MEDICATION GUIDE
Levofloxacin
(LEE-voe-FLOX-a-sin)
in 5% Dextrose Injection, for Intravenous Use

Read this Medication Guide before you start taking Levofloxacin in 5% Dextrose Injection 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 Levofloxacin in 5% Dextrose Injection? Levofloxacin in 5% Dextrose Injection, a fluoroquinolone antibiotic, can cause serious side effects. Some of these serious side effects can happen at the same time and could result in death.
If you have any of the following serious side effects while you take Levofloxacin in 5% Dextrose Injection, you should stop taking Levofloxacin in 5% Dextrose Injection and get medical help right away.

1. Tendon rupture or swelling of the tendon (tendinitis).
- **Tendon problems can happen in people of all ages who take Levofloxacin in 5% Dextrose Injection.** Tendons are tough cords of tissue that connect muscles to bones.
  Some tendon problems include pain, swelling, tears, and swelling of tendons including the back of the ankle (Achilles), shoulder, hand, or other tendon sites.
- The risk of getting tendon problems while you take Levofloxacin in 5% Dextrose 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 take Levofloxacin in 5% Dextrose 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 Levofloxacin in 5% Dextrose Injection immediately and get medical help right away at the first sign of tendon pain, swelling, or inflammation. Avoid exercise and using the affected area.
  The most common area of pain and swelling is the Achilles tendon at the back of your ankle. This can also happen with other tendons. 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 taking Levofloxacin in 5% Dextrose Injection. Tendon ruptures can happen within hours or days of taking Levofloxacin in 5% Dextrose Injection and have happened up to several months after people have finished taking their fluoroquinolone.
- Stop taking Levofloxacin in 5% Dextrose Injection 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 Levofloxacin in 5% Dextrose Injection. Stop taking Levofloxacin in 5% Dextrose Injection 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 Levofloxacin in 5% Dextrose Injection. Tell your healthcare provider if you have a history of seizures before you start taking Levofloxacin in 5% Dextrose Injection. CNS side effects may happen as soon as after taking the first dose of Levofloxacin in 5% Dextrose Injection. Stop taking Levofloxacin in 5% Dextrose Injection 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 problem that causes muscle weakness). Fluoroquinolones like Levofloxacin in 5% Dextrose 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 Levofloxacin in 5% Dextrose Injection. Call your healthcare provider right away if you have any worsening muscle weakness or breathing problems.

What is Levofloxacin in 5% Dextrose Injection?
Levofloxacin in 5% Dextrose Injection is a fluoroquinolone antibiotic medicine used in adults age 18 years or older to treat certain infections caused by certain germs called bacteria. These bacterial infections include:
- nosocomial pneumonia
- community-acquired pneumonia
- acute sinus infection
- acute worsening of chronic bronchitis
- skin infections, complicated and uncomplicated
- chronic prostate infection
- urinary tract infections, complicated and uncomplicated
- acute kidney infection (pyelonephritis)
- inhalational anthrax
- plague

Studies of Levofloxacin in 5% Dextrose Injection for use in the treatment of plague and anthrax were done in animals only, because plague and anthrax could not be studied in people.

Levofloxacin in 5% Dextrose Injection should not be used in patients with uncomplicated urinary tract infections, acute bacterial exacerbation of chronic bronchitis, or acute bacterial sinusitis if there are other treatment options available.

Levofloxacin in 5% Dextrose Injection is also used to treat children who are 6 months of age or older and may have breathed in anthrax germs, have plague, or been exposed to plague germs.

It is not known if Levofloxacin in 5% Dextrose Injection is safe and effective in children under 6 months of age.

The safety and effectiveness in children treated with Levofloxacin in 5% Dextrose Injection for more than 14 days is not known.

Who should not take Levofloxacin in 5% Dextrose Injection?

Do not take Levofloxacin in 5% Dextrose Injection if you have ever had a severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to levofloxacin or any of the ingredients in Levofloxacin in 5% Dextrose Injection. See the end of this leaflet for a complete list of ingredients in Levofloxacin in 5% Dextrose Injection.

What should I tell my healthcare provider before taking Levofloxacin in 5% Dextrose Injection?

Before you take Levofloxacin in 5% Dextrose Injection, tell your healthcare provider if you:
- have tendon problems; Levofloxacin in 5% Dextrose Injection should not be used in patients who have a history of tendon problems
- have a problem that causes muscle weakness (myasthenia gravis); Levofloxacin in 5% Dextrose Injection should not be used in patients who have a known history of myasthenia gravis
- have central nervous system problems such as seizures (epilepsy)
- have nerve problems; Levofloxacin in 5% Dextrose Injection 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 bone problems
- have joint problems including rheumatoid arthritis (RA)
- have kidney problems. You may need a lower dose of Levofloxacin in 5% Dextrose Injection if your kidneys do not work well.
- have liver problems
- have diabetes or problems with low blood sugar (hypoglycemia)
- are pregnant or plan to become pregnant. It is not known if Levofloxacin in 5% Dextrose Injection will harm your unborn child.
- are breastfeeding or plan to breastfeed. It is not known if Levofloxacin in 5% Dextrose Injection passes into your breast milk. You and your healthcare provider should decide if you will take Levofloxacin in 5% Dextrose Injection or breastfeed. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Levofloxacin in 5% Dextrose Injection and other medicines can affect each other causing side effects.

Especially tell your healthcare provider if you take:
- a steroid medicine
- an anti-psychotic medicine
- a tricyclic antidepressant
- a water pill (diuretic)
- a blood thinner (warfarin, Coumadin, Jantoven)
- an oral anti-diabetes medicine or insulin
- an NSAID (Non-Steroidal Anti-Inflammatory Drug). Many common medicines for pain relief are NSAIDs. Taking an NSAID while you take Levofloxacin in 5% Dextrose Injection or other fluoroquinolones may increase your risk of central nervous system effects and seizures.
- theophylline (Theo-24®, Elixophyllin®, Theochron®, Uniphyl®, Theolair®)
- a medicine to control your heart rate or rhythm (antiarrhythmics)

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.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use LEVOFLOXACIN IN 5% DEXTROSE INJECTION safely and effectively. See full prescribing information for LEVOFLOXACIN IN 5% DEXTROSE INJECTION.

