

MEDICATION GUIDE

Moxifloxacin (MOX-i-FLOX-a-sin) Tablets, USP for oral use

Read the Medication Guide that comes with moxifloxacin tablets 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 moxifloxacin tablets?

Moxifloxacin tablets are in a class of antibiotics called fluoroquinolones. Moxifloxacin tablets can cause serious side effects that can happen at the same time and could result in death. If you get any of the following serious side effects, you should stop taking moxifloxacin tablets and get medical help right away. Talk with your healthcare provider about whether you should continue to take moxifloxacin tablets.

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

- **Tendon problems can happen in people of all ages who take moxifloxacin 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 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 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).
- **Stop taking moxifloxacin tablets immediately and call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation.** Stop taking moxifloxacin 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 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 stopped taking moxifloxacin tablets.** Tendon ruptures can happen within hours or days after taking moxifloxacin tablets and have happened up to several months after people have stopped taking their fluoroquinolone.

- **Stop taking moxifloxacin tablets immediately and 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 put weight on the area.

2. Changes in sensation and possible nerve damage (Peripheral Neuropathy). Damage to the nerves in arms, hands, legs, or feet can happen in people who take fluoroquinolones, including moxifloxacin tablets. Stop taking moxifloxacin tablets immediately and talk to 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

Moxifloxacin tablets may need to be stopped to prevent permanent nerve damage.

3. Central Nervous System (CNS) effects. Seizures have been reported in people who take fluoroquinolone antibiotic medicines, including moxifloxacin tablets. Tell your healthcare provider if you have a history of seizures before you start taking moxifloxacin tablets. CNS side effects may happen as soon as after taking the first dose of moxifloxacin tablets. Stop taking moxifloxacin tablets immediately and talk to your healthcare provider right away if you get any of these side effects, or other changes in mood or behavior:

- 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 lightheaded or dizzy
- feel more suspicious (paranoia)
- suicidal thoughts or acts
- headaches that will not go away (with or without blurred vision)

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

Fluoroquinolones like moxifloxacin hydrochloride may cause worsening of myasthenia gravis symptoms, including muscle weakness and breathing problems. Tell your healthcare provider if you have a history of myasthenia gravis. Moxifloxacin hydrochloride tablets should not be used in people who have a history of myasthenia gravis. 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 tablets?**” for more information about side effects.

What are moxifloxacin tablets?

Moxifloxacin 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:

- Community Acquired Pneumonia
- Uncomplicated Skin and Skin Structure Infections
- Complicated Skin and Skin Structure Infections
- Complicated Intra-Abdominal Infections
- Plague

- Acute Bacterial Sinusitis
- Acute Bacterial Exacerbation of Chronic Bronchitis

Moxifloxacin tablets should not be used in people with acute bacterial sinusitis or acute bacterial exacerbation of chronic bronchitis if there are other treatment options available.

Studies of moxifloxacin hydrochloride 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 tablets are 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 tablets, do not kill viruses.

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

Who should not take moxifloxacin tablets?

Do not take moxifloxacin tablets if you have ever had an allergic reaction to moxifloxacin, other fluoroquinolone antibiotics, or any of the ingredients in moxifloxacin tablets. Ask your healthcare provider if you are not sure. See the end of this medication guide for a complete list of ingredients in moxifloxacin tablets.

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

- See “**What is the most important information I should know about moxifloxacin tablets?**”

Tell your healthcare provider about all your medical conditions, including if you:

- Have tendon problems; moxifloxacin tablets should not be used in people who have a history of tendon problems.
- Have a disease that causes muscle weakness (myasthenia gravis); moxifloxacin tablets should not be used in people who have a history of myasthenia gravis.
- Have central nervous system problems (such as epilepsy)
- Have nerve problems; moxifloxacin tablets should not be used in people who have a history of a nerve problem called peripheral neuropathy.
- 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 tablets will harm your unborn baby.
- Are breast-feeding or plan to breastfeed. It is not known if moxifloxacin hydrochloride passes into breast milk. You and your healthcare provider should decide whether you will take

moxifloxacin tablets or breastfeed.

