

FLOXAR SR®
Ciprofloxacin 1000 mg SR

WARNING:

Fluoroquinolones, including Ciprofloxacin 1000 mg SR Tablets, are associated with an increased risk of tendinitis and tendon rupture in all ages. This risk is further increased in older patients usually over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney; heart or lung transplants.

Fluoroquinolones, including Ciprofloxacin 1000 mg SR, may exacerbate muscle weakness in persons with myasthenia gravis. Avoid Ciprofloxacin 1000 mg SR in patients with known history of myasthenia gravis.

What is Floxar SR?

Floxar SR is a fluoroquinolone antibiotic medicine, used to treat certain infections caused by certain germs called bacteria. Each extended release film coated tablet contains: Ciprofloxacin 1000 mg.

Indications and Usage

Floxar SR is indicated only for the treatment of urinary tract infections, including the following:

- Complicated Urinary Tract Infections caused by *Escherichia coli*, *Klebsiella pneumoniae*, vancomycin-susceptible *Enterococcus faecalis*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*.
- Acute Uncomplicated Pyelonephritis caused by *Escherichia coli*.

Do not take Ciprofloxacin 1000 mg SR Tablets if you are (Contraindications):

- Hypersensitive to ciprofloxacin, any member of the quinolone class of antimicrobial agents, or any of the product components.
- Taking tizanidine.

Before taking Ciprofloxacin 1000 mg SR tablets tell your Doctor 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 Ciprofloxacin 1000 mg SR Tablets 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 Ciprofloxacin 1000 mg SR Tablets will harm your unborn child.
- Are breast-feeding or planning to breast-feed. Ciprofloxacin 1000 mg SR Tablets passes into breast milk. You and your Doctor should decide whether you will take ciprofloxacin 1000 mg SR or breast-feed.

Interaction with Other Medications

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including prescription and non-prescription medicines, vitamins and herbal and dietary

supplements. Ciprofloxacin 1000 mg SR Tablets and other medicines can affect each other causing side effects. Especially tell your Doctor if you take:

- An NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take Ciprofloxacin 1000 mg SR Tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See "What are the possible side effects of Ciprofloxacin 1000 mg SR Tablets?."
- A blood thinner (such as warfarin).
- Tizanidine. You should not take Ciprofloxacin 1000 mg SR Tablets if you are already taking tizanidine. See "Who should not take Ciprofloxacin 1000 mg SR Tablets?".
- Theophylline.
- Glyburide, See "What are the possible side effects of Ciprofloxacin 1000 mg SR Tablets?".
- Phenytoin
- Products that contain caffeine.
- A medicine to control your heart rate or rhythm (antiarrhythmics).
- 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.
- Methotrexate.
- Probenecid.
- Metoclopramide.
- Ropinirole.
- Lidocaine (Xylocaine® intravenous infusion).
- Clozapine.
- Pentoxifylline
- Sildenafil (Viagra®).
- Cyclosporine.
- Omeprazole.

Certain medicines may keep Ciprofloxacin 1000 mg SR Tablets from working correctly. Take Ciprofloxacin 1000 mg SR Tablets on 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
- Didanosine

* Ask your Doctor 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 Doctor and pharmacist when you get a new medicine.

Dosage and Administration

Floxar SR tablets should be administered orally once daily as described in the following table:

Indication	Unit Dose	Frequency	Usual Duration
Complicated Urinary Tract Infection	1000 mg	Q24h	7-14 Days
Acute Uncomplicated Pyelonephritis	1000 mg	Q24h	7-14 Days

- Patients whose therapy is started with Ciprofloxacin I.V. for urinary tract infections may be switched to Floxar SR when clinically indicated at the discretion of the physician.
- Take Floxar SR exactly as prescribed by your Doctor.
- Take Floxar SR 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 Doctor if you cannot swallow the tablet whole.
- Floxar SR can be taken with or without food.
- Floxar SR 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.

Pediatric Use

Safety and effectiveness of floxar SR tablest in pediatric patients and adolescents less than 18 years of age have not been established.

If you stop taking Floxar SR

Do not skip any doses, or stop taking Floxar SR 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 Ciprofloxacin 1000 mg SR?”),
- You have a serious allergic reaction (see “What are the possible side effects of Ciprofloxacin 1000 mg SR?”), or
- Your Doctor 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 FLOXAR SR. If this happens, Floxar SR and other antibiotic medicines may not work in the future.

If you forget to take Floxar SR

If you miss a dose, take it as soon as you remember. Do not take more than one dose in one day.

If you take more Floxar SR than you should (Overdose)

If you take too much, call your Doctor or get medical help immediately.

