

Medication Guide

Moxifloxacin Injection (mox) (FLOX a inj) (in jek-stun) 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.

Tendon rupture or swelling of the tendon (tendinitis).

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).

Stopping 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 rupture can happen within hours or days after taking moxifloxacin and have happened up to several months later 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:

- Pain or tenderness at the site of a tear or pop at a tendon area.
- Swelling or redness at the site of a tendon area.
- Difficulty moving the affected joint or tendon area.
- Unable to bear the affected joint or tendon weight.

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:

- numbness
- tingling
- weakness

The nerve damage may be permanent.

Central Nervous System (CNS) effects. Seizures have been reported in people who take fluoroquinolone antibacterial medicines, including moxifloxacin. Talk to 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
- nervousness, see things, or sense things
- that are not there (hallucinations)
- feel lightheaded or dizzy
- feel more suspicious (paranoia)
- feel restless
- tremors
- feel anxious or nervous
- headaches that will not go away, with or without blurred vision or confusion
- depression

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

Fluoroquinolones, including 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.

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

Some serious 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 are in your family, has a regular 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 renal-arterial stenosis (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 may increase your risk of bleeding.
- Moxifloxacin injection or other fluoroquinolones may increase your risk of central nervous system effects and seizures.
- Do not take any other medicines, central or peripheral anticholinergics, or antispasmodics.
- A blood thinner (warfarin, Coumadin, Jantrolin).
- A diuretic (furosemide, Lasix, Torsemide).
- An anti-seizure medicine.
- Atrioycic antidepressant.
- An oral anti-diabetic medicine or insulin.
- Ethinonrym.
- 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 shake, freeze, or stop receiving moxifloxacin injection even if you begin to feel better, until you finish your prescribed treatment, unless your healthcare provider tells you to stop.
- 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?").
- You have certain serious allergic reactions (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.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MOXIFLOXACIN INJECTION safely and effectively. See full prescribing information for MOXIFLOXACIN INJECTION.

MOXIFLOXACIN INJECTION, for intravenous use

To reduce the development of drug-resistant bacteria and maintain the effectiveness of moxifloxacin injection and other antibacterial drugs, moxifloxacin injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDONITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS

See full prescribing information for complete boxed warning

- Fluoroquinolones, including moxifloxacin, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together (5.1) including: Tendinitis and tendon rupture (5.2)
- Peripheral neuropathy (5.3)
- Central nervous system effects (5.4)

Discontinue moxifloxacin injection immediately and avoid the use of fluoroquinolones, including moxifloxacin, in patients who experience any of these serious adverse reactions.

- Fluoroquinolones, including moxifloxacin, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid moxifloxacin in patients with known history of myasthenia gravis (5.5).
- Because fluoroquinolones, including moxifloxacin, have been associated with serious adverse reactions (5.1 to 5.14), reserve moxifloxacin for use in patients who have no alternative treatment options for the following indications: • Acute bacterial sinusitis (1.5)
- Acute bacterial exacerbation of chronic bronchitis (1.6)

—RECENT MAJOR CHANGES

Warnings and Precautions, Central Nervous System Effects (5.4) 7/2018

Warnings and Precautions, Risk of Aortic Aneurysm and Dissection (5.9) 3/2019

Warnings and Precautions, Blood Glucose Disturbances (5.13) 7/2018

—INDICATIONS AND USAGE

Moxifloxacin injection is a fluoroquinolone antibiotic drug indicated for treating infections in adults 18 years of age caused by designated, susceptible bacteria (1, 12, 4)

- Community Acquired Pneumonia (1.1)
- Skin and Skin Structure Infections: Uncomplicated (1.2) and Complicated (1.3)
- Complicated Intra-Abdominal Infections (1.4)
- Acute Bacterial Sinusitis (1.5)
- Acute Bacterial Exacerbation of Chronic Bronchitis (1.6)

—DOSAGE AND ADMINISTRATION

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- 2.2 Preparation for Administration of Moxifloxacin Injection

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5.2 Tendinitis and Tendon Rupture

5.3 Peripheral Neuropathy

5.4 Central Nervous System Effects

5.5 Exacerbation of Myasthenia Gravis

5.6 QT Prolongation

5.7 Hypersensitivity Reactions

5.8 Other Serious and Sometimes Fatal Adverse Reactions

5.9 Risk of Aortic Aneurysm and Dissection

5.10 Clostridium Difficile-Associated Diarrhea

5.11 High Sodium Load

5.12 Adverse Effects in Animals

5.13 Blood Glucose Disturbances

5.14 Pharmacokinetics

5.15 Development of Drug Resistant Bacteria

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10.2 Acute Bacterial Sinusitis