- Have diabetes or problems with low blood sugar (hypoglycemia).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal and dietary supplements. Moxifloxacin tablets and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:

- A Non-Steroidal Anti-Inflammatory Drugs(NSAID) Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take moxifloxacin tablets or other fluoroquinolones may increase your risk of central nervous system effects and seizures. See “**What are the possible side effects of moxifloxacin 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 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 tablets?**”
- Certain medicines may keep moxifloxacin tablets from working correctly. Take moxifloxacin 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 tablets?

- Take moxifloxacin tablets 1 time each day exactly as prescribed by your healthcare provider.
- Take moxifloxacin tablets at about the same time each day.
- Moxifloxacin tablets can be taken with or without food.
- If you miss a dose of moxifloxacin hydrochloride tablets and it is:
 - **8 hours or more** until your next scheduled dose, take your missed dose right away. Then take the next dose at your regular time.
 - **less than 8 hours** until your next scheduled dose, do not take the missed dose. Take the next dose at your regular time.
- Do not take 2 doses of moxifloxacin hydrochloride tablets to make up for a missed dose. If you are not sure about when to take moxifloxacin hydrochloride Tablets after a missed dose, ask your doctor or pharmacist
- Drink plenty of fluids while taking moxifloxacin tablets.
- Do not skip any doses, or stop taking moxifloxacin tablets even if you begin to feel better, until you finish your prescribed treatment, unless:
 - You have tendon problems. (see “**What is the most important information I should**

know about moxifloxacin tablets?”).

- You have nerve problems. See “**What is the most important information I should know about moxifloxacin tablets?”**”
- You have central nervous system problems. See “**What is the most important information I should know about moxifloxacin tablets?”**”
- You have a serious allergic reaction (see “**What are the possible side effects of moxifloxacin tablets?”**”), or your healthcare provider tells you to stop taking moxifloxacin hydrochloride tablets.
- This will help make sure that all of the bacteria are killed and lower the chance that the bacteria will become resistant to moxifloxacin tablets. If this happens, moxifloxacin tablets and other antibiotic medicines may not work in the future.
- If you take too much, call your healthcare provider or get medical help immediately.

What should I avoid while taking moxifloxacin tablets?

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

Moxifloxacin tablets can cause side effects that may be serious or even cause death, including:

- See “**What is the most important information I should know about moxifloxacin tablets?”**”
- **Serious heart rhythm changes** (QT prolongation and torsade de pointes). Tell your healthcare provider right away if you have a change in your heartbeat (a fast or irregular heartbeat), or if you faint. Moxifloxacin hydrochloride 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)
- **Serious allergic reactions.** Allergic reactions can happen in people taking fluoroquinolones, including moxifloxacin tablets, even after only one dose. Stop taking moxifloxacin 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
 - Fast heartbeat
 - Faint
 - Yellowing of the skin or eyes. Stop taking moxifloxacin 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 tablets (a liver problem).

- **Skin rash.** Skin rash may happen in people taking moxifloxacin tablets even after only one dose. Stop taking moxifloxacin 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 tablets.
- **Aortic aneurysm and dissection.** Tell your healthcare provider if you have ever been told that you have, a swelling of the large artery that carries blood from the heart to the body (aortic aneurysm). Get emergency medical help right away if you have sudden chest, stomach, or back pain.
- **Intestine infection (Pseudomembranous colitis).** Pseudomembranous colitis can happen with most antibiotics, including moxifloxacin 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 stopped taking moxifloxacin hydrochloride tablets.
- **Changes in blood sugar.** People who take moxifloxacin 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 tablets, stop taking moxifloxacin 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 tablets?”

The most common side effects of moxifloxacin tablets include:

- nausea
- diarrhea
- headache
- dizziness

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

- Store moxifloxacin tablets at 20° to 25°C (68° to 77°); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]
- Keep moxifloxacin tablets away from moisture (humidity)

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

General Information about safe and effective use of moxifloxacin tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use moxifloxacin tablets for a condition for which it is not prescribed. Do not give moxifloxacin 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 moxifloxacin tablets. If you would like more information about moxifloxacin tablets, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about moxifloxacin tablets that is written for healthcare professionals. For more information call 1-800-912-9561.

What are the ingredients in moxifloxacin tablets?

Moxifloxacin tablets, USP:

- Active ingredient: moxifloxacin hydrochloride, USP
- Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, ferric oxide red, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol 400, polyvinyl pyrrolidone, pregelatinised starch and titanium dioxide.

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