

FDA-Approved Medication Guide

MEDICATION GUIDE

Moxifloxacin Hydrochloride Tablets

(mox'' i flox' a sin hye'' droe klor' ide)

Rx only

Read the Medication Guide that comes with moxifloxacin hydrochloride tablets before you start taking them 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 moxifloxacin hydrochloride tablets?

Moxifloxacin hydrochloride tablets belong to a class of antibiotics called fluoroquinolones. Moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets.

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

- **Tendon problems can happen in people of all ages who take moxifloxacin hydrochloride tablets.** 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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride 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 in 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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride 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 which causes muscle weakness).

Fluoroquinolones like moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets?”** for more information about side effects.

What are moxifloxacin hydrochloride tablets?

Moxifloxacin hydrochloride tablets are a fluoroquinolone antibiotic medicine used to treat certain types of infections caused by certain germs called bacteria in adults 18 years or older. These bacterial infections include:

- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis
- Community Acquired Pneumonia
- Uncomplicated Skin and Skin Structure Infections
- Complicated Skin and Skin Structure Infections
- Complicated Intra-Abdominal Infections
- Plague

Studies of moxifloxacin hydrochloride tablets for use in the treatment of plague were done in animals only, because plague could not be studied in people.

It is not known if moxifloxacin hydrochloride tablet is safe and works in people under 18 years of age. Children have a higher chance of getting bone, joint, and tendon (musculoskeletal) problems while taking fluoroquinolone antibiotic medicines.

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 moxifloxacin hydrochloride tablets, do not kill viruses. Call your healthcare provider if you think your condition is not getting better while you are taking moxifloxacin hydrochloride tablets.

Who should not take moxifloxacin hydrochloride tablets?

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

What should I tell my healthcare provider before taking moxifloxacin hydrochloride tablets?

See **“What is the most important information I should know about moxifloxacin hydrochloride 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 slow heartbeat (bradycardia)
- Have a history of seizures
- Have kidney problems
- Have rheumatoid arthritis (RA) or other history of joint problems
- Are pregnant or planning to become pregnant. It is not known if moxifloxacin hydrochloride tablets will harm your unborn child
- Are breast-feeding or planning to breast-feed. It is not known if moxifloxacin hydrochloride passes into breast milk. You and your healthcare provider should decide whether you will take moxifloxacin hydrochloride tablets or breast-feed.
- Have diabetes or problems with low blood sugar (hypoglycemia)

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, herbal, and dietary supplements. Moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See **“What are the possible side effects of moxifloxacin hydrochloride tablets?”**
- A blood thinner (warfarin, Coumadin, Jantoven).
- A medicine to control your heart rate or rhythm (antiarrhythmic). See **“What are the possible side effects of moxifloxacin hydrochloride tablets?”**
- An anti-psychotic medicine.
- A tricyclic antidepressant.
- An oral anti-diabetes medicine or insulin.
- Erythromycin.
- 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 moxifloxacin hydrochloride tablets?”**
- Certain medicines may keep moxifloxacin hydrochloride tablets from working correctly. Take moxifloxacin hydrochloride tablets either 4 hours before or 8 hours after taking these products:
 - An antacid, multivitamin, or other product that has magnesium, aluminum, iron, or zinc
- Sucralfate (Carafate®)
- Didanosine oral suspension or solution

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 moxifloxacin hydrochloride tablets?

- Take moxifloxacin hydrochloride tablets once a day exactly as prescribed by your healthcare provider.
- Take moxifloxacin hydrochloride tablets at about the same time each day.
- Moxifloxacin hydrochloride tablets should be swallowed.
- Moxifloxacin hydrochloride tablets can be taken with or without food.
- Drink plenty of fluids while taking moxifloxacin hydrochloride tablets.
- Do not skip any doses, or stop taking moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets?”**).
 - You have a serious allergic reaction (see **“What are the possible side effects of moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets. If this happens, moxifloxacin hydrochloride tablets and other antibiotic medicines may not work in the future.
 - If you miss a dose of moxifloxacin hydrochloride tablets, take it as soon as you remember. Do not take more than 1 dose of moxifloxacin hydrochloride tablets in one day.
 - If you take too much, call your healthcare provider or get medical help immediately.

What should I avoid while taking moxifloxacin hydrochloride tablets?

- Moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets affect you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Moxifloxacin hydrochloride 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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets?

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

Other serious side effects of moxifloxacin hydrochloride tablets include:

- **Central Nervous System effects**

Seizures have been reported in people who take fluoroquinolone antibiotics including moxifloxacin hydrochloride tablets. Tell your healthcare provider if you have a history of seizures. Ask your healthcare provider whether taking moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets. Talk to your healthcare provider right away if you have any of these side effects, or other changes in mood or behavior:

- Feeling 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
 - Feel more suspicious (paranoia)
 - Suicidal thoughts or acts
 - Nightmares
 - Vision Loss
- **Serious allergic reactions**

Allergic reactions can happen in people taking fluoroquinolones, including moxifloxacin hydrochloride tablets, even after only one dose. Stop taking moxifloxacin hydrochloride 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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets (a liver problem).

• **Skin rash**

Skin rash may happen in people taking moxifloxacin hydrochloride tablets even after only one dose. Stop taking moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets.

• **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. Moxifloxacin hydrochloride 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 moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets. Stop moxifloxacin 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.

- **Changes in blood sugar**

People who take moxifloxacin hydrochloride tablets and other fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia). 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 moxifloxacin hydrochloride tablets, stop taking moxifloxacin hydrochloride tablets and call your healthcare provider right away. Your antibiotic medicine may need to be changed.

- **Sensitivity to sunlight (photosensitivity)**

See “**What should I avoid while taking moxifloxacin hydrochloride tablets?**” The most common side effects of moxifloxacin hydrochloride tablets include nausea and diarrhea.

These are not all the possible side effects of moxifloxacin hydrochloride 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 moxifloxacin hydrochloride tablets?


- Store moxifloxacin hydrochloride tablets at 20° to 25°C (68° to 77°F).
- Keep moxifloxacin hydrochloride tablets away from moisture (humidity).

Keep moxifloxacin hydrochloride tablets and all medicines out of the reach of children.

General information about moxifloxacin hydrochloride tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use moxifloxacin hydrochloride tablets for a condition for which it is not prescribed. Do not give moxifloxacin hydrochloride tablets to other people, even if they have the same symptoms that you have. They may harm them.

This Medication Guide summarizes the most important information about moxifloxacin hydrochloride tablets. If you would like more information about moxifloxacin hydrochloride tablets, talk with your healthcare

provider. You can ask your healthcare provider or pharmacist for information about moxifloxacin hydrochloride tablets that is written for healthcare professionals. For more information call Aurobindo Pharma USA, Inc. at 1-866-850-2876 .

What are the ingredients in moxifloxacin hydrochloride tablets?

- Active ingredient: moxifloxacin hydrochloride
- Inactive ingredients: hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium starch glycolate, and titanium dioxide.

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

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