LEVOFLOXACIN in 5% DEXTROSE injection, solution for intravenous use
Initial U.S. Approval: 1996

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 (5.1), including:**
  - **Tendinitis and tendon rupture (5.2)**
  - **Peripheral neuropathy (5.3)**
  - **Central nervous system effects (5.4)**

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 (5.1)
- **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 *[see Warnings and Precautions (5.5)]***
- **Because fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with serious adverse reactions (5.1-5.15), reserve Levofloxacin in 5% Dextrose Injection for use in patients who have no alternative treatment options for the following indications:**
  - **Uncomplicated urinary tract infection (1.12)**
  - **Acute bacterial exacerbation of chronic bronchitis (1.13)**
  - **Acute bacterial sinusitis (1.14)**

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Levofloxacin in 5% Dextrose Injection and other antibacterial drugs, Levofloxacin in 5% Dextrose Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.(1.15)

RECENT MAJOR CHANGES

Boxed Warning	06/2016
Indications and Usage (1)	06/2016
Dosage and Administration (2)	06/2016
Warnings and Precautions (5)	06/2016

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 (1, 12.4).
- Pneumonia: Nosocomial (1.1) and Community-Acquired (1.2, 1.3)
- Skin and Skin Structure Infections: Complicated (1.4) and Uncomplicated (1.5)
- Chronic Bacterial Prostatitis (1.6)
- Inhalational Anthrax, Post-Exposure (1.7)
- Plague (1.8)
- Urinary Tract Infections: Complicated (1.9, 1.10) and Uncomplicated (1.12)
- Acute Pyelonephritis (1.11)
- Acute Bacterial Exacerbation of Chronic Bronchitis (1.13)
- Acute Bacterial Sinusitis (1.14)

DOSAGE AND ADMINISTRATION
- Dosage in patients with normal renal function (2.1)

Type of Infection	Dose Every 24 hours	Duration (days)
Nosocomial Pneumonia (1.1)	750 mg	7 to 14
Community-Acquired Pneumonia (1.2)	500 mg	7 to 14
Community-Acquired Pneumonia (1.3)	750 mg	5
Complicated Skin and Skin Structure Infections (SSSI) (1.6)	750 mg	7 to 14
Uncomplicated SSSI (1.7)	500 mg	7 to 10
Chronic Bacterial Prostatitis (1.8)	500 mg	28
Inhalational Anthrax (Post-Exposure) (1.13)		
Adults and Pediatric Patients > 50 kg	500 mg	60
Pediatric Patients < 50 kg and ≥ 6 months of age	8 mg/kg BID (not to exceed 250 mg/dose)	60
Plague (1.14)		
Adults and Pediatric Patients > 50 kg	500 mg	10 to 14
Pediatric Patients < 50 kg and ≥ 6 months of age	8 mg/kg BID (not to exceed 250 mg/dose)	10 to 14
Complicated Urinary Tract Infection (1.9) or Acute Pyelonephritis (1.11)	750 mg	5
Complicated Urinary Tract Infection (1.10) or Acute Pyelonephritis (1.11)	250 mg	10
Uncomplicated Urinary Tract Infection (1.12)	250 mg	3
Acute Bacterial Exacerbation of Chronic Bronchitis (1.5)	500 mg	7
Acute Bacterial Sinusitis (1.4)	750 mg	5
	500 mg	10 to 14

- Adjust dose for creatinine clearance < 50 mL/min (2.3, 8.6, 12.3)
- IV Injection, Premix: Slow IV infusion only, over 60 or 90 minutes depending on dose. Avoid rapid or bolus IV (2.5)
- Do not mix with other medications in IV line (2.6)

DOSAGE FORMS AND STRENGTHS

Formulation (3)	Strength
Injection: premix single-use flexible containers	250 mg in 50 mL 500 mg in 100 mL 750 mg in 150 mL

CONTRAINDICATIONS
Known hypersensitivity to Levofloxacin in 5% Dextrose Injection or other quinolones (4, 5.7).

WARNINGS AND PRECAUTIONS
- Anaphylactic reactions and allergic skin reactions, serious, occasionally fatal, may occur after first dose (4, 5.7)
- Hematologic (including agranulocytosis, thrombocytopenia), and renal toxicities may occur after multiple doses (5.6)
- Hepatotoxicity: Severe, and sometimes fatal, hepatotoxicity has been reported. Discontinue immediately if signs and symptoms of hepatitis occur (5.8)
- *Clostridium difficile*-associated colitis: evaluate if diarrhea occurs (5.10)
- 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 (5.11, 8.5)

ADVERSE REACTIONS
The most common reactions (≥ 3%) were nausea, headache, diarrhea, insomnia, constipation and dizziness (6.2).

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176 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 (2.4, 7.1)
Warfarin	Effect may be enhanced. Monitor prothrombin time, INR, watch for bleeding (7.2)
Anti-diabetic agents	Carefully monitor blood glucose (5.13, 7.3)

USE IN SPECIFIC POPULATIONS
- **Geriatrics:** Severe hepatotoxicity has been reported. The majority of reports describe patients 65 years of age or older (5.8, 8.5, 17). May have increased risk of tendinopathy (including rupture), especially with concomitant corticosteroid use (5.2, 8.5, 17). May be more susceptible to prolongation of the QT interval (5.11, 8.5, 17).
- **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 (5.12, 8.4, 13.2). 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) (1.7, 2.2, 8.4, 14.9) and plague (1.8, 2.2, 8.4, 14.10).

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

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

- **Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together *[see Warnings and Precautions (5.1)]*, including:**
  - **Tendinitis and tendon rupture *[see Warnings and Precautions (5.2)]***
  - **Peripheral neuropathy *[see Warnings and Precautions (5.3)]***
  - **Central nervous system effects *[see Warnings and Precautions (5.4)]***

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 *[see Warnings and Precautions (5.1)]*
- **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 *[see Warnings and Precautions (5.5)]***
- **Because fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with serious adverse reactions *[see Warnings and Precautions (5.1-5.15)]*, reserve Levofloxacin in 5% Dextrose Injection for use in patients who have no alternative treatment options for the following indications:**
  - **Uncomplicated urinary tract infection *[see Indications and Usage (1.12)]***
  - **Acute bacterial exacerbation of chronic bronchitis *[see Indications and Usage (1.13)]***
  - **Acute bacterial sinusitis *[see Indications and Usage (1.14)]***

1 INDICATIONS AND USAGE
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of adults (≥ 18 years of age) with mild, moderate, and severe infections caused by susceptible isolates of the designated microorganisms in the conditions listed in this section. Levofloxacin in 5% Dextrose Injection is indicated when intravenous administration offers a route of administration advantageous to the patient (e.g., patient cannot tolerate an oral dosage form).

1.1 Nosocomial Pneumonia
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of nosocomial pneumonia due to methicillin-susceptible *Staphylococcus aureus, Pseudomonas aeruginosa, Serratia marcescens, Escherichia coli, Klebsiella pneumoniae, Haemophilus influenzae*, or *Streptococcus pneumoniae*. Adjunctive therapy should be used as clinically indicated. Where *Pseudomonas aeruginosa* is a documented or presumptive pathogen, combination therapy with an anti-pseudomonal β-lactam is recommended *[see Clinical Studies (14.1)]*.

1.2 Community-Acquired Pneumonia: 7 to 14 day Treatment Regimen
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus, Streptococcus pneumoniae* (including multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Chlamydophila pneumoniae, Legionella pneumophila*, or *Mycoplasma pneumoniae [see Dosage and Administration (2.1) and Clinical Studies (14.2)]*.

MDRSP isolates are isolates resistant to two or more of the following antibacterials: penicillin (MIC ≥ 2 mcg/mL), 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

1.3 Community-Acquired Pneumonia: 5-day Treatment Regimen
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of community-acquired pneumonia due to *Streptococcus pneumoniae* (excluding multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae, Haemophilus parainfluenzae, Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae [see Dosage and Administration (2.1) and Clinical Studies (14.3)]*.