10.3 Complicated Skin and Skin Structure Infections

10.4 Uncomplicated Skin and Skin Structure Infections

10.5 Complicated Intra-Abdominal Infections

10.6 Acute Bacterial Sinusitis

10.7 Acute Bacterial Exacerbation of Chronic Bronchitis

10.8 Acute Bacterial Exacerbation of Chronic Bronchitis

10.9 Acute Bacterial Exacerbation of Chronic Bronchitis

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10.15 Acute Bacterial Exacerbation of Chronic Bronchitis

10.16 Acute Bacterial Exacerbation of Chronic Bronchitis

Table 2: Common (> 1%) Adverse Reactions Reported in Active-Controlled Clinical Trials with Moxifloxacin

System Organ Class	Adverse Reaction*	% (n=14,881)
Blood and Lymphatic System Disorders	Anemia	1.1
Gastrointestinal Disorders	Nausea	6.9
	Diarrhea	6.9
	Vomiting	2.4
	Constipation	1.9
	Abdominal pain	1.5
	Abdominal pain upper	1.1
	Dyspepsia	1
General Disorders and Administration Site Conditions	Pyrexia	1.1
Investigations	Alanine aminotransferase increase	1.1
Metabolism and Nutritional Disorders	Hypokalemia	1
Nervous System Disorders	Headache	4.2
	Dizziness	3
Psychiatric Disorders	Insomnia	1.9

Table 3: Less Common (0.1 to < 1%) Adverse Reactions Reported in Active-Controlled Clinical Trials with Moxifloxacin (See Table 1)

System Organ Class	Adverse Reaction*
Blood and Lymphatic System Disorders	Thrombocytopenia Eosinophilia Neutropenia Thrombocytopenia Leukopenia
Cardiac Disorders	Arrhythmia Palpitation Tachycardia Cardiac failure congestive Angina pectoris Chest pain Cardiac arrest Bradycardia
Ear and Labyrinth Disorders	Vertigo Tinnitus
Eye Disorders	Vision blurred
Gastrointestinal Disorders	Dry mouth Abdominal discomfort Flatulence Abdominal distention Gastritis Gastroesophageal reflux disease
General Disorders and Administration Site Conditions	Fatigue Chest pain Headache Edema peripheral Edema Malaise Infusion site extravasation Edema Chills Pain Discomfort Facial pain
Hepatobiliary Disorders	Hepatic function abnormal
Infections and Infestations	Myocardial candidiasis Oral candidiasis Yeast vaginitis Vulvovaginal mycotic infection Trichomoniasis increased Vaginal infection Adenitis Fungal infection Fungal infection
Investigations	Aspartate aminotransferase increased Gamma-glutamyltransferase increased Hepatic enzyme increased Electrocardiogram QT prolonged Blood lactate dehydrogenase increased Platelet count increased Blood ammonia increased Blood glucose increased Blood urea nitrogen increased Hemoglobin decreased Blood creatinine increased Synovial fluid leukocyte count increased Platelet count increased Blood glucose increased Blood urea nitrogen increased Blood creatinine increased Blood urea nitrogen increased
Metabolism and Nutrition Disorders	Hypoglycemia Anorexia Hypoglycemia Decreased appetite Dyslipidemia
Musculoskeletal and Connective Tissue Disorders	Back pain Arthralgia Arthritis Myalgia Muscle spasms Musculoskeletal chest pain Musculoskeletal pain
Nervous System Disorders	Dysgeusia Somnolence Tinnitus Lethargy Parosmia Tension headache Hypoaesthesia
Psychiatric Disorders	Anxiety Confusional state Depression Restlessness Hallucination Disorientation
Renal and Urinary Disorders	Renal failure Odynuria Renal failure acute Musculoskeletal pain
Respiratory, Thoracic, and Mediastinal Disorders	Dyspnea Hemoptysis Wheezing Bronchospasm
Skin and Subcutaneous Tissue Disorders	Rash Pruritus Erythema Erythema Dermatitis allergic Photosensitivity Hypertension Phlebitis

Table 4: Postmarketing Adverse Reactions

Adverse reactions reported in patients taking moxifloxacin injection include:

• Anemia

• Constipation

• Dizziness

• Headache

• Insomnia

• Nausea

• Vomiting

• Diarrhea

• Pyrexia

• Tachycardia

• Tinnitus

• Vision blurred

• Abdominal discomfort

• Abdominal distention

• Gastritis

• Gastroesophageal reflux disease

• Fatigue

• Chest pain

• Headache

• Edema peripheral

• Edema

• Malaise

• Infusion site extravasation

