is used to treat bacterial infections)



GENERIC NAME: ciprofloxacin

DRUG CLASS AND MECHANISM

Ciprofloxacin is an antibiotic that is used to treat bacterial infections. Ciprofloxacin belongs to the fluoroquinolone class of antibiotics which includes levofloxacin (Levaquin), ofloxacin (Floxin), gatifloxacin (Tequin), norfloxacin (Noroxin), moxifloxacin (Avelox), trovafloxacin (Trovan) and others. Ciprofloxacin stops the multiplication of bacteria by inhibiting the reproduction and repair of their genetic material (DNA). The FDA approved ciprofloxacin in October 1987.

PRESCRIPTION: Yes

GENERIC AVAILABLE: Yes

PREPARATIONS

Tablets: 250, 500, and 750 mg. Tablets extended release (XR): 500 and 1000 mg. Microcapsules for suspension: 250 mg/5 ml, 500 mg/5 ml. Injection or Injection concentrate: 200 and 400 mg.

PRESCRIBED FOR

Ciprofloxacin is used to treat infections of the skin, lungs, airways, bones, and joints caused by susceptible bacteria. Ciprofloxacin is also frequently used to treat urinary infections caused by bacteria such as *E. coli*. Ciprofloxacin is effective in treating infectious diarrheas caused by *E. coli*, *Campylobacter jejuni*, and *Shigella* bacteria.

DOSING

For most infections the recommended oral dose for adults is 250-750 mg (immediate release tablets) every 12 hours or 500-1000 mg (extended release tablets) every 24 hours. The usual intravenous dose is 200-400 mg every 8-12 hours.

DRUG INTERACTIONS

Ciprofloxacin administered together with theophylline can lead to elevated, toxic blood levels of theophylline. Theophylline is used to open airways in the treatment of asthma. Toxic levels of theophylline can lead to seizures, and disturbances in heart rhythm. If concurrent use of ciprofloxacin and theophylline cannot be avoided, frequent blood tests to monitor theophylline blood levels are recommended.

Iron salts (for example, ferrous sulfate) may reduce the absorption of ciprofloxacin because of formation of a ciprofloxacin-iron complex that is not absorbable. Antacids also may reduce the absorption of ciprofloxacin. If patients are receiving iron salts or antacids and ciprofloxacin, the ciprofloxacin should be given two hours before or six hours after the iron salt or antacid.

Ciprofloxacin may increase the blood thinning effect of warfarin (Coumadin). The reason for this is unknown. Anticoagulant activity should be monitored after starting or stopping ciprofloxacin.

Sevelamer (Renagel) may reduce the absorption of ciprofloxacin and possibly reduce the effectiveness of ciprofloxacin. Milk and orange juice also may reduce the absorption of ciprofloxacin. Ciprofloxacin, as with iron and antacids, should be given two hours before or six hours after milk or orange juice.

USES

This medication is used to treat a variety of bacterial infections. Ciprofloxacin belongs to a class of drugs called quinolone antibiotics. It works by stopping the growth of bacteria. This antibiotic treats only bacterial infections. It will not work for virus infections (e.g., common cold, flu). Unnecessary use or overuse of any antibiotic can lead to its decreased effectiveness.

HOW TO USE

Read the Medication Guide provided by your pharmacist before you start using ciprofloxacin and each time you get a refill. If you have any questions, consult your doctor or pharmacist. This medication may be taken with or without food, usually twice a day in the morning and evening or as directed by your doctor. The dosage and length of treatment is based on your medical condition and response to treatment. Drink plenty of fluids while taking this medication unless your doctor tells you otherwise. Take this medication at least 2 hours before or 6 hours after taking other products that may bind to it, decreasing its effectiveness. Ask your pharmacist about the other products you take. Some examples include: quinapril, vitamins/minerals (including

iron and zinc supplements), and products containing magnesium, aluminum, or calcium (such as antacids, didanosine solution, calcium supplements). Calcium-rich foods, including dairy products (such as milk, yogurt) or calcium-enriched juice, can also decrease the effect of this medication. Do not eat calcium-rich foods within 6 hours before or 2 hours after taking ciprofloxacin, unless you are eating these foods as part of a larger meal that contains other (non-calcium-rich) foods. These other foods decrease the calcium binding effect. Ask your doctor or pharmacist about safely using nutritional supplements/replacements with this medication. Antibiotics work best when the amount of medicine in your body is kept at a constant level. It is important not to miss a dose. To help you remember and to keep the drug at a constant level, take it at the same times every day. Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may allow bacteria to continue to grow, which may result in a return of the infection. Tell your doctor if your condition persists or worsens.

