Moxifloxacin

Injection



Fresenius Kabi offers a growing portfolio of premix medications in innovative **freeflex**® bags not made with PVC or DEHP. We are committed to bringing quality medicines and technologies to clinicians, when and where they need them most.



- Preservative-free
- · Bar-coded
- Container closure is not made with natural rubber latex
- Not made with PVC/DEHP

Fill Volume	Product Code	NDC
250 mL	850174	63323-850-74

Strength	Concentration	Units/case
400 mg per 250 mL	1.6 mg per mL	12

UPC



Wholesaler/Distributor Information				
Cardinal	Cencora	McKesson	Morris & Dickson	
5116710	10153551	3472305	298521	

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, 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 including:
 - Tendinitis and tendon rupture
- Peripheral neuropathy
- Central nervous system effects

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.
- Because fluoroquinolones, including moxifioxacin, have been associated with serious adverse reactions, reserve moxifioxacin for use in patients who have no alternative treatment options for the following indications:
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis

Please see Important Safety Information on the following page.

For more information or to place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300 | freseniuskabipremixbags.com



INDICATIONS AND USAGE

Moxifloxacin injection is a fluoroquinolone antibacterial drug indicated for treating infections in adults \geq 18 years of age caused by designated, susceptible bacteria: community acquired pneumonia, uncomplicated and complicated skin and skin structure infections, complicated intra-abdominal infections, acute bacterial sinusitis, and acute bacterial exacerbation of chronic bronchitis.

IMPORTANT SAFETY INFORMATION

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Moxifloxacin injection is contraindicated in patients with known hypersensitivity to moxifloxacin or other quinolones.

Prolongation of the QT interval and isolated cases of torsades de pointes have been reported. Avoid use in patients with known prolongation, hypokalemia, and with drugs that prolong the QT interval. Use caution in patients with proarrhythmic conditions such as clinically significant bradycardia or acute myocardial ischemia.

Serious and sometimes fatal hypersensitivity reactions, including anaphylactic reactions, may occur after first or subsequent doses. Discontinue moxifloxacin at the first sign of skin rash, jaundice or any other sign of hypersensitivity.

Clostridium difficile-associated diarrhea: evaluate if diarrhea occurs.

High sodium load: Each unit dose contains 52.5 mEq (1,207 mg) of sodium. Avoid in patients with sodium restriction.

The most common adverse reactions (\geq 3%) were nausea, diarrhea, headache, and dizziness.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Drug Interactions:

Interacting Drug	Interaction
Warfarin	Anticoagulant effect of warfarin may be enhanced. Monitor prothrombin time/INR, watch for bleeding.
Class IA and Class III antiarrhythmics:	Proarrhythmic effect may be enhanced. Avoid concomitant use.
Antidiabetic agents	Carefully monitor blood glucose.

Pregnancy: Based on animal data may case fetal harm.

Geriatrics: Increased risk for severe tendon disorders further increased by concomitant corticosteroid therapy and increased risk of prolongation of the QT interval.

This Important Safety Information does not include all the information needed to use Moxifloxacin Injection safely and effectively. Please see accompanying <u>full prescribing information</u> for MOXIFLOXACIN INJECTION, including BOXED WARNING. Full prescribing information is also available at www.fresenius-kabi.com/us.

