

## Medication Guide

### Moxifloxacin Injection

(mox i FLOX a sin) (in jek' shŭn)

solution for intravenous use

Read the Medication Guide that comes with Moxifloxacin Injection before you start receiving it and each time you receive it. 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 injection?**

Moxifloxacin injection belongs to a class of antibiotics called fluoroquinolones. Moxifloxacin injection 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 and get medical help right away. Talk with your healthcare provider about whether you should continue to receive moxifloxacin injection.

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

- **Tendon problems can happen in people of all ages who receive moxifloxacin injection.** 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 receive moxifloxacin injection 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 receive moxifloxacin injection.**

- 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 immediately and call your healthcare provider right away at the first sign of tendon pain, swelling or inflammation.**

Stop receiving moxifloxacin injection 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 injection.**

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 receiving moxifloxacin injection.**

Tendon ruptures can happen within hours or days after taking moxifloxacin and have happened up to several months after patients have finished receiving their fluoroquinolone.

- **Stop taking moxifloxacin 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 bear weight.

**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. Stop taking moxifloxacin 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

The nerve damage may be permanent.

**3. Central Nervous System (CNS) effects.** Seizures have been reported in people who take fluoroquinolone antibacterial medicines, including moxifloxacin. Tell your healthcare provider if you have a history of seizures before you start taking moxifloxacin. CNS side effects may happen as soon as after taking the first dose of moxifloxacin. Stop taking moxifloxacin 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 injection 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 before you start taking moxifloxacin. 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 injection?**” for more information about side effects.

### **What is moxifloxacin injection?**

Moxifloxacin injection is a fluoroquinolone antibiotic medicine used to treat certain types of infections caused by certain germs called bacteria in adults 18 years or older. It is not known if

moxifloxacin injection 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.

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

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

### **Who should not receive moxifloxacin injection?**

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

### **What should I tell my healthcare provider before receiving moxifloxacin injection?**

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

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

- Have tendon problems; moxifloxacin should not be used in patients who have a history of tendon problems
- Have a disease that causes muscle weakness (myasthenia gravis); moxifloxacin should not be used in patients who have a history of myasthenia gravis

- Have central nervous system problems (such as epilepsy)
- Have nerve problems; moxifloxacin should not be used in patients 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 congestive heart failure
- Have a history of seizures
- Have kidney problems
- Have rheumatoid arthritis (RA) or other history of joint problems
- Are on a salt-restricted diet
- Have diabetes or problems with low blood sugar (hypoglycemia)
- Are pregnant or planning to become pregnant. It is not known if moxifloxacin injection will harm your unborn child.
- Are breastfeeding or planning to breastfeed. It is not known if moxifloxacin injection passes into breast milk. You and your healthcare provider should decide whether you will receive moxifloxacin injection or breastfeed.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins and herbal and dietary supplements. Moxifloxacin injection 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 receive moxifloxacin injection or other fluoroquinolones may increase your risk of central nervous system effects and seizures.

- 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 injection?”**
- 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 injection?”**

**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 receive moxifloxacin injection?**

- Moxifloxacin injection is given to you by intravenous (IV) infusion into your vein slowly, over 60 minutes, as prescribed by your healthcare provider.
- **Do not** skip any doses, or stop receiving moxifloxacin injection 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 injection?”**).
  - You have nerve problems. See **“What is the most important information I should know about moxifloxacin injection?”**

- You have central nervous system problems. See **“What is the most important information I should know about moxifloxacin injection?”**
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- You have a serious allergic reaction (see **“What are the possible side effects of moxifloxacin injection?”**), 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 injection. If this happens, moxifloxacin injection and other antibiotic medicines may not work in the future.

### **What should I avoid while receiving moxifloxacin injection?**

- Moxifloxacin injection 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 injection affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Moxifloxacin injection 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 receiving moxifloxacin injection, 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 injection?**

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

Other serious side effects of moxifloxacin injection include:

- **Serious heart rhythm changes (QT prolongation and torsades 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 injection 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 injection, even after only 1 dose. Stop receiving moxifloxacin injection 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 receiving moxifloxacin injection 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 injection (a liver problem).
- **Skin rash.** Skin rash may happen in people receiving moxifloxacin injection even after only 1 dose. Stop receiving moxifloxacin injection 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 injection.

1 • **Intestine infection (Pseudomembranous colitis).** Pseudomembranous colitis can  
2 happen with most antibiotics, including moxifloxacin injection. Call your healthcare  
3 provider right away if you get watery diarrhea, diarrhea that does not go away, or bloody  
4 stools. You may have stomach cramps and a fever. Pseudomembranous colitis can  
5 happen 2 or more months after you have finished your antibiotic.

6 • **Changes in blood sodium.** Increased blood sodium can happen in people who receive  
7 moxifloxacin injection. Tell your healthcare provider if you are on a salt-restricted diet  
8 or have congestive heart failure. Your antibiotic medicine may need to be changed.

9 • **Changes in blood sugar.** People who receive moxifloxacin injection and other  
10 fluoroquinolone medicines with oral anti-diabetes medicines or with insulin can get low  
11 blood sugar (hypoglycemia) and high blood sugar (hyperglycemia). Follow your  
12 healthcare provider's instructions for how often to check your blood sugar. If you have  
13 diabetes and you get low blood sugar while receiving moxifloxacin injection, stop  
14 receiving moxifloxacin injection and call your healthcare provider right away. Your  
15 antibiotic medicine may need to be changed.

16 • **Sensitivity to sunlight (photosensitivity).**

17 See “What should I avoid while receiving moxifloxacin injection?”

18 The most common side effects of moxifloxacin injection include:

- 19 • Nausea
- 20 • Diarrhea
- 21 • Headache
- 22 • Dizziness

23 These are not all the possible side effects of moxifloxacin injection. Tell your healthcare  
24 provider about any side effect that bothers you or that does not go away. Call your doctor

1 for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-  
2 1088.

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4 **How should I store moxifloxacin injection?**

- 5 • Store moxifloxacin injection at room temperature between 68°F to 77°F (20°C to 25°C).
- 6 • Keep the moxifloxacin injection bag in the outer bag and out of the light until you are  
7 ready to use it. Moxifloxacin injection should be used right away after removing it from  
8 the outer bag.
- 9 • **Do not** refrigerate.
- 10 • Moxifloxacin injection is for single use only.
- 11 • Keep moxifloxacin injection and all medicines out of the reach of children.

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13 **General Information about the safe and effective use of moxifloxacin injection.**

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

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19 This Medication Guide summarizes the most important information about moxifloxacin  
20 injection. If you would like more information about moxifloxacin injection, talk with your  
21 healthcare provider. You can ask your healthcare provider or pharmacist for information  
22 about moxifloxacin injection that is written for healthcare professionals. For more  
23 information call 1-800-551-7176.

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25 **What are the ingredients in moxifloxacin injection?**

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1 **Active ingredient:** moxifloxacin

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3 **Inactive ingredients:** sodium acetate-trihydrate, disodium sulfate, sulfuric acid (for pH

4 adjustment), and water for injection

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7 Manufactured for:



9 This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised 07 2016

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