1.4 Complicated Skin and Skin Structure Infections
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of complicated skin and skin structure infections due to methicillin-susceptible *Staphylococcus aureus, Enterococcus faecalis, Streptococcus pyogenes*, or *Proteus mirabilis [see Clinical Studies (14.5)]*.

1.5 Uncomplicated Skin and Skin Structure Infections
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of uncomplicated skin and skin structure infections (mild to moderate) including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections, due to methicillin-susceptible *Staphylococcus aureus*, or *Streptococcus pyogenes*.

1.6 Chronic Bacterial Prostatitis
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of chronic bacterial prostatitis due to *Escherichia coli, Enterococcus faecalis*, or methicillin-susceptible *Staphylococcus epidermidis [see Clinical Studies (14.6)]*.

1.7 Inhalational Anthrax (Post-Exposure)
Levofloxacin in 5% Dextrose Injection is indicated for inhalational anthrax (post-exposure) to reduce the incidence or progression of disease following exposure to aerosolized *Bacillus anthracis*. The effectiveness of levofloxacin is based on plasma concentrations achieved in humans, a surrogate endpoint reasonably likely to predict clinical benefit. Levofloxacin in 5% Dextrose Injection has not been tested in humans for the post-exposure prevention of inhalation anthrax. The safety of Levofloxacin in 5% Dextrose Injection in adults for durations of therapy beyond 28 days or in pediatric patients for durations of therapy beyond 14 days has not been studied. Prolonged Levofloxacin in 5% Dextrose Injection therapy should only be used when the benefit outweighs the risk *[see Dosage and Administration (2.1, 2.2) and Clinical Studies (14.9)]*.

1.8 Plague
Levofloxacin in 5% Dextrose Injection is indicated for treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (*Y. pestis*) and prophylaxis for plague in adults and pediatric patients, 6 months of age and older. Efficacy studies of Levofloxacin in 5% Dextrose Injection could not be conducted in humans with plague for ethical and feasibility reasons. Therefore, approval of this indication was based on an efficacy study conducted in animals *[see Dosage and Administration (2.1, 2.2) and Clinical Studies (14.10)]*.

1.9 Complicated Urinary Tract Infections: 5-day Treatment Regimen
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of complicated urinary tract infections due to *Escherichia coli, Klebsiella pneumoniae*, or *Proteus mirabilis [see Clinical Studies (14.7)]*.

1.10 Complicated Urinary Tract Infections: 10-day Treatment Regimen
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of complicated urinary tract infections (mild to moderate) due to *Enterococcus faecalis, Enterobacter cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis*, or *Pseudomonas aeruginosa [see Clinical Studies (14.8)]*.

1.11 Acute Pyelonephritis: 5 or 10-day Treatment Regimen
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of acute pyelonephritis caused by *Escherichia coli*, including cases with concurrent bacteremia *[see Clinical Studies (14.7, 14.8)]*.

1.12 Uncomplicated Urinary Tract Infections
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of uncomplicated urinary tract infections (mild to moderate) due to *Escherichia coli, Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*.

Because fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with serious adverse reactions *[see Warnings and Precautions (5.1-5.15)]* and for some patients uncomplicated urinary tract infection is self-limiting, reserve Levofloxacin in 5% Dextrose Injection for treatment of uncomplicated urinary tract infections in patients who have no alternative treatment options.

1.13 Acute Bacterial Exacerbation of Chronic Bronchitis
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of acute bacterial exacerbation of chronic bronchitis (ABECB) due to methicillin-susceptible *Staphylococcus aureus, Streptococcus pneumoniae, Haemophilus influenzae, Haemophilus parainfluenzae*, or *Moraxella catarrhalis*.

Because fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with serious adverse reactions *[see Warnings and Precautions (5.1-5.15)]* and for some patients ABECB is self-limiting, reserve levofloxacin for treatment of ABECB in patients who have no alternative treatment options.

1.14 Acute Bacterial Sinusitis: 5-day and 10 to 14 day Treatment Regimens
Levofloxacin in 5% Dextrose Injection is indicated for the treatment of acute bacterial sinusitis (ABS) due to *Streptococcus pneumoniae, Haemophilus influenzae*, or *Moraxella catarrhalis [see Clinical Studies (14.4)]*.

Because fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with serious adverse reactions *[see Warnings and Precautions (5.1-5.15)]* and for some patients ABS is self-limiting, reserve Levofloxacin in 5% Dextrose Injection for treatment of ABS in patients who have no alternative treatment options.

1.15 Usage
To reduce the development of drug-resistant bacteria and maintain the effectiveness of Levofloxacin in 5% Dextrose Injection and other antibacterial drugs, Levofloxacin in 5% Dextrose Injection should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Culture and susceptibility testing
Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing the infection and to determine their susceptibility to levofloxacin *[see Microbiology (12.4)]*. Therapy with Levofloxacin in 5% Dextrose Injection, may be initiated before results of these tests are known; once results become available, appropriate therapy should be selected.

As with other drugs in this class, some isolates of *Pseudomonas aeruginosa* may develop resistance fairly rapidly during treatment with levofloxacin. Culture and susceptibility testing performed periodically during therapy will provide information about the continued susceptibility of the pathogens to the antimicrobial agent and also the possible emergence of bacterial resistance.

2 DOSAGE AND ADMINISTRATION
2.1 Dosage in Adult Patients with Normal Renal Function
The usual dose of Levofloxacin in 5% Dextrose Injection is 250 mg or 500 mg administered by slow infusion over 60 minutes every 24 hours or 750 mg administered by slow infusion over 90 minutes every 24 hours, as indicated by infection and described in Table 1.
These recommendations apply to patients with creatinine clearance ≥ 50 mL/min. For patients with creatinine clearance < 50 mL/min, adjustments to the dosing regimen are required *[see Dosage and Administration (2.3)]*.

Table 1: Dosage in Adult Patients with Normal Renal Function (creatinine clearance ≥ 50 mL/min)

Type of Infection*	Dosed Every 24 hours	Duration (days)†
Nosocomial Pneumonia	750 mg	7 to 14
Community-Acquired Pneumonia‡	500 mg	7 to 14
Community-Acquired Pneumonia§	750 mg	5
Complicated Skin and Skin Structure Infections (SSSI)	750 mg	7 to 14
Uncomplicated SSSI	500 mg	7 to 10
Chronic Bacterial Prostatitis	500 mg	28
Inhalational Anthrax (Post-Exposure), adult and pediatric patients > 50 kg[þ,β]	500 mg	60[β]
Pediatric patients < 50 kg and ≥ 6 months of age[þ,β]	see Table 2 below (2.2)	60[β]
Plague, adult and pediatric patients > 50 kg[à]	500 mg	10 to 14
Pediatric patients < 50 kg and ≥ 6 months of age	see Table 2 below (2.2)	10 to 14
Complicated Urinary Tract Infection (cUTI) or Acute Pyelonephritis (AP)¶	750 mg	5
Complicated Urinary Tract Infection (cUTI) or Acute Pyelonephritis (AP)#	250 mg	10
Uncomplicated Urinary Tract Infection	250 mg	3
Acute Bacterial Exacerbation of Chronic Bronchitis (ABECB)	500 mg	7
Acute Bacterial Sinusitis (ABS)	750 mg	5
	500 mg	10 to 14