SIDE EFFECTS

See also Warning section. Nausea, diarrhea, dizziness, lightheadedness, headache, or trouble sleeping may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly. Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor immediately if any of these unlikely but serious side effects occur: mental/mood changes (e.g., anxiety, confusion, hallucinations, depression, rare thoughts of suicide), shaking (tremors), skin that sunburns more easily (sun sensitivity). Ciprofloxacin may rarely cause serious nerve problems that may be reversible if identified and treated early. Seek immediate medical attention if you develop any of the following symptoms: pain/numbness/burning/tingling/weakness in any part of the body, changes in how you sense touch/pain/temperature/body position/vibration. Tell your doctor immediately if any of these rare but very serious side effects occur: unusual bruising/bleeding, severe/persistent headache, signs of a new infection (e.g., new/persistent fever, persistent sore throat), unusual change in the amount of urine, change in color of urine (red/pink urine), signs of liver problems (e.g., unusual tiredness, stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine), vision changes. Seek immediate medical attention if any of these rare but very serious side effects occur: severe dizziness, fainting, fast/irregular heartbeat, seizures. This medication may rarely cause a severe intestinal condition (Clostridium difficile-associated diarrhea) due to a type of resistant bacteria. This condition may occur during treatment or weeks to months after treatment has stopped. Do not use anti-diarrhea products or narcotic pain medications if you have any of the following symptoms because these products may make them worse. Tell your doctor immediately if you develop: persistent diarrhea, abdominal or stomach pain/cramping, blood/mucus in your stool. Use of this medication for prolonged or repeated periods may result in oral thrush or a new vaginal yeast infection. Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge, or other new symptoms. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist. In the US - Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS

Before taking ciprofloxacin, tell your doctor or pharmacist if you are allergic to it; or to other quinolone antibiotics such as norfloxacin, gemifloxacin, levofloxacin, moxifloxacin, or ofloxacin; or if you have any other allergies. Before using this medication, tell your doctor or pharmacist your medical history, especially of: diabetes, heart problems (e.g., recent heart attack), joint/tendon problems (e.g., tendonitis, bursitis), kidney disease, liver disease, nervous system disorder (e.g., peripheral neuropathy), seizure disorder, conditions that increase your risk of seizures (e.g., brain/head injury, brain tumors, cerebral atherosclerosis). Ciprofloxacin may cause a condition that affects the heart rhythm (QT prolongation). QT prolongation can infrequently result in serious (rarely fatal) fast/irregular heartbeat and other symptoms (such as severe dizziness, fainting) that require immediate medical attention. The risk of QT prolongation may be increased if you have certain medical conditions or are taking other drugs that may affect the heart rhythm (see also Drug Interactions section). Before using ciprofloxacin, tell your doctor or pharmacist if you have any of the following conditions: certain heart problems (heart failure, slow heartbeat, QT prolongation in the EKG), family history of certain heart problems (QT prolongation in the EKG, sudden cardiac death). Low levels of potassium or

magnesium in the blood may also increase your risk of QT prolongation. This risk may increase if you use certain drugs (such as diuretics/"water pills") or if you have conditions such as severe sweating, diarrhea, or vomiting. Talk to your doctor about using ciprofloxacin safely. This medication may rarely cause serious changes in blood sugar levels, especially if you have diabetes. Watch for symptoms of high blood sugar including increased thirst and urination. Also watch for symptoms of low blood sugar such as nervousness, shakiness, fast heartbeat, sweating, or hunger. Check your blood sugar regularly as directed by your doctor and report any changes. If you experience symptoms of low blood sugar, you may raise your blood sugar by using glucose tablets/gel or eating a quick source of sugar such as table sugar, honey, or candy, or drink fruit juice or non-diet soda. Tell your doctor immediately about the reaction and the use of this product. To help prevent low blood sugar, eat meals on a regular schedule, and do not skip meals. This drug may make you dizzy. Do not drive, use machinery, or do any activity that requires alertness until you are sure you can perform such activities safely. Limit alcoholic beverages. This medication may make you more sensitive to the sun. Avoid prolonged sun exposure, tanning booths, and sunlamps. Use a sunscreen and wear protective clothing when outdoors. Caution is advised when using this drug in children because they may be more sensitive to its possible side effects (e.g., joint/tendon problems). Discuss the risks and benefits with the doctor. Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, older adults may be more sensitive to its side effects such as tendon problems (especially if they are also taking corticosteroids such as prednisone or hydrocortisone) or heart problems. Discuss the risks and benefits with your doctor. During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Breastfeeding is not recommended while taking this drug. Consult your doctor before breast-feeding.

OVERDOSE

If overdose is suspected, contact your local poison control center or emergency room immediately. US residents can call the US National Poison Hotline at 1-800-222-1222. Canada residents can call a provincial poison control center.

MISSED DOSE

If you miss a dose, take it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature below 86 degrees F (30 degrees C) away from light and moisture. Do not store in the bathroom. Keep all medicines away from children and pets. Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

WARNING: This medication may rarely cause tendon damage (e.g., tendonitis, tendon rupture) during or after treatment. Your risk for tendon problems is greater if you are over 60 years of age, if you are taking corticosteroids (such as prednisone), or if you have a kidney, heart or lung transplant. Stop exercising, rest, and seek immediate medical attention if you develop joint/muscle/tendon pain or swelling.

Note : This product information is intended only for residents of the India. Taj Pharmaceuticals Limited, medicines help to treat and prevent a range of conditions—from the most common to the most challenging—for people around the world.



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