

MEDICATION GUIDE

CIPRO[®] (*Sip-row*) (ciprofloxacin hydrochloride) TABLETS

CIPRO[®] (*Sip-row*) (ciprofloxacin) ORAL SUSPENSION

CIPRO[®] XR (*Sip-row*) (ciprofloxacin extended-release tablets)

CIPRO[®] I.V. (*Sip-row*) (ciprofloxacin) For Intravenous Infusion

Read the Medication Guide that comes with CIPRO[®] before you start taking it and each time you get a refill. There may be new information. This Medication Guide 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 CIPRO?

CIPRO belongs to a class of antibiotics called fluoroquinolones. CIPRO can cause side effects that may be serious or even cause death. If you get any of the following serious side effects, get medical help right away. Talk with your healthcare provider about whether you should continue to take CIPRO.

- **Tendon rupture or swelling of the tendon (tendinitis)**
 - Tendons are tough cords of tissue that connect muscles to bones.
 - Pain, swelling, tears and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites can happen in people of all ages who take fluoroquinolone antibiotics, including CIPRO. The risk of getting tendon problems is higher if you:
 - are over 60 years of age
 - are taking steroids (corticosteroids)
 - have had a kidney, heart or lung transplant
 - Swelling of the tendon (tendinitis) and tendon rupture (breakage) have also happened in patients who take fluoroquinolones who do not have the above risk factors.
 - Other reasons for tendon ruptures can include:
 - physical activity or exercise
 - kidney failure
 - tendon problems in the past, such as in people with rheumatoid arthritis (RA)
- Call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation. Stop taking CIPRO until tendinitis or tendon rupture has been ruled out by your healthcare provider. Avoid exercise and using the affected area. 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. Talk to your healthcare provider about the risk of tendon rupture with continued use of CIPRO. You may need a different antibiotic that is not a fluoroquinolone to treat your infection.

- Tendon rupture can happen while you are taking or after you have finished taking CIPRO. Tendon ruptures have happened up to several months after patients have finished taking their fluoroquinolone.
- 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
- **Worsening of myasthenia gravis (a disease which causes muscle weakness).** Fluoroquinolones like CIPRO may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

See the section “**What are the possible side effects of CIPRO?**” for more information about side effects.

What is CIPRO?

CIPRO is a fluoroquinolone antibiotic medicine used to treat certain infections caused by certain germs called bacteria.

Children less than 18 years of age have a higher chance of getting bone, joint, or tendon (musculoskeletal) problems such as pain or swelling while taking CIPRO. CIPRO should not be used as the first choice of antibiotic medicine in children under 18 years of age.

CIPRO Tablets, CIPRO Oral Suspension and CIPRO I.V. should not be used in children under 18 years old, except to treat specific serious infections, such as complicated urinary tract infections and to prevent anthrax disease after breathing the anthrax bacteria germ (inhalational exposure). It is not known if CIPRO XR is safe and works in children under 18 years of age. Sometimes infections are caused by viruses rather than by bacteria. Examples include viral infections in the sinuses and lungs, such as the common cold or flu. Antibiotics, including CIPRO, do not kill viruses. Call your healthcare provider if you think your condition is not getting better while you are taking CIPRO.

Who should not take CIPRO?

Do not take CIPRO if you:

- have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or are allergic to any of the ingredients in CIPRO. Ask your healthcare provider if you are not sure. See the list of ingredients in CIPRO at the end of this Medication Guide.
- also take a medicine called tizanidine (Zanaflex[®]). Serious side effects from tizanidine are likely to happen.

What should I tell my healthcare provider before taking CIPRO?

See “**What is the most important information I should know about CIPRO?**”

Tell your healthcare provider about all your medical conditions, including if you:

- have tendon problems
- have a disease that causes muscle weakness (myasthenia gravis)
- have central nervous system problems (such as epilepsy)
- have nerve problems
- have or anyone in your family has an irregular heartbeat, especially a condition called “QT prolongation”
- have a history of seizures
- have kidney problems. You may need a lower dose of CIPRO if your kidneys do not work well.
- have rheumatoid arthritis (RA) or other history of joint problems
- have trouble swallowing pills
- are pregnant or planning to become pregnant. It is not known if CIPRO will harm your unborn child.
- are breast-feeding or planning to breast-feed. CIPRO passes into breast milk. You and your healthcare provider should decide whether you will take CIPRO or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal and dietary supplements. CIPRO and other medicines can affect each other causing side effects. Especially tell your healthcare provider if you take:

- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take CIPRO or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See "**What are the possible side effects of CIPRO?**"
- a blood thinner (warfarin, Coumadin[®], Jantoven[®])
- tizanidine (Zanaflex[®]). You should not take CIPRO if you are already taking tizanidine. See "**Who should not take CIPRO?**"
- theophylline (Theo-24[®], Elixophyllin[®], Theochron[®], Uniphyll[®], Theolair[®])
- glyburide (Micronase[®], Glynase[®], Diabeta[®], Glucovance[®]). See "**What are the possible side effects of CIPRO?**"
- phenytoin (Fosphenytoin Sodium[®], Cerebyx[®], Dilantin-125[®], Dilantin[®], Extended Phenytoin Sodium[®], Prompt Phenytoin Sodium[®], Phenytek[®])
- products that contain caffeine
- a medicine to control your heart rate or rhythm (antiarrhythmics) See "**What are the possible side effects of CIPRO?**"
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- a steroid medicine. Corticosteroids taken by mouth or by injection may increase the chance of tendon injury. See "**What is the most important information I should know about CIPRO?**"
- methotrexate (Trexall[®])
- Probenecid (Probalan[®], Col-probenecid[®])
- Metoclopramide (Reglan[®], Reglan ODT[®])
- Certain medicines may keep CIPRO Tablets, CIPRO Oral Suspension from working correctly. Take CIPRO Tablets and Oral Suspension either 2 hours before or 6 hours after taking these products:
 - an antacid, multivitamin, or other product that has magnesium, calcium, aluminum, iron, or zinc
 - sucralfate (Carafate[®])
 - didanosine (Videx[®], Videx EC[®])

Ask your healthcare provider if you are not sure if any of your medicines are listed above.

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

How should I take CIPRO?

- Take CIPRO exactly as prescribed by your healthcare provider.
- Take CIPRO 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 can not swallow the tablet whole.
- Take CIPRO Oral Suspension in the morning and evening at about the same time each day. Shake the CIPRO Oral Suspension bottle well each time before use for about 15 seconds to make sure the suspension is mixed well. Close the bottle completely after use.
- Take CIPRO XR one time each day 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 can not swallow the tablet whole.
- CIPRO I.V. is given to you by intravenous (I.V.) infusion into your vein, slowly, over 60 minutes, as prescribed by your healthcare provider.
- CIPRO can be taken with or without food.
- CIPRO 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 CIPRO.
- Do not skip any doses, or stop taking CIPRO even if you begin to feel better, until you finish your prescribed treatment, unless:
 - you have tendon effects (see “**What is the most important information I should know about CIPRO?**”),
 - you have a serious allergic reaction (see “**What are the possible side effects of CIPRO?**”), or
 - your healthcare provider tells you to stop.

This will help make sure that all of the bacteria are killed and lower the chance that the bacteria will become resistant to CIPRO. If this happens, CIPRO and other antibiotic medicines may not work in the future.

- If you miss a dose of CIPRO Tablets or Oral Suspension, take it as soon as you remember. Do not take two doses at the same time, and do not take more than two doses in one day.
- If you miss a dose of CIPRO XR, take it as soon as you remember. Do not take more than one dose in one day.
- If you take too much, call your healthcare provider or get medical help immediately.

If you have been prescribed CIPRO Tablets, CIPRO Oral Suspension or CIPRO I.V. after being exposed to anthrax:

- CIPRO Tablets, Oral Suspension and I.V. has been approved to lessen the chance of getting anthrax disease or worsening of the disease after you are exposed to the anthrax bacteria germ.
- Take CIPRO exactly as prescribed by your healthcare provider. Do not stop taking CIPRO without talking with your healthcare provider. If you stop taking CIPRO too soon, it may not keep you from getting the anthrax disease.
- Side effects may happen while you are taking CIPRO Tablets, Oral Suspension or I.V. When taking your CIPRO to prevent anthrax infection, you and your healthcare provider

should talk about whether the risks of stopping CIPRO too soon are more important than the risks of side effects with CIPRO.

- If you are pregnant, or plan to become pregnant while taking CIPRO, you and your healthcare provider should decide whether the benefits of taking CIPRO Tablets, Oral Suspension or I.V. for anthrax are more important than the risks.

What should I avoid while taking CIPRO?