* Due to the designated pathogens *[see Indications and Usage (1)]*.
† Sequential therapy (intravenous to oral) may be instituted at the discretion of the physician.
‡ Due to methicillin-susceptible *Staphylococcus aureus, Streptococcus pneumoniae* (including multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Moraxella catarrhalis, Chlamydophila pneumoniae, Legionella pneumophila*, or *Mycoplasma pneumoniae [see Indications and Usage (1.2)]*.
§ Due to *Streptococcus pneumoniae* (excluding multi-drug-resistant isolates [MDRSP]), *Haemophilus influenzae, Haemophilus parainfluenzae, Mycoplasma pneumoniae*, or *Chlamydophila pneumoniae [see Indications and Usage (1.3)]*.
¶ This regimen is indicated for cUTI due to *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis* and AP due to *E. coli*, including cases with concurrent bacteremia.
\# This regimen is indicated for cUTI due to *Enterococcus faecalis, Enterococcus cloacae, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa*; and for AP due to *E. coli*.
þ Drug administration should begin as soon as possible after suspected or confirmed exposure to aerosolized *B. anthracis*. This indication is based on a surrogate endpoint. Levofloxacin plasma concentrations achieved in humans are reasonably likely to predict clinical benefit *[see Clinical Studies (14.9)]*.
β The safety of levofloxacin in adults for durations of therapy beyond 28 days or in pediatric patients for durations beyond 14 days has not been studied. An increased incidence of musculoskeletal adverse events compared to controls has been observed in pediatric patients *[see Warnings and Precautions (5.12), Use in Specific Populations (8.4) and Clinical Studies (14.9)]*. Prolonged levofloxacin therapy should only be used when the benefit outweighs the risk.
à Drug administration should begin as soon as possible after suspected or confirmed exposure to *Yersinia pestis*. Higher doses of levofloxacin typically used for treatment of pneumonia can be used for treatment of plague, if clinically indicated.

2.2 Dosage in Pediatric Patients
The dosage in pediatric patients ≥ 6 months of age is described below in Table 2.

Table 2: Dosage in Pediatric Patients ≥ 6 months of age

Type of Infection*	Dose	Freq. Once Every	Duration†
Inhalational Anthrax (post-exposure)‡, §			
Pediatric patients > 50 kg	500 mg	24 hr	60 days§
Pediatric patients < 50 kg and ≥ 6 months of age	8 mg/kg (not to exceed 250 mg per dose)	12 hr	60 days§
Plague¶			
Pediatric patients > 50 kg	500 mg	24 hr	10 to 14 days
Pediatric patients < 50 kg and ≥ 6 months of age	8 mg/kg (not to exceed 250 mg per dose)	12 hr	10 to 14 days

* Due to *Bacillus anthracis [see Indications and Usage (1.13)]* and *Yersinia pestis [see Indications and Usage (1.14)]*.
† Sequential therapy (intravenous to oral) may be instituted at the discretion of the physician.
‡ Drug administration should begin as soon as possible after suspected or confirmed exposure to aerosolized *B. anthracis*. This indication is based on a surrogate endpoint. Levofloxacin plasma concentrations achieved in humans are reasonably likely to predict clinical benefit *[see Clinical Studies (14.9)]*.
§ The safety of levofloxacin in pediatric patients for durations of therapy beyond 14 days has not been studied. An increased incidence of musculoskeletal adverse events compared to controls has been observed in pediatric patients *[see Warnings and Precautions (5.12), Use in Specific Populations (8.4) and Clinical Studies (14.9)]*. Prolonged levofloxacin therapy should only be used when the benefit outweighs the risk.
¶ Drug administration should begin as soon as possible after suspected or confirmed exposure to *Yersinia pestis*.

2.3 Dosage Adjustment in Adults with Renal Impairment
Administer levofloxacin with caution in the presence of renal insufficiency. Careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of levofloxacin may be reduced.

No adjustment is necessary for patients with a creatinine clearance ≥ 50 mL/min.

In patients with impaired renal function (creatinine clearance < 50 mL/min), adjustment of the dosage regimen is necessary to avoid the accumulation of levofloxacin due to decreased clearance *[see Use in Specific Populations (8.6)]*.

Table 3 shows how to adjust dose based on creatinine clearance.

Table 3: Dosage Adjustment in Adult Patients with Renal Impairment (creatinine clearance < 50 mL/min)

Dosage in Normal Renal Function Every 24 hours	Creatinine Clearance 20 to 49 mL/min	Creatinine Clearance 10 to 19 mL/min	Hemodialysis or Chronic Ambulatory Peritoneal Dialysis (CAPD)
750 mg	750 mg every 48 hours	750 mg initial dose, then 500 mg every 48 hours	750 mg initial dose, then 500 mg every 48 hours
500 mg	500 mg initial dose, then 250 mg every 24 hours	500 mg initial dose, then 250 mg every 48 hours	500 mg initial dose, then 250 mg every 48 hours
250 mg	No dosage adjustment required	250 mg every 48 hours. If treating uncomplicated UTI, then no dosage adjustment is required	No information on dosing adjustment is available

2.4 Drug Interaction with Chelation Agents: Antacids, Sucralfate, Metal Cations, Multivitamins
Levofloxacin in 5% dextrose injection should not be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line *[see Dosage and Administration (2.6)]*.

2.5 Administration Instructions
Caution: Rapid or bolus intravenous infusion of levofloxacin has been associated with hypotension and must be avoided. Levofloxacin in 5% dextrose injection should be infused intravenously slowly over a period of not less than 60 or 90 minutes, depending on the dosage. Levofloxacin in 5% dextrose injection should be administered only by intravenous infusion. It is not for intramuscular, intrathecal, intraperitoneal, or subcutaneous administration.

Hydration for Patients Receiving Levofloxacin in 5% Dextrose Injection
Adequate hydration of patients receiving intravenous levofloxacin should be maintained to prevent the formation of highly concentrated urine. Crystalluria and cylindruria have been reported with quinolones *[see Adverse Reactions (6.1) and Patient Counseling Information (17)]*.

2.6 Preparation of Intravenous Product
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Because only limited data are available on the compatibility of levofloxacin in 5% dextrose injection with other intravenous substances, additives or other medications should not be added to Levofloxacin Injection Premix Solution in Single-Use Flexible Containers, or infused simultaneously through the same intravenous line. If the same intravenous line is used for sequential infusion of several different drugs, the line should be flushed before and after infusion of levofloxacin in 5% dextrose injection with an infusion solution compatible with levofloxacin in 5% dextrose injection and with any other drug(s) administered via this common line.

Levofloxacin Injection Premix in Single-Use Flexible Containers (5 mg/mL)
Levofloxacin in 5% dextrose injection is supplied in flexible containers within a foil overwrap. These contain a premixed, ready to use levofloxacin solution in 5% dextrose (D5W) for single-use. The 50 mL premixed flexible container contains 250 mg/50 mL of levofloxacin solution. The 100 mL premixed flexible container contains 500 mg/100 mL of levofloxacin solution. The 150 mL premixed flexible container contains 750 mg/150 mL of levofloxacin solution. The concentration of each container is 5 mg/mL. No further dilution of these preparations is necessary. Because the premix flexible containers are for single-use only, any unused portion should be discarded.