Special Populations

Impaired Renal Function

- In patients with complicated urinary tract infections and acute uncomplicated pyelonephritis, who have a creatinine clearance of ≤ 30 mL/min, the dose of Ciprofloxacin 1000 mg SR tablets should be reduced from 1000 mg to 500 mg daily. The use of Ciprofloxacin 1000 mg SR tablets is not recommended in this patient population.
- For patients on hemodialysis or peritoneal dialysis, administer Ciprofloxacin SR after the dialysis procedure is completed (maximum dose should be Ciprofloxacin 500 mg SR q 24 h). The use of Ciprofloxacin 1000 mg SR is not recommended in this patient population.

Impaired Hepatic Function

No dosage adjustment is required with Ciprofloxacin 1000 mg SR in patients with stable chronic cirrhosis. The kinetics of ciprofloxacin in patients with acute hepatic insufficiency, however, has not been fully elucidated.

Children and adolescents

Dosing in children (less than 18 years of age) with impaired renal or hepatic function has not been studied.

What should I avoid while taking Ciprofloxacin 1000 mg SR?

- Ciprofloxacin 1000 mg SR 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 1000 mg SR affects you.

- Avoid sun lamps, tanning beds, and try to limit your time in the sun. Ciprofloxacin 1000 mg SR can make your skin sensitive to the sun (photosensitivity) and the light from sun lamps and tanning beds. You could get severe sunburn, blisters or swelling of your skin. If you get any of these symptoms while taking Ciprofloxacin 1000 mg SR, call your Doctor 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 1000 mg SR?

Theophylline

You may have serious seizure and breathing problems when you take theophylline with Ciprofloxacin 1000 mg SR tablets. 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 Ciprofloxacin 1000 mg SR tablets. Tell your Doctor if you have a history of seizures. Ask your Doctor whether taking Ciprofloxacin 1000 mg SR tablets 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 Ciprofloxacin 1000 mg SR tablets. Talk to your Doctor 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 Ciprofloxacin 1000 mg SR tablets, even after only one dose. Stop taking Ciprofloxacin 1000 mg SR 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.
- Yellowing of the skin or eyes. Stop taking Ciprofloxacin 1000 mg SR tablets 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 Ciprofloxacin 1000 mg SR tablets (a liver problem).

Skin rash

Skin rash may happen in people taking Ciprofloxacin 1000 mg SR tablets even after only one dose. Stop taking Ciprofloxacin 1000 mg SR 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 1000 mg SR tablets.

Serious heart rhythm changes (QT prolongation and torsade de pointes)

Tell your Doctor right away if you have a change in your heart beat (a fast or irregular heartbeat), or if you faint. Ciprofloxacin 1000 mg SR 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)

Intestine infection (Pseudomembranous colitis)

Pseudomembranous colitis can happen with most antibiotics, including Ciprofloxacin 1000 mg SR tablets. Call your Doctor 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 nerve damage (Peripheral Neuropathy)

- Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including Ciprofloxacin 1000 mg SR tablets. Stop Ciprofloxacin 1000 mg SR tablets and talk with your Doctor 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
- Change in sensation to light touch, pain or temperature.

- Peripheral neuropathy Symptoms can occur at any time during treatment with fluoroquinolone, may occur soon after fluoroquinolone are taken and can last for months to years after the drug is stopped or be permanent.

- If the patient develops symptoms of peripheral neuropathy happened, fluoroquinolone should be stopped and the patient should be switched to another non-fluoroquinolone antibacterial drug, unless the benefit of continued treatment with a fluoroquinolone outweighs the risk.

Low blood sugar (hypoglycemia)

People who take Ciprofloxacin 1000 mg SR tablets and other fluoroquinolone medicines with the oral anti-diabetes medicine glyburide can get low blood sugar (hypoglycemia) which can sometimes be severe. Tell your Doctor if you get low blood sugar with Ciprofloxacin 1000 mg SR tablets. Your antibiotic medicine may need to be changed.

Sensitivity to sunlight (photosensitivity)

- See “What should I avoid while taking Ciprofloxacin 1000 mg SR”.

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 Ciprofloxacin 1000 mg SR tablets.

The most common side effects of Ciprofloxacin 1000 mg SR tablets 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 Ciprofloxacin 1000 mg SR. Tell your Doctor about any side effect that bothers you, or that does not go away.

Storage

Keep out of reach of children

Store below 30° C

Pack Size

-5 tablets wrapped with PVC-PVDC/Aluminium foil blister

-7 tablets wrapped with PVC-PVDC/Aluminium foil blister

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