

MEDICATION GUIDE

FLOXIN® [Flox in] (ofloxacin)

Read the Medication Guide that comes with FLOXIN® 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 FLOXIN®?

FLOXIN® belongs to a class of antibiotics called fluoroquinolones. FLOXIN® 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 FLOXIN®.

• **Tendon rupture or swelling of the tendon (tendinitis)**

- Tendons are the 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 FLOXIN®. The risk of getting tendon problems is higher if you:
 - are over 60 years of age or
 - are taking steroids (corticosteroids) or
 - 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 FLOXIN® 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 FLOXIN®. 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 FLOXIN®. 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 that causes muscle weakness).** Fluoroquinolones like FLOXIN[®] 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 FLOXIN[®]?**” for more information about side effects.

What is FLOXIN[®]?

FLOXIN[®] is a fluoroquinolone antibiotic medicine used in adults to treat certain infections caused by certain germs called bacteria. It is not known if FLOXIN[®] is safe and works in people under 18 years of age. 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 FLOXIN[®].

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 FLOXIN[®] do not kill viruses.

Call your healthcare provider if you think your condition is not getting better while you are taking FLOXIN[®].

Who should not take FLOXIN[®]?

Do not take FLOXIN[®] if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to any of the ingredients in FLOXIN[®]. Ask your healthcare provider if you are not sure. See the list of the ingredients in FLOXIN[®] at the end of this Medication Guide.

What should I tell my healthcare provider before taking FLOXIN[®]?

See “**What is the most important information I should know about FLOXIN[®]?**”

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 low blood potassium (hypokalemia)
- have a history of seizures
- have kidney problems. You may need a lower dose of FLOXIN[®] if your kidney does not work well.
- have liver problems

- have rheumatoid arthritis (RA) or other history of joint problems
- are pregnant or planning to become pregnant. It is not known if FLOXIN[®] will harm your unborn child
- are breast-feeding or planning to breast-feed. FLOXIN[®] passes into breast milk. You and your healthcare provider should decide whether you will take FLOXIN[®] or breast-feed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal and dietary supplements. FLOXIN[®] 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 FLOXIN[®] or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See **“What are the possible side effects of FLOXIN[®]?”**
- theophylline
- a blood thinner (warfarin, Coumadin, Jantoven)
- an oral anti-diabetes medicine or insulin
- a medicine to control your heart rate or rhythm (antiarrhythmics). See **“What are the possible side effects of FLOXIN[®]?”**.
- 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 FLOXIN[®]?”**.
- Certain medicines may keep FLOXIN[®] from working correctly. Take FLOXIN[®] either 2 hours before or 2 hours after taking these products:
 - an antacid, multivitamins, or other product that has calcium, magnesium, aluminum, iron, or zinc.
 - sulcrafate (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 FLOXIN[®]?

- Take FLOXIN[®] exactly as prescribed by your healthcare provider.
- Take FLOXIN[®] at about the same time each day.
- Drink plenty of fluids while taking FLOXIN[®].
- FLOXIN[®] can be taken with or without food.
- Do not skip any doses, or stop taking FLOXIN[®], 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 FLOXIN®?**”),
 - you have a serious allergic reaction (see “**What are the possible side effects of FLOXIN®?**”), 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 FLOXIN®. If this happens, FLOXIN® and other antibiotic medicines may not work in the future.
 - If you miss a dose of FLOXIN®, take it as soon as you remember. Do not take two doses of FLOXIN® at the same time. Do not take more than two doses in one day.
 - If you take too much, call your healthcare provider or get medical help immediately.

What should I avoid while taking FLOXIN®?

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

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

Other serious side effects of FLOXIN® include:

- **Central Nervous System Effects:** Seizures have been reported in people who take fluoroquinolone antibiotics including FLOXIN®. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking FLOXIN® 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 FLOXIN®. Talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:

- feel lightheaded
- 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 FLOXIN[®], even after only one dose. Stop taking FLOXIN[®] 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 FLOXIN[®] 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 FLOXIN[®] (a liver problem).
 - **Skin rash:** Skin rash may happen in people who take FLOXIN[®], even after only one dose. Stop taking FLOXIN[®] at the first sign of a skin rash and call your healthcare provider. Skin rash may be sign of a more serious reaction to FLOXIN[®].
 - **Intestine infection (Pseudomembranous colitis):** Pseudomembranous colitis can happen with most antibiotics, including FLOXIN[®]. Call your healthcare provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody stools. You may also 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 taking fluoroquinolones, including FLOXIN[®]. 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

FLOXIN[®] may need to be stopped to prevent permanent nerve damage.
 - **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. FLOXIN[®] 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 happening 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)
- **Sensitivity to sunlight** (photosensitivity): See **“What should I avoid while taking FLOXIN®?”**
- **Low blood sugar** (hypoglycemia). People who take FLOXIN® and other fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low blood sugar (hypoglycemia). Follow your healthcare provider’s instructions for how often to check your blood sugar. If you have diabetes and you get low blood sugar while taking FLOXIN®, stop taking FLOXIN® right away and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

The most common side effects of FLOXIN® include:

- Sleep problems
- headache
- dizziness
- nausea
- vomiting
- diarrhea
- itching
- external genital itching in women
- vaginal inflammation (vaginitis)
- taste changes

FLOXIN® may cause false-positive urine screening results for opiates when testing is done with some commercially available kits. A positive result should be confirmed using a more specific test.

These are not all the possible side effects of FLOXIN®. 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 FLOXIN®?

- Store FLOXIN® at 59° to 86° F (15°C to 30°C).
- Keep the bottle that FLOXIN® comes in closed tightly.
- Keep FLOXIN® and all medicines out of the reach of children.

General information about FLOXIN®

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use FLOXIN® for a condition for which it is not prescribed. Do not give FLOXIN® 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 FLOXIN®. If you would like more information about FLOXIN®, talk with your healthcare provider. You

can ask your healthcare provider or pharmacist for information about FLOXIN[®] that is written for healthcare professionals. For more information call 1-800-526-7736.

What are the ingredients in FLOXIN[®]?

- Active ingredient: ofloxacin
- Inactive ingredients: anhydrous lactose, modified corn starch, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, polysorbate 80, sodium starch glycolate, titanium dioxide and may also contain synthetic yellow iron oxide.

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