Instructions for the Use of Levofloxacin Injection Premix in Single-Use Flexible Containers:
1. Tear outer wrap at the notch and remove solution container.
2. Check the container for minute leaks by squeezing the inner bag firmly. If leaks are found, or if the seal is not intact, discard the solution, as the sterility may be compromised.
3. Do not use if the solution is cloudy or a precipitate is present.
4. Use sterile equipment.
5. **WARNING: Do not use flexible containers in series connections.** Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is complete.

Preparation for Administration:
1. Close flow control clamp of administration set.
2. Remove cover from port at bottom of container.
3. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated. **NOTE: See full directions on administration set carton.**
4. Suspend container from hanger.
5. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion of Levofloxacin Injection Premix in Flexible Containers.
6. Open flow control clamp to expel air from set. Close clamp.
7. Regulate rate of administration with flow control clamp.

3 DOSAGE FORMS AND STRENGTHS
Levofloxacin in 5% dextrose injection is supplied in single-use flexible containers for intravenous infusion, and is clear yellow to clear greenish-yellow in appearance.
- 250 mg, in flexible container, 50 mL fill
- 500 mg, in flexible container, 100 mL fill
- 750 mg, in flexible container, 150 mL fill

4 CONTRAINDICATIONS
Levofloxacin in 5% Dextrose Injection is contraindicated in persons with known hypersensitivity to levofloxacin, or other quinolone antibacterials *[see Warnings and Precautions (5.3)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient. Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These reactions can occur within hours to weeks after starting Levofloxacin in 5% Dextrose Injection. Patients of any age or without pre-existing risk factors have experienced these adverse reactions *[see Warnings and Precautions (5.2, 5.3, 5.4)]*.

Discontinue Levofloxacin in 5% Dextrose Injection immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.

5.2 Tendinitis and Tendon Rupture
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection have been associated with an increased risk of tendinitis and tendon rupture in all ages *[see Warnings and Precautions (5.1) and Adverse Reactions (6.2)]*. This adverse reaction most frequently involves the Achilles tendon and has also been reported with the rotator cuff (the shoulder), the hand, the biceps, the thumb, and other tendon sites. Tendinitis or tendon rupture can occur within hours or days of starting Levofloxacin in 5% Dextrose Injection or as long as several months after completion of fluoroquinolone therapy. Tendinitis and tendon rupture can occur bilaterally.

The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is increased in patients usually over 60 years of age, in those taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Other factors, that may independently increase the risk of tendon rupture include strenuous physical activity, renal failure, and previous tendon disorders such as rheumatoid arthritis. Tendinitis and tendon rupture have been reported in patients taking fluoroquinolones who do not have the above risk factors. Discontinue Levofloxacin in 5% Dextrose Injection immediately if the patient experiences pain, swelling, inflammation or rupture of a tendon. Patients should be advised to rest at the first sign of tendinitis or tendon rupture, and to contact their healthcare provider regarding changing to a non-quinolone antimicrobial drug. Avoid Levofloxacin in 5% Dextrose Injection in patients who have a history of tendon disorders or tendon rupture *[see Adverse Reactions (6.3) and Patient Counseling Information (17)]*.

5.3 Peripheral Neuropathy
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with an increased risk of peripheral neuropathy. Cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving fluoroquinolones, including Levofloxacin in 5% Dextrose Injection. Symptoms may occur soon after initiation of Levofloxacin in 5% Dextrose Injection and may be irreversible in some patients *[see Warnings and Precautions (5.1) and Adverse Reactions (6.1, 6.2)]*.

Discontinue Levofloxacin in 5% Dextrose Injection immediately if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation. Avoid fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, in patients who have previously experienced peripheral neuropathy *[see Adverse Reactions (6), Patient Counseling Information (17)]*.

5.4 Central Nervous System Effects
Psychiatric Adverse Reactions
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with an increased risk of psychiatric adverse reactions, including: toxic psychoses, hallucinations, or paranoia; depression, or suicidal thoughts; anxiety, agitation, restlessness, or nervousness; confusion, delirium, disorientation, or disturbances in attention; insomnia or nightmares, memory impairment. Attempted or completed suicide have been reported, especially in patients with a medical history of depression, or an underlying risk factor for depression. These reactions may occur following the first dose. If these reactions occur in patients receiving Levofloxacin in 5% Dextrose Injection, discontinue Levofloxacin in 5% Dextrose Injection and institute appropriate measures.

Central Nervous System Adverse Reactions of Seizures, Increased Intracranial Pressure, and Tremors
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with an increased risk of seizures (convulsions), increased intracranial pressure (including pseudotumor cerebri), tremors, and lightheadedness. As with other fluoroquinolones, Levofloxacin in 5% Dextrose Injection should be used with caution in patients with a known or suspected central nervous system (CNS) disorder that may predispose them to seizures or lower the seizure threshold (e.g., severe cerebral arteriosclerosis, epilepsy) or in the presence of other risk factors that may predispose them to seizures or lower the seizure threshold (e.g., certain drug therapy, renal dysfunction). If these reactions occur in patients receiving Levofloxacin in 5% Dextrose Injection, discontinue Levofloxacin in 5% Dextrose Injection and institute appropriate measures. *[see Adverse Reactions (6), Drug Interactions (7.4, 7.5), Patient Counseling Information (17)]*.

5.5 Exacerbation of Myasthenia Gravis
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have neuromuscular blocking activity and may exacerbate muscle weakness in patients with myasthenia gravis. Post-marketing serious adverse reactions, including deaths and requirement for ventilatory support, have been associated with fluoroquinolone use in patients with myasthenia gravis. Avoid Levofloxacin in 5% Dextrose Injection in patients with a known history of myasthenia gravis *[see Adverse Reactions (6.3) and Patient Counseling Information (17)]*.

5.6 Other Serious and Sometimes Fatal Adverse Reactions
Other serious and sometimes fatal adverse reactions, some due to hypersensitivity, and some due to uncertain etiology, have been reported rarely in patients receiving therapy with fluoroquinolones, including Levofloxacin in 5% Dextrose Injection. These events may be severe and generally occur following the administration of multiple doses. Clinical manifestations may include one or more of the following:
- fever, rash, or severe dermatologic reactions (e.g., toxic epidermal necrolysis, Stevens-Johnson Syndrome);
- vasculitis; arthralgia; myalgia; serum sickness;
- allergic pneumonitis;
- interstitial nephritis; acute renal insufficiency or failure;
- hepatitis; jaundice; acute hepatic necrosis or failure;
- anemia, including hemolytic and aplastic; thrombocytopenia, including thrombotic thrombocytopenic purpura; leukopenia; agranulocytosis; pancytopenia; and/or other hematologic abnormalities.

Discontinue Levofloxacin in 5% Dextrose Injection immediately at the first appearance of skin rash, jaundice, or any other sign of hypersensitivity and institute supportive measures *[see Adverse Reactions (6) and Patient Counseling Information (17)]*.