- CIPRO 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 CIPRO affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. CIPRO can make your skin sensitive to the sun (photosensitivity) and the light from sunlamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking CIPRO, 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 CIPRO?

- CIPRO can cause side effects that may be serious or even cause death. See “**What is the most important information I should know about CIPRO?**”

Other serious side effects of CIPRO include:

- **Central Nervous System effects**
Seizures have been reported in people who take fluoroquinolone antibiotics including CIPRO. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking CIPRO will change your risk of having a seizure. Central Nervous System (CNS) side effects may happen as soon as after taking the first dose of CIPRO. Talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:
 - feel dizzy
 - seizures
 - hear voices, see things, or sense things that are not there (hallucinations)
 - feel restless
 - tremors
 - feel anxious or nervous
 - confusion
 - depression
 - trouble sleeping
 - nightmares
 - feel more suspicious (paranoia)
 - suicidal thoughts or acts

- **Serious allergic reactions**

Allergic reactions can happen in people taking fluoroquinolones, including CIPRO, even after only one dose. Stop taking CIPRO 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
- yellowing of the skin or eyes. Stop taking CIPRO and tell your healthcare provider right away if you get 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 CIPRO (a liver problem).
- **Skin rash**
Skin rash may happen in people taking CIPRO even after only one dose. Stop taking CIPRO 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 CIPRO.
- **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. CIPRO 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)
- **Intestine infection** (Pseudomembranous colitis)
Pseudomembranous colitis can happen with most antibiotics, including CIPRO. 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 antibiotic.
- **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 CIPRO. Talk with 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
 CIPRO may need to be stopped to prevent permanent nerve damage.
- **Low blood sugar** (hypoglycemia)
People who take CIPRO and other fluoroquinolone medicines with the oral anti-diabetes medicine glyburide (Micronase, Glynase, Diabeta, Glucovance) can get low blood sugar (hypoglycemia) which can sometimes be severe. Tell your healthcare provider if you get low blood sugar with CIPRO. Your antibiotic medicine may need to be changed.
- **Sensitivity to sunlight** (photosensitivity)
See “**What should I avoid while taking CIPRO?**”
- **Joint Problems**

Increased chance of problems with joints and tissues around joints in children under 18 years old. Tell your child's healthcare provider if your child has any joint problems during or after treatment with CIPRO.

The most common side effects of CIPRO include:

- nausea
- headache
- diarrhea
- vomiting
- vaginal yeast infection
- changes in liver function tests
- pain or discomfort in the abdomen

These are not all the possible side effects of CIPRO. Tell your healthcare provider about any side effect that bothers you, or that does not go away.

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 CIPRO?

- **CIPRO Tablets**
 - Store CIPRO below 86°F (30°C)
- **CIPRO Oral Suspension**
 - Store CIPRO Oral Suspension below 86°F (30°C) for up to 14 days
 - Do not freeze
 - After treatment has been completed, any unused oral suspension should be safely thrown away
- **CIPRO XR**
 - Store CIPRO XR at 59°F to 86°F (15°C to 30°C)

Keep CIPRO and all medicines out of the reach of children.

General Information about CIPRO

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

This Medication Guide summarizes the most important information about CIPRO. If you would like more information about CIPRO, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about CIPRO that is written for healthcare professionals. For more information go to www.CIPRO.com or call 1-800-526-4099.

What are the ingredients in CIPRO?

- **CIPRO Tablets:**
 - Active ingredient: ciprofloxacin
 - Inactive ingredients: cornstarch, microcrystalline cellulose, silicon dioxide, crospovidone, magnesium stearate, hypromellose, titanium dioxide, and polyethylene glycol
- **CIPRO Oral Suspension:**
 - Active ingredient: ciprofloxacin

- Inactive ingredients: The components of the suspension have the following compositions: Microcapsules—ciprofloxacin, povidone, methacrylic acid copolymer, hypromellose, magnesium stearate, and Polysorbate 20. Diluent—medium-chain triglycerides, sucrose, lecithin, water, and strawberry flavor.
- **CIPRO XR:**
 - Active ingredient: ciprofloxacin
 - Inactive ingredients: crospovidone, hypromellose, magnesium stearate, polyethylene glycol, silica colloidal anhydrous, succinic acid, and titanium dioxide.
- **CIPRO I.V.:**
 - **Active ingredient:** ciprofloxacin
 - **Inactive ingredients:** lactic acid as a solubilizing agent, hydrochloric acid for pH adjustment

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