Medication Guide

Ciprofloxacin Tablets, USP for oral use

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Read this Medication Guide before you start taking ciprofloxacin tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about ciprofloxacin tablets?

Ciprofloxacin tablet is a fluoroquinolone antibacterial medicine, can cause serious side effects. Some of these serious side effects can happen at the same time and could result in death.

If you get any of the following serious side effects while you take ciprofloxacin tablets, you should stop taking ciprofloxacin tablets immediately and get medical help right away.

1. **Tendon rupture or swelling of the tendon (tendinitis).**

- **Tendon problems can happen in people of all ages who take ciprofloxacin tablets.** Tendons are tough cords of tissue that connect muscles to bones. **Symptoms of tendon problems may include:**

- pain
- swelling
- tears and swelling of the tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites.

- **The risk of getting tendon problems while you take ciprofloxacin tablets is higher if you:**

- are over 60 years of age
- are taking steroids (corticosteroids)
- have had a kidney, heart or lung transplant

- Tendon problems can happen in people who do not have the above risk factors when they take ciprofloxacin tablets.
- Other reasons that can increase your risk of tendon problems can include:

- physical activity or exercise
- kidney failure
- tendon problems in the past, such as in people with rheumatoid arthritis (RA)

- **Stop taking ciprofloxacin tablets immediately and get medical help right away at the first sign of tendon pain, swelling or inflammation.**

The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons.

- **Tendon rupture can happen while you are taking or after you have finished taking ciprofloxacin tablets.** Tendon ruptures can happen within hours or days of taking ciprofloxacin tablets have happened up to several months after people have finished taking their fluoroquinolone.
- **Stop taking ciprofloxacin tablets immediately and get medical help right away if you get any of the following signs or symptoms of a tendon rupture:**

- hear or feel a snap or pop in a tendon area
- bruising right after an injury in a tendon area
- unable to move the affected area or bear weight

2. Changes in sensation and possible nerve damage (Peripheral Neuropathy). Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including ciprofloxacin tablets. Stop taking ciprofloxacin tablets immediately and talk to your healthcare provider right away if you get any of the following symptoms of peripheral neuropathy in your arms, hands, legs, or feet:

• pain

• burning

• tingling

• numbness

• weakness

Ciprofloxacin tablets may need to be stopped to prevent permanent nerve damage.

3. Central Nervous System (CNS) effects. Seizures have been reported in people who take fluoroquinolone antibacterial medicines, including ciprofloxacin tablets. Tell your healthcare provider if you have a history of seizures before you start taking ciprofloxacin tablets. CNS side effects may happen as soon as after taking the first dose of ciprofloxacin tablets. Stop taking ciprofloxacin tablets immediately and talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:

• seizures

• hear voices, see things, or sense things that are not there (hallucinations)

• feel restless

• tremors

• trouble sleeping

• nightmares

• feel lightheaded or dizzy

• feel more suspicious (paranoia)

• suicidal thoughts or acts

• feel anxious or nervous

• confusion

• depression

• headaches that will not go away, with or without blurred vision

4. **Worsening of myasthenia gravis (a problem that causes muscle weakness).** Fluoroquinolones like ciprofloxacin tablets may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Tell your healthcare provider if you have a history of myasthenia gravis before you start taking ciprofloxacin tablets. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

What are ciprofloxacin tablets?

Ciprofloxacin tablets are a fluoroquinolone antibacterial medicine used in adults age 18 years and older to treat certain infections caused by certain germs called bacteria. These bacterial infections include:

- urinary tract infection
- chronic prostate infection
- lower respiratory tract infection
- sinus infection
- skin infection
- bone and joint infection
- nosocomial pneumonia
- intra-abdominal infection, complicated
- infectious diarrhea
- typhoid (enteric) fever
- cervical and urethral gonorrhea, uncomplicated
- people with a low white blood cell count and a fever
- inhalational anthrax
- plague

- Studies of ciprofloxacin tablets for use in the treatment of plague and anthrax were done in animals only, because plague and anthrax could not be studied in people.
- Ciprofloxacin tablets should not be used in patients with acute exacerbation of chronic bronchitis, acute uncomplicated cystitis, and sinus infections, if there are other treatment options available.
- Ciprofloxacin tablets should not be used as the first choice of antibacterial medicine to treat lower respiratory tract infections cause by a certain type of bacterial called *Streptococcus pneumoniae*.
- **Ciprofloxacin tablets are also used in children younger than 18 years of age** to treat complicated urinary tract and kidney infections or who may have breathed in anthrax germs, have plague or have been exposed to plague germs.
- Children younger than 18 years of age have a higher chance of getting bone, joint, or tendon (musculoskeletal) problems such as pain or swelling while taking ciprofloxacin tablets. Ciprofloxacin tablets should not be used as the first choice of antibacterial medicine in children under 18 years of age.