5.7 Hypersensitivity Reactions
Serious and occasionally fatal hypersensitivity and/or anaphylactic reactions have been reported in patients receiving therapy with fluoroquinolones, including Levofloxacin in 5% Dextrose Injection. These reactions often occur following the first dose. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat, or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath, and acute respiratory distress), dyspnea, urticaria, itching, and other serious skin reactions. Levofloxacin in 5% Dextrose Injection should be discontinued immediately at the first appearance of a skin rash or any other sign of hypersensitivity. Serious acute hypersensitivity reactions may require treatment with epinephrine and other resuscitative measures, including oxygen, intravenous fluids, antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated *[see Adverse Reactions (6) and Patient Counseling Information (17)]*.

5.8 Hepatotoxicity
Post-marketing reports of severe hepatotoxicity (including acute hepatitis and fatal events) have been received for patients treated with Levofloxacin in 5% Dextrose Injection. No evidence of serious drug-associated hepatotoxicity was detected in clinical trials of over 7,000 patients. Severe hepatotoxicity generally occurred within 14 days of initiation of therapy and most cases occurred within 6 days. Most cases of severe hepatotoxicity were not associated with hypersensitivity *[see Warnings and Precautions (5.6)]*. The majority of fatal hepatotoxicity reports occurred in patients 65 years of age or older and most were not associated with hypersensitivity. Levofloxacin in 5% Dextrose Injection should be discontinued immediately if the patient develops signs and symptoms of hepatitis *[see Adverse Reactions (6) and Patient Counseling Information (17)]*.

5.9 Risk of Aortic Aneurysm and Dissection
Epidemiologic studies report an increased rate of aortic aneurysm and dissection within two months following use of fluoroquinolones, particularly in elderly patients. The cause for the increased risk has not been identified. In patients with a known aortic aneurysm or patients who are at greater risk for aortic aneurysms, reserve Levofloxacin in 5% Dextrose Injection for use only when there are no alternative antibacterial treatments available.

5.10 *Clostridium difficile*-Associated Diarrhea
Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Levofloxacin in 5% Dextrose Injection, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated *[see Adverse Reactions (6.2) and Patient Counseling Information (17)]*.

5.11 Prolongation of the QT Interval
Some fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with prolongation of the QT interval on the electrocardiogram and infrequent cases of arrhythmia. Rare cases of torsades de pointes have been spontaneously reported during post-marketing surveillance in patients receiving fluoroquinolones, including Levofloxacin in 5% Dextrose Injection. Levofloxacin should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving Class IA (quinidine, procainamide), or Class III (amiodarone, sotalol) antiarrhythmic agents. Elderly patients may be more susceptible to drug-associated effects on the QT interval *[see Adverse Reactions (6.3), Use in Specific Populations (8.5) and Patient Counseling Information (17)]*.

5.12 Musculoskeletal Disorders in Pediatric Patients and Arthropathic Effects in Animals
Levofloxacin in 5% Dextrose Injection is indicated in pediatric patients (6 months of age and older) only for the prevention of inhalational anthrax (post-exposure) and for plague *[see Indications and Usage (1.7, 1.8)]*. An increased incidence of musculoskeletal disorders (arthralgia, arthritis, tendinopathy, and gait abnormality) compared to controls has been observed in pediatric patients receiving Levofloxacin in 5% Dextrose Injection *[see Use in Specific Populations (8.4)]*.

In immature rats and dogs, the oral and intravenous administration of levofloxacin resulted in increased osteochondrosis. Histopathological examination of the weight-bearing joints of immature dogs dosed with levofloxacin revealed persistent lesions of the cartilage. Other fluoroquinolones also produce similar erosions in the weight-bearing joints and other signs of arthropathy in immature animals of various species *[see Animal Toxicology and/or Pharmacology (13.2)]*.

5.13 Blood Glucose Disturbances
Fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, have been associated with disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia, usually in diabetic patients receiving concomitant treatment with an oral hypoglycemic agent (e.g., glyburide) or with insulin. In these patients, careful monitoring of blood glucose is recommended. Severe cases of hypoglycemia resulting in coma or death have been reported. If a hypoglycemic reaction occurs in a patient being treated with Levofloxacin in 5% Dextrose Injection, discontinue Levofloxacin in 5% Dextrose Injection and initiate appropriate therapy immediately *[see Adverse Reactions (6.2), Drug Interactions (7.3) and Patient Counseling Information (17)]*

5.14 Photosensitivity/Phototoxicity
Moderate to severe photosensitivity/phototoxicity reactions, the latter of which may manifest as exaggerated sunburn reactions (e.g., burning, erythema, exudation, vesicles, blistering, edema) involving areas exposed to light (typically the face, "V" area of the neck, extensor surfaces of the forearms, dorsa of the hands), can be associated with the use of fluoroquinolones after sun or UV light exposure. Therefore, excessive exposure to these sources of light should be avoided. Drug therapy should be discontinued if photosensitivity/phototoxicity occurs *[see Adverse Reactions (6.3) and Patient Counseling Information (17)]*.

5.15 Development of Drug-Resistant Bacteria
Prescribing Levofloxacin in 5% Dextrose Injection in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria *[see Patient Counseling Information (17)]*.

6 ADVERSE REACTIONS

6.1 Serious and Otherwise Important Adverse Reactions
The following serious and otherwise important adverse drug reactions are discussed in greater detail in other sections of labeling:
- Disabling and Potentially Irreversible Serious Adverse Reactions *[see Warnings and Precautions (5.1)]*
- Tendinitis and Tendon Rupture *[see Warnings and Precautions (5.2)]*
- Peripheral Neuropathy *[see Warnings and Precautions (5.3)]*
- Central Nervous System Effects *[see Warnings and Precautions (5.4)]*
- Exacerbation of Myasthenia Gravis *[see Warnings and Precautions (5.5)]*
- Other Serious and Sometimes Fatal Adverse Reactions *[see Warnings and Precautions (5.6)]*
- Hypersensitivity Reactions *[see Warnings and Precautions (5.7)]*
- Hepatotoxicity *[see Warnings and Precautions (5.8)]*
- *Clostridium difficile*-Associated Diarrhea *[see Warnings and Precautions (5.10)]*
- Prolongation of the QT Interval *[see Warnings and Precautions (5.11)]*
- Musculoskeletal Disorders in Pediatric Patients *[see Warnings and Precautions (5.12)]*
- Blood Glucose Disturbances *[see Warnings and Precautions (5.13)]*
- Photosensitivity/Phototoxicity *[see Warnings and Precautions (5.14)]*
- Development of Drug-Resistant Bacteria *[see Warnings and Precautions (5.15)]*

Hypotension has been associated with rapid or bolus intravenous infusion of Levofloxacin in 5% Dextrose Injection. Levofloxacin in 5% Dextrose Injection should be infused slowly over 60 to 90 minutes, depending on dosage *[see Dosage and Administration (2.5)]*.

Crystalluria and cylindruria have been reported with quinolones, including Levofloxacin in 5% Dextrose Injection. Therefore, adequate hydration of patients receiving Levofloxacin in 5% Dextrose Injection should be maintained to prevent the formation of a highly concentrated urine *[see Dosage and Administration (2.5)]*.

