

## MEDICATION GUIDE

### Ofloxacin Tablets, USP (oh-FLOX-a-sin)

#### Rx only

Read the Medication Guide that comes with ofloxacin 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 ofloxacin tablets?

Ofloxacin belongs to a class of antibiotics called fluoroquinolones. Ofloxacin tablets 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 ofloxacin tablets.

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

- **Tendon problems can happen in people of all ages who take ofloxacin tablets.** 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.
- **The risk of getting tendon problems while you take ofloxacin tablets 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 ofloxacin tablets. 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 ofloxacin tablets 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 ofloxacin tablets.** 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 ofloxacin tablets.** 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 that causes muscle weakness).

Fluoroquinolones like ofloxacin tablets 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 ofloxacin tablets?” for more information about side effects.

#### What is ofloxacin?

Ofloxacin tablets are a fluoroquinolone antibiotic medicine used in adults to treat certain infections caused by certain germs called bacteria. It is not known if ofloxacin tablets are safe and work 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 ofloxacin tablets.

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 ofloxacin tablets do not kill viruses.

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

#### Who should not take ofloxacin tablets?

Do not take ofloxacin tablets 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 ofloxacin. Ask your healthcare provider if you are not sure. See the list of the ingredients in ofloxacin tablets at the end of this Medication Guide.

#### What should I tell my healthcare provider before taking ofloxacin tablets?

See “What is the most important information I should know about ofloxacin tablets?”

#### 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 ofloxacin tablets if your kidneys do 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 ofloxacin tablets will harm your unborn child
- are breastfeeding or planning to breastfeed. Ofloxacin passes into breast milk. You and your healthcare provider should decide whether you will take ofloxacin tablets or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal and dietary supplements. Ofloxacin tablets 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 ofloxacin tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See “What are the possible side effects of ofloxacin tablets?”
- 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 ofloxacin tablets?”.
- 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 ofloxacin tablets?”.
- Certain medicines may keep ofloxacin tablets from working correctly. Take ofloxacin tablets either 2 hours before or 2 hours after taking these products:
  - an antacid, multivitamin, or other product that has magnesium, 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 ofloxacin tablets?

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

- Ofloxacin tablets 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 ofloxacin tablets affect you.

- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Ofloxacin tablets 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 ofloxacin tablets, 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 ofloxacin tablets?

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

Other serious side effects of ofloxacin tablets include:

- **Central Nervous System Effects:** Seizures have been reported in people who take fluoroquinolone antibiotics including ofloxacin tablets. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking ofloxacin 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 ofloxacin tablets. 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 ofloxacin tablets, even after only one dose. Stop taking ofloxacin 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 ofloxacin 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 ofloxacin tablets (a liver problem).

#### • Skin rash

Skin rash may happen in people who taking ofloxacin tablets, even after only one dose. Stop taking ofloxacin 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 ofloxacin.

#### • Intestine infection (Pseudomembranous colitis)

Pseudomembranous colitis can happen with most antibiotics, including ofloxacin tablets. 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 taking fluoroquinolones, including ofloxacin tablets. Stop ofloxacin 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.

#### • 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. Ofloxacin 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 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 ofloxacin tablets?”
- **Low blood sugar (hypoglycemia).** People who take ofloxacin tablets 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 ofloxacin tablets, stop taking ofloxacin tablets right away and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

The most common side effects of ofloxacin tablets include:

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

Ofloxacin tablets 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 ofloxacin tablets. 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 ofloxacin tablets?

- Store ofloxacin tablets at 20° to 25° C (68°F to 77°F).
- Keep the bottle that ofloxacin tablets come in closed tightly.
- Keep ofloxacin tablets and all medicines out of the reach of children.

#### General Information about ofloxacin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ofloxacin tablets for a condition for which it is not prescribed. Do not give ofloxacin tablets 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 ofloxacin tablets. If you would like more information about ofloxacin tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ofloxacin tablets that is written for healthcare professionals. For more information go to [www.cadilapharma.com](http://www.cadilapharma.com) or call 1-202-355-9785.

#### What are the ingredients in ofloxacin tablets?

- Active ingredient: ofloxacin , USP
- Inactive ingredients: lactose monohydrate, pregelatinized maize starch, hydroxy propyl methyl cellulose, talc, magnesium stearate, polyethylene glycol, sodium starch glycolate, and titanium dioxide. Additionally, the 200 mg and 400 mg tablets contain iron oxide yellow.

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

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#### Manufactured by:

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