MEDICATION GUIDE

CIPROFLOXACIN (sip-row-FLOX-a-sin) INJECTION, USP

For Intravenous Infusion

Read the Medication Guide that comes with CIPROFLOXACIN 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 CIPROFLOXACIN?

CIPROFLOXACIN belongs to a class of antibiotics called fluoroquinolones. CIPROFLOXACIN 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 CIPROFLOXACIN.

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

- **Tendon problems can happen in people of all ages who take CIPROFLOXACIN.** Tendons are tough cords of tissue that connect muscles to bones. Symptoms of tendon problems may include:
- Pain, swelling, tears and inflammation of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites.
- **The risk of getting tendon problems while you take CIPROFLOXACIN 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. 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)
- **Call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation.** Stop taking CIPROFLOXACIN 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 CIPROFLOXACIN.** 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 CIPROFLOXACIN.** 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

2. Worsening of myasthenia gravis (a disease which causes muscle weakness).

Fluoroquinolones like CIPROFLOXACIN 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 CIPROFLOXACIN?" for more information about side effects.

What is CIPROFLOXACIN?

CIPROFLOXACIN 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 CIPROFLOXACIN. CIPROFLOXACIN should not be used as the first choice of antibiotic medicine in children under 18 years of age.

CIPROFLOXACIN INJECTION, USP 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).

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 CIPROFLOXACIN, do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking CIPROFLOXACIN.

Who should not take CIPROFLOXACIN?

Do not take CIPROFLOXACIN 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 CIPROFLOXACIN. Ask your healthcare provider if you are not sure. See the list of ingredients in CIPROFLOXACIN 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 CIPROFLOXACIN?

See "**What is the most important information I should know about CIPROFLOXACIN?**"

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 CIPROFLOXACIN if your kidneys do not work well.
- Have rheumatoid arthritis (RA) or other history of joint problems.
- Have trouble swallowing pills.
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Are pregnant or planning to become pregnant. It is not known if CIPROFLOXACIN will harm your unborn child.
- Are breast-feeding or planning to breast-feed. CIPROFLOXACIN passes into breast milk. You and your healthcare provider should decide whether you will take CIPROFLOXACIN 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. CIPROFLOXACIN 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 CIPROFLOXACIN or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See " **What are the possible side effects of CIPROFLOXACIN?**".
- A blood thinner (such as warfarin, Coumadin ®, Jantoven ®).
- Tizanidine (Zanaflex ®). You should not take CIPROFLOXACIN if you are already taking tizanidine. See " **Who should not take CIPROFLOXACIN?**".
- Theophylline (such as Theo-24 ®, Elixophyllin ®, Theochron ®, Uniphyl ®, Theolair ®).
- Glyburide (Micronase ®, Glynase ®, Diabeta ®, Glucovance ®). See " **What are the possible side effects of CIPROFLOXACIN?**".
- 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 CIPROFLOXACIN?**".
- 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 CIPROFLOXACIN?**".
- Methotrexate (Trexall ®).
- Probenecid (Probalan ®, Col-probenecid ®).
- Metoclopromide (Reglan ®, Reglan ODT ®).
- Ropinirole (Requip ®).
- Lidocaine (Xylocaine ® intravenous infusion).
- Clozapine (Clozaril ®, Fazaclo ® ODT ®).
- Pentoxifylline (Trental ®).
- Sildenafil (Viagra ®, Revatio ®).
- Cyclosporine (Gengraf ®, Neoral ®, Sandimmune ®, Sangcya ®).
- Omeprazole.

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 CIPROFLOXACIN?

- Take CIPROFLOXACIN exactly as prescribed by your healthcare provider.
- CIPROFLOXACIN INJECTION, USP is given to you by intravenous (IV) infusion into your vein, slowly, over 60 minutes, as prescribed by your healthcare provider.

- CIPROFLOXACIN can be taken with or without food.
- CIPROFLOXACIN 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.
- Do not skip any doses, or stop taking CIPROFLOXACIN 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?**"),
- You have a serious allergic reaction (see " **What are the possible side effects of CIPROFLOXACIN?**"), 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 CIPROFLOXACIN. If this happens, CIPROFLOXACIN and other antibiotic medicines may not work in the future.

- If you take too much, call your healthcare provider or get medical help immediately.

If you have been prescribed CIPROFLOXACIN INJECTION, USP after being exposed to anthrax:

CIPROFLOXACIN INJECTION, USP 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 CIPROFLOXACIN exactly as prescribed by your healthcare provider. Do not stop taking CIPROFLOXACIN without talking with your healthcare provider. If you stop taking CIPROFLOXACIN too soon, it may not keep you from getting the anthrax disease.

Side effects may happen while you are taking CIPROFLOXACIN INJECTION, USP. When taking your CIPROFLOXACIN to prevent anthrax infection, you and your healthcare provider should talk about whether the risks of stopping CIPROFLOXACIN too soon are more important than the risks of side effects with CIPROFLOXACIN.

- If you are pregnant, or plan to become pregnant while taking CIPROFLOXACIN, you and your healthcare provider should decide whether the benefits of taking CIPROFLOXACIN INJECTION, USP for anthrax are more important than the risks.

What should I avoid while taking CIPROFLOXACIN?

- CIPROFLOXACIN 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 affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. CIPROFLOXACIN 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 CIPROFLOXACIN, 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?

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

Other serious side effects of CIPROFLOXACIN include:

- **Theophylline**
  You may have serious seizure and breathing problems when you take theophylline with CIPROFLOXACIN. 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. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking CIPROFLOXACIN 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. 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 CIPROFLOXACIN, even after only one dose. Stop taking CIPROFLOXACIN 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 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 (a liver problem).

- **Skin rash**
  Skin rash may happen in people taking CIPROFLOXACIN even after only one dose. Stop taking CIPROFLOXACIN 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.
- **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 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. 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 nerve damage** (Peripheral Neuropathy)
  Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including CIPROFLOXACIN. Stop CIPROFLOXACIN and 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

  The nerve damage may be permanent.

- **Low blood sugar** (hypoglycemia)
  People who take CIPROFLOXACIN 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 CIPROFLOXACIN. Your antibiotic medicine may need to be changed.
- **Sensitivity to sunlight** (photosensitivity). See " **What should I avoid while taking CIPROFLOXACIN?**"
- **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.
  The most common side effects of CIPROFLOXACIN 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. 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.

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

General Information about CIPROFLOXACIN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CIPROFLOXACIN for a condition for which it is not prescribed. Do not give CIPROFLOXACIN 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 CIPROFLOXACIN. If you would like more information about CIPROFLOXACIN, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about CIPROFLOXACIN that is written for healthcare professionals.

What are the ingredients in CIPROFLOXACIN?

- **CIPROFLOXACIN INJECTION, USP:**
  - **Active ingredient:** ciprofloxacin
  - **Inactive ingredients:** dextrose monohydrate as a tonicity agent, 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.