6.2 Clinical Trial Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect exposure to Levofloxacin in 5% Dextrose Injection in 7,537 patients in 29 pooled Phase 3 clinical trials. The population studied had a mean age of 50 years (approximately 74% of the population was < 65 years of age), 50% were male, 71% were Caucasian, 19% were Black. Patients were treated with Levofloxacin in 5% Dextrose Injection for a wide variety of infectious diseases *[see Indications and Usage (1)]*. Patients received Levofloxacin in 5% Dextrose Injection doses of 750 mg once daily, 250 mg once daily, or 500 mg once or twice daily. Treatment duration was usually 3 to 14 days, and the mean number of days on therapy was 10 days.

The overall incidence, type and distribution of adverse reactions was similar in patients receiving Levofloxacin in 5% Dextrose Injection doses of 750 mg once daily, 250 mg once daily, and 500 mg once or twice daily. Discontinuation of Levofloxacin in 5% Dextrose Injection due to adverse drug reactions occurred in 4.3% of patients overall, 3.8% of patients treated with the 250 mg and 500 mg doses and 5.4% of patients treated with the 750 mg dose. The most common adverse drug reactions leading to discontinuation with the 250 and 500 mg doses were gastrointestinal (1.4%), primarily nausea (0.6%); vomiting (0.4%); dizziness (0.3%); and headache (0.2%). The most common adverse drug reactions leading to discontinuation with the 750 mg dose were gastrointestinal (1.2%), primarily nausea (0.6%), vomiting (0.5%); dizziness (0.3%); and headache (0.3%).

Adverse reactions occurring in ≥ 1% of Levofloxacin in 5% Dextrose Injection-treated patients and less common adverse reactions, occurring in 0.1 to < 1% of Levofloxacin in 5% Dextrose Injection-treated patients, are shown in Table 4 and Table 5, respectively. The most common adverse drug reactions (≥ 3%) are nausea, headache, diarrhea, insomnia, constipation, and dizziness.

Table 4: Common (≥ 1%) Adverse Reactions Reported in Clinical Trials with Levofloxacin

System/Organ Class	Adverse Reaction	% (N = 7,537)
Infections and Infestations	moniliasis	1
Psychiatric Disorders	insomnia* *[see Warnings and Precautions (5.4)]*	4
Nervous System Disorders	headache dizziness *[see Warnings and Precautions (5.4)]*	6 3
Respiratory, Thoracic and Mediastinal Disorders	dyspnea *[see Warnings and Precautions (5.7)]*	1
Gastrointestinal Disorders	nausea diarrhea constipation abdominal pain vomiting dyspepsia	7 5 3 2 2 2
Skin and Subcutaneous Tissue Disorders	rash *[see Warnings and Precautions (5.7)]* pruritus	2 1
Reproductive System and Breast Disorders	vaginitis	1†
General Disorders and Administration Site Conditions	edema injection site reaction chest pain	1 1 1

* N = 7,274
† N = 3,758 (women)

Table 5: Less Common (0.1 to 1%) Adverse Reactions Reported in Clinical Trials with Levofloxacin (N = 7,537)

System/Organ Class	Adverse Reaction
Infections and Infestations	genital moniliasis
Blood and Lymphatic System Disorders	anemia thrombocytopenia granulocytopenia *[see Warnings and Precautions (5.6)]*
Immune System Disorders	allergic reaction *[see Warnings and Precautions (5.6, 5.7)]*
Metabolism and Nutrition Disorders	hyperglycemia hypoglycemia *[see Warnings and Precautions (5.13)]* hyperkalemia
Psychiatric Disorders	anxiety agitation confusion depression hallucination nightmare* *[see Warnings and Precautions (5.4)]* sleep disorder* anorexia abnormal dreaming*
Nervous System Disorders	tremor convulsions *[see Warnings and Precautions (5.4)]* paresthesia *[see Warnings and Precautions (5.3)]* vertigo hypertonia hyperkinesias abnormal gait somnolence* syncope
Respiratory, Thoracic and Mediastinal Disorders	epistaxis
Cardiac Disorders	cardiac arrest palpitation ventricular tachycardia ventricular arrhythmia
Vascular Disorders	phlebitis
Gastrointestinal Disorders	gastritis stomatitis pancreatitis esophagitis gastroenteritis glossitis pseudomembranous/*C. difficile* colitis *[see Warnings and Precautions (5.10)]*
Hepatobiliary Disorders	abnormal hepatic function increased hepatic enzymes increased alkaline phosphatase
Skin and Subcutaneous Tissue Disorders	urticaria *[see Warnings and Precautions (5.7)]*
Musculoskeletal and Connective Tissue Disorders	arthralgia tendinitis *[see Warnings and Precautions (5.2)]* myalgia skeletal pain
Renal and Urinary Disorders	abnormal renal function acute renal failure *[see Warnings and Precautions (5.6)]*

* N = 7,274

In clinical trials using multiple-dose therapy, ophthalmologic abnormalities, including cataracts and multiple punctate lenticular opacities, have been noted in patients undergoing treatment with quinolones, including levofloxacin. The relationship of the drugs to these events is not presently established.

6.3 Post-marketing Experience
Table 6 lists adverse reactions that have been identified during post-approval use of Levofloxacin in 5% Dextrose Injection. Because these reactions are reported voluntarily from a population of uncertain size, reliably estimating their frequency or establishing a causal relationship to drug exposure is not always possible.

Table 6: Post-marketing Reports of Adverse Drug Reactions

System/Organ Class	Adverse Reaction
Blood and Lymphatic System Disorders	pancytopenia aplastic anemia leukopenia hemolytic anemia *[see Warnings and Precautions (5.6)]* eosinophilia
Immune System Disorders	hypersensitivity reactions, sometimes fatal including: anaphylactic/anaphylactoid reactions anaphylactic shock angioneurotic edema serum sickness *[see Warnings and Precautions (5.6, 5.7)]*
Psychiatric Disorders	psychosis paranoia isolated reports of suicide ideation, suicide attempt and completed suicide *[see Warnings and Precautions (5.4)]*
Nervous System Disorders	exacerbation of myasthenia gravis *[see Warnings and Precautions (5.2)]* anosmia ageusia parosmia dysgeusia peripheral neuropathy (may be irreversible) *[see Warnings and Precautions (5.3)]* isolated reports of encephalopathy abnormal electroencephalogram (EEG) dysphonia pseudotumor cerebri *[see Warnings and Precautions (5.4)]*
Eye Disorders	uveitis vision disturbance, including diplopia visual acuity reduced vision blurred scotoma
Ear and Labyrinth Disorders	hypoacusis tinnitus
Cardiac Disorders	isolated reports of torsades de pointes electrocardiogram QT prolonged *[see Warnings and Precautions (5.11)]* tachycardia
Vascular Disorders	vasodilatation
Respiratory, Thoracic and Mediastinal Disorders	isolated reports of allergic pneumonitis *[see Warnings and Precautions (5.6)]*
Hepatobiliary Disorders	hepatic failure (including fatal cases) hepatitis jaundice *[see Warnings and Precautions (5.6, 5.8)]*
Skin and Subcutaneous Tissue Disorders	bullous eruptions to include: Stevens-Johnson Syndrome toxic epidermal necrolysis Acute Generalized Exanthematous Pustulosis (AGEP) fixed drug eruptions erythema multiforme *[see Warnings and Precautions (5.6)]* photosensitivity/phototoxicity reaction *[see Warnings and Precautions (5.14)]* leukocytoclastic vasculitis
Musculoskeletal and Connective Tissue Disorders	tendon rupture *[see Warnings and Precautions (5.2)]* muscle injury, including rupture rhabdomyolysis
Renal and Urinary Disorders	interstitial nephritis *[see Warnings and Precautions (5.6)]*
General Disorders and Administration Site Conditions	multi-organ failure pyrexia
Investigations	prothrombin time prolonged international normalized ratio prolonged muscle enzymes increased

7 DRUG INTERACTIONS

7.1 Chelation Agents: Antacids, Sucralfate, Metal Cations, Multivitamins
There are no data concerning an interaction of intravenous fluoroquinolones with oral antacids, sucralfate, multivitamins, didanosine, or metal cations. However, no fluoroquinolone should be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line *[see Dosage and Administration (2.5)]*.

