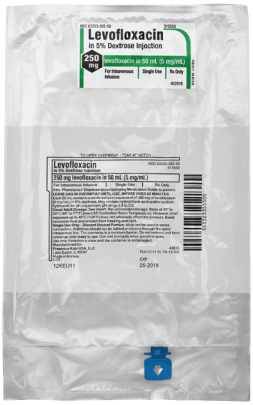
Levofloxacin

In 5% Dextrose Injection

freeflex®

Fresenius Kabi has a growing portfolio of premix medications in **free***flex*® bags. All **free***flex* bags are designed with the clinician in mind, to help reduce infusion errors, injury and waste so they can focus on patient care.



Product Code	NDC Code	Strength	Concentration	Fill Size (mL)	Container Size	Units per Case
315550	63323-355-50	250 mg per 50 mL	5 mg per mL	50 mL	50 mL	24
315565	63323-355-65	500 mg per 100 mL	5 mg per mL	100 mL	100 mL	24
315560	63323-355-60	750 mg per 150 mL	5 mg per mL	150 mL	150 mL	24

• Preservative free • Non-PVC and Non-DEHP • The container closure is not made with natural rubber latex

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 Levofloxacin in 5% Dextrose Injection, 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 Levofloxacin in 5% Dextrose Injection immediately and avoid the use of fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, in patients who experience any of these serious adverse reactions

- **Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Levofloxacin in 5% Dextrose Injection in patients with a known history of myasthenia gravis**
- **Because fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with serious adverse reactions, reserve Levofloxacin in 5% Dextrose Injection for use in patients who have no alternative treatment options for the following indications:**
  - **Uncomplicated urinary tract infection**
  - **Acute bacterial exacerbation of choronic bronchitis**
  - **Acute bacterial sinusitis**

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 | freeflexivbags.com

FRESENIUS KABI
caring for life

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2057-LVF-02-08/21

INDICATIONS AND USAGE

Levofloxacin in 5% Dextrose Injection is a fluoroquinolone antibacterial indicated in adults (≥ 18 years of age) with infections caused by designated, susceptible bacteria.

- Pneumonia: Nosocomial and Community-Acquired
- Skin and Skin Structure Infections: Complicated and Uncomplicated
- Chronic Bacterial Prostatitis
- Inhalational Anthrax, Post-Exposure
- Plague
- Urinary Tract Infections: Complicated and Uncomplicated
- Acute Pyelonephritis
- Acute Bacterial Exacerbation of Chronic Bronchitis
- Acute Bacterial Sinusitis

IMPORTANT SAFETY INFORMATION

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Levofloxacin in 5% Dextrose Injection is contraindicated in patients with known hypersensitivity to Levofloxacin in 5% Dextrose Injection or other quinolones.

Anaphylactic reactions and allergic skin reactions, serious, occasionally fatal, may occur after first dose.

Hematologic (including agranulocytosis, thrombocytopenia), and renal toxicities may occur after multiple doses.

Hepatotoxicity: Severe, and sometimes fatal, hepatotoxicity has been reported. Discontinue immediately if signs and symptoms of hepatitis occur.

Clostridium difficile-associated colitis: evaluate if diarrhea occurs.

Prolongation of the QT interval and isolated cases of torsades de pointes have been reported. Avoid use in patients with known prolongation, those with hypokalemia, and with other drugs that prolong the QT interval.

The most common adverse reactions (≥ 3%) were nausea, headache, diarrhea, insomnia, constipation, 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
Multivalent cation-containing products including antacids, metal cations or didanosine	Absorption of levofloxacin is decreased when the tablet or oral solution formulation is taken within 2 hours of these products. Do not co-administer the intravenous formulation in the same IV line with a multivalent cation, e.g., magnesium.
Warfarin	Effect may be enhanced. Monitor prothrombin time, INR, watch for bleeding.
Antidiabetic agents	Carefully monitor blood glucose.

Geriatrics: Severe hepatotoxicity has been reported. The majority of reports describe patients 65 years of age or older. May have increased risk of tendinopathy (including rupture), especially with concomitant corticosteroid use. May be more susceptible to prolongation of the QT interval.

Pediatrics: Musculoskeletal disorders (arthralgia, arthritis, tendinopathy, and gait abnormality) seen in more levofloxacin-treated patients than in comparator. Shown to cause arthropathy and osteochondrosis in juvenile animals. Safety in pediatric patients treated for more than 14 days has not been studied. Risk-benefit appropriate only for the treatment of inhalational anthrax (post-exposure) and plague.

This Important Safety Information does not include all the information needed to use Levofloxacin in 5% Dextrose Injection safely and effectively. Please see full prescribing information for LEVOFLOXACIN IN 5% DEXTROSE INJECTION, including BOXED WARNING. Full prescribing information is also available at www.fresenius-kabi.com/us.

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