

BAYER Cipro Sip Row Ciprofloxacin Extended Release Tablets Instructions

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Arsalan POST COMPLETE



Introduction

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.

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-feeds. 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 (such as warfarin, Coumadin®, Jan oven®).
- Tizanidine (Zanaflex®). You should not take CIPRO if you are already taking tizanidine. See "Who should not take CIPRO?".
- Theophylline (such as Theo-24®, Elixophyllin®, Theocon®, Unhiply®, Theo lair®).
- Glyburide (Micronase®, Glynis®, Diabetes®, Glucovance®). See "What are the possible side effects of CIPRO?".
- Phenytoin (Fosphenytoin Sodium®, Careys®, Dilantin-125®, Dilantin®, Extended Phenytoin Sodium®, Prompt Phenytoin Sodium®, Phenetic®).
- 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 (Rexall®)
- Probenecid (Probalan®, Col-probenecid®).
- Metoclopramide (Reglan®, Reglan ODT®).
- Ropinirole (Requip®).
- Lidocaine (Xylocaine® intravenous infusion).
- Clozapine (Clozaril®, Fascicle® ODT®).
- Pentoxifylline (Trental®).
- Sildenafil (Viagra®, Revatio®).
- Cyclosporine (Genogram®, Neoral®, Sandimmune®, Sangcya®).
- · Omeprazole.
- 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 (Vides®, 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 cannot swallow the tablet whole.
- CIPRO IV is given to you by intravenous (IV) 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 IV after being exposed to anthrax:
 - CIPRO Tablets, Oral Suspension and IV 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 IV 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 IV 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:

Theophylline

You may have serious seizure and breathing problems when you take theophylline with CIPRO. These problems may lead to death. Get emergency help right away if you have seizures or trouble breathing.

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, including death, 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, Glynis, Diabetes, 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
- Diarrhea
- · Changes in liver function tests
- Vomiting
- Rash
- · Vaginal yeast infection
- · Pain or discomfort in the abdomen

Headache

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 call 1-888-84 BAYER (1-888-842-2937).

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: Microcapsulesciprofloxacin, 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 IV:

- Active ingredient: ciprofloxacin
- Inactive ingredients: lactic acid as a solubilizing agent, hydrochloric acid for pH adjustment

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

Customer Support

Manufactured for:

Bayer HealthCare
Pharmaceuticals

Bayer HealthCare Pharmaceuticals Inc.
Wayne, NJ 07470

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Documents / Resources



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References

- FDA Drugs@FDA: FDA-Approved Drugs
- User Manual

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