7.2 Warfarin
No significant effect of Levofloxacin in 5% Dextrose Injection on the peak plasma concentrations, AUC, and other disposition parameters for R- and S- warfarin was detected in a clinical study involving healthy volunteers. Similarly, no apparent effect of warfarin on levofloxacin absorption and disposition was observed. However, there have been reports during the post-marketing experience in patients that Levofloxacin in 5% Dextrose Injection enhances the effects of warfarin. Elevations of the prothrombin time in the setting of concurrent warfarin and Levofloxacin in 5% Dextrose Injection use have been associated with episodes of bleeding. Prothrombin time, International Normalized Ratio (INR), or other suitable anticoagulation tests should be closely monitored if Levofloxacin in 5% Dextrose Injection is administered concomitantly with warfarin. Patients should also be monitored for evidence of bleeding *[see Adverse Reactions (6.3) and Patient Counseling Information (17)]*.

7.3 Anti-diabetic Agents
Disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported in patients treated concomitantly with fluoroquinolones and an anti-diabetic agent. Therefore, careful monitoring of blood glucose is recommended when these agents are co-administered *[see Warnings and Precautions (5.13), Adverse Reactions (6.2) and Patient Counseling Information (17)]*.

7.4 Non-Steroidal Anti-Inflammatory Drugs
The concomitant administration of a non-steroidal anti-inflammatory drug with a fluoroquinolone, including Levofloxacin in 5% Dextrose Injection, may increase the risk of CNS stimulation and convulsive seizures *[see Warnings and Precautions (5.4)]*.

7.5 Theophylline
No significant effect of Levofloxacin in 5% Dextrose Injection on the plasma concentrations, AUC, and other disposition parameters for theophylline was detected in a clinical study involving healthy volunteers. Similarly, no apparent effect of theophylline on levofloxacin absorption and disposition was observed. However, concomitant administration of other fluoroquinolones with theophylline has resulted in prolonged elimination half-life, elevated serum theophylline levels, and a subsequent increase in the risk of theophylline-related adverse reactions in the patient population. Therefore, theophylline levels should be closely monitored and appropriate dosage adjustments made when Levofloxacin in 5% Dextrose Injection is co-administered. Adverse reactions, including seizures, may occur with or without an elevation in serum theophylline levels *[see Warnings and Precautions (5.4)]*.

7.6 Cyclosporine
No significant effect of Levofloxacin in 5% Dextrose Injection on the peak plasma concentrations, AUC, and other disposition parameters for cyclosporine was detected in a clinical study involving healthy volunteers. However, elevated serum levels of cyclosporine have been reported in the patient population when co-administered with some other fluoroquinolones. Levofloxacin C_{max} and k_e were slightly lower while T_{max} and $t_{½}$ were slightly longer in the presence of cyclosporine than those observed in other studies without concomitant medication. The differences, however, are not considered to be clinically significant. Therefore, no dosage adjustment is required for Levofloxacin in 5% Dextrose Injection or cyclosporine when administered concomitantly.

7.7 Digoxin
No significant effect of Levofloxacin in 5% Dextrose Injection on the peak plasma concentrations, AUC, and other disposition parameters for digoxin was detected in a clinical study involving healthy volunteers. Levofloxacin absorption and disposition kinetics were similar in the presence or absence of digoxin. Therefore, no dosage adjustment for Levofloxacin in 5% Dextrose Injection or digoxin is required when administered concomitantly.

7.8 Probenecid and Cimetidine
No significant effect of probenecid or cimetidine on the C_{max} of levofloxacin was observed in a clinical study involving healthy volunteers. The AUC and $t_{½}$ of levofloxacin were higher while CL/F and CL_R were lower during concomitant treatment of Levofloxacin in 5% Dextrose Injection with probenecid or cimetidine compared to Levofloxacin in 5% Dextrose Injection alone. However, these changes do not warrant dosage adjustment for Levofloxacin in 5% Dextrose Injection when probenecid or cimetidine is co-administered.

7.9 Interactions with Laboratory or Diagnostic Testing
Some fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, may produce false-positive urine screening results for opiates using commercially available immunoassay kits. Confirmation of positive opiate screens by more specific methods may be necessary.

How should I take Levofloxacin in 5% Dextrose Injection?

- Take Levofloxacin in 5% Dextrose Injection exactly as your healthcare provider tells you to take it.
- Take Levofloxacin in 5% Dextrose Injection at about the same time each day.
- Drink plenty of fluids while you take Levofloxacin in 5% Dextrose Injection.
- If you miss a dose of Levofloxacin in 5% Dextrose Injection, take it as soon as you remember. Do not take more than 1 dose in 1 day.
- Levofloxacin in 5% Dextrose Injection is given by slow intravenous (IV) infusion into your vein over 60 or 90 minutes as prescribed by your healthcare provider.
- Do not skip any doses of Levofloxacin in 5% Dextrose Injection or stop taking it, 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 Levofloxacin in 5% Dextrose Injection?"**.
  - you have a nerve problem. See **"What are the possible side effects of Levofloxacin in 5% Dextrose Injection?"**.
  - you have a central nervous system problem. See **"What are the possible side effects of Levofloxacin in 5% Dextrose Injection?"**.
  - you have a serious allergic reaction. See **"What are the possible side effects of Levofloxacin in 5% Dextrose Injection?"**.
  - your healthcare provider tells you to stop taking Levofloxacin in 5% Dextrose Injection.

Taking all of your Levofloxacin in 5% Dextrose Injection doses will help make sure that all of the bacteria are killed. Taking all of your Levofloxacin in 5% Dextrose Injection doses will help you lower the chance that the bacteria will become resistant to Levofloxacin in 5% Dextrose Injection. If your infection does not get better while you take Levofloxacin in 5 % Dextrose Injection, it may mean that the bacteria causing your infection may be resistant to Levofloxacin in 5% Dextrose Injection. If your infection does not get better, call your healthcare provider. If your infection does not get better, Levofloxacin in 5% Dextrose Injection and other similar antibiotic medicines may not work for you in the future.

- If you take too much Levofloxacin in 5% Dextrose Injection, call your healthcare provider or get medical help right away.

What should I avoid while taking Levofloxacin