Who should not take ciprofloxacin tablets?

Do not take ciprofloxacin tablets if you:

- Have ever had a severe allergic reaction to an antibacterial medicine known as a fluoroquinolone, or are allergic to ciprofloxacin hydrochloride or any of the ingredients in ciprofloxacin tablets. See the end of this Medication Guide for a complete list of ingredients in ciprofloxacin tablets.
- Also take a medicine called tizanidine (Zanaflex®).

Ask your healthcare provider if you are not sure.

What should I tell my healthcare provider before taking ciprofloxacin tablets?

Before you take ciprofloxacin tablets, tell your healthcare provider if you:

- have tendon problems; ciprofloxacin tablets should not be used in patients who have a history of tendon problems
- have a disease that causes muscle weakness (myasthenia gravis); ciprofloxacin tablets should not be used in patients who have a known history of myasthenia gravis
- have liver problems
- have central nervous system problems (such as epilepsy)
- have nerve problems; ciprofloxacin tablets should not be used in patients who have a history of nerve problem called peripheral neuropathy
- have or anyone in your family has an irregular heartbeat, especially a condition called "QT prolongation"
- have or have had seizures
- have kidney problems. You may need a lower dose of ciprofloxacin tablets if your kidneys do not work well.
- have joint problems including rheumatoid arthritis (RA)
- have trouble swallowing pills
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ciprofloxacin tablets will harm your unborn baby.
- are breastfeeding or plan to breastfeed. Ciprofloxacin passes into breast milk. You and your healthcare provider should decide whether you will take ciprofloxacin tablets or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Ciprofloxacin tablets and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

- a steroid medicine
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- theophylline (such as Theo-24®, Elixophyllin®, Theochron®, Uniphyl®, Theolair®)
- a medicine to control your heart rate or rhythm (antiarrhythmics)
- an oral anti-diabetes medicine
- phenytoin (Fosphenytoin Sodium®, Cerebyx®, Dilantin-125®, Dilantin®, Extended Phenytoin Sodium®, Prompt Phenytoin Sodium®, Phenytek®)
- cyclosporine (Gengraf®, Neoral®, Sandimmune®, Sangcya®).
- a blood thinner (such as warfarin, Coumadin®, Jantoven®)

- methotrexate (Trexall®)
- ropinirole (Requip®)
- clozapine (Clozaril®, Fazaclo® ODT®)
- sildenafil (Viagra®, Revatio®)
- duloxetine
- products that contain caffeine
- probenecid (Probalan®, Col-probenecid®)
- certain medicines may keep ciprofloxacin tablets from working correctly. Take ciprofloxacin tablets either 2 hours before or 6 hours after taking these medicines, vitamins, or supplements:
  - an antacid, multivitamin, or other medicine or supplements that has magnesium, calcium, aluminum, iron, or zinc
  - sucralfate (Carafate®)
  - didanosine (Videx®, Videx EC®)

- a Non-Steroidal Anti-Inflammatory Drug (NSAID). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take ciprofloxacin tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures.

Ask your healthcare provider for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ciprofloxacin tablets?

- Take ciprofloxacin tablets exactly as your healthcare provider tells you to take them.
- Your healthcare provider will tell you how much ciprofloxacin tablets to take and when to take it.
- Take ciprofloxacin tablets in the morning and evening at about the same time each day. Swallow the tablet whole. Do not split, crush or chew the tablet. Tell your healthcare provider if you cannot swallow the tablet whole.
- Ciprofloxacin tablets can be taken with or without food.
- Ciprofloxacin tablets should not be taken with dairy products (like milk or yogurt) or calcium-fortified juices alone, but may be taken with a meal that contains these products.
- Drink plenty of fluids while taking ciprofloxacin tablets.
- Do not skip any doses of ciprofloxacin tablets, or stop taking them, even if you begin to feel better, until you finish your prescribed treatment unless:

- you have tendon problems. See "**What is the most important information I should know about ciprofloxacin tablets?**"
- you have nerve problems. See **"What is the most important information I should know about ciprofloxacin tablets?"**
- you have central nervous system problems. See **"What is the most important information I should know about ciprofloxacin tablets?"**
- you have a serious allergic reaction. See "**What are the possible side effects of ciprofloxacin tablets?**"
- your healthcare provider tells you to stop taking ciprofloxacin tablets

Taking all of your ciprofloxacin tablet doses will help make sure that all of the bacteria are killed. Taking all of your ciprofloxacin tablet doses will help lower the chance that the bacteria will become resistant to ciprofloxacin tablets. If you become resistant to ciprofloxacin tablets, ciprofloxacin tablets and other antibacterial medicines may not work for you in the future.

- If you take too much ciprofloxacin tablets, call your healthcare provider or get medical help right away.

What should I avoid while taking ciprofloxacin tablets?

- Ciprofloxacin tablets can make you feel dizzy and lightheaded. **Do not** drive, operate machinery, or do other activities that require mental alertness or coordination until you know how ciprofloxacin tablets affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Ciprofloxacin tablets can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get a severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while you take ciprofloxacin tablets, call your healthcare provider right away. You should use a sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight.

What are the possible side effects of ciprofloxacin tablets?

Ciprofloxacin tablets may cause serious side effects, including:

- See **"What is the most important information I should know about ciprofloxacin tablets?"**

- **Serious allergic reactions.** Serious allergic reactions, including death, can happen in people taking fluoroquinolones, including ciprofloxacin tablets, even after only 1 dose. Stop taking ciprofloxacin tablets and get emergency medical help right away if you get any of the following symptoms of a severe allergic reaction:

- hives
- trouble breathing or swallowing
- swelling of the lips, tongue, face
- throat tightness, hoarseness
- rapid heartbeat
- faint
- skin rash

Skin rash may happen in people taking ciprofloxacin tablets even after only 1 dose. Stop taking ciprofloxacin tablets at the first sign of a skin rash and call your healthcare provider. Skin rash may be a sign of a more serious reaction to ciprofloxacin tablets.

- **Liver damage (hepatotoxicity).** Hepatotoxicity can happen in people who take ciprofloxacin tablets. Call your healthcare provider right away if you have unexplained symptoms such as:

- nausea or vomiting
- stomach pain

- fever
- weakness
- abdominal pain or tenderness
- itching
- unusual tiredness
- loss of appetite
- light colored bowel movements
- dark colored urine
- yellowing of your skin or the whites of your eyes

Stop taking ciprofloxacin tablets and tell your healthcare provider right away if you have yellowing of your skin or white part of your eyes, or if you have dark urine. These can be signs of a serious reaction to ciprofloxacin tablets (a liver problem).

- **Intestine infection (Pseudomembranous colitis).** Pseudomembranous colitis can happen with many antibacterial medicines, including ciprofloxacin tablets. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may have stomach cramps and a fever. Pseudomembranous colitis can happen 2 or more months after you have finished your antibacterial medicine.

- **Serious heart rhythm changes (QT prolongation and torsade de pointes).** Tell your healthcare provider right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint. Ciprofloxacin tablets may cause a rare heart problem known as prolongation of the QT interval. This condition can cause an abnormal heartbeat and can be very dangerous. The chances of this event are higher in people:

- who are elderly
- with a family history of prolonged QT interval
- with low blood potassium (hypokalemia)
- who take certain medicines to control heart rhythm (antiarrhythmics)

- **Joint Problems.** Increased chance of problems with joints and tissues around joints in children under 18 years old can happen. Tell your child's healthcare provider if your child has any joint problems during or after treatment with ciprofloxacin tablets.

- **Sensitivity to sunlight (photosensitivity).** See **"What should I avoid while taking ciprofloxacin tablets?"**

The most common side effects of ciprofloxacin tablets include:

- nausea
- diarrhea
- changes in liver function tests
- vomiting
- rash

Tell your healthcare provider about any side effect that bothers you, or that does not go away.

These are not all the possible side effects of ciprofloxacin tablets. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ciprofloxacin tablets?

Ciprofloxacin Tablets

• Store at 20° to 25°C (68° to 77°F).

Keep ciprofloxacin tablets and all medicines out of the reach of children.

General Information about the safe and effective use of ciprofloxacin tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ciprofloxacin tablets for a condition for which it is not prescribed. Do not give ciprofloxacin tablets to other people, even if they have the same symptoms that you have. They may harm them.

This Medication Guide summarizes the most important information about ciprofloxacin tablets. If you would like more information about ciprofloxacin tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ciprofloxacin tablets that is written for healthcare professionals.

For more information call 1-888-375-3784.

What are the ingredients in ciprofloxacin tablets?

Ciprofloxacin Tablets:

Active ingredient: ciprofloxacin hydrochloride

Inactive ingredients: colloidal silicon dioxide, hypromellose, magnesium stearate,microcrystalline cellulose, polyethylene glycol 400, sodium starch glycolate, corn starch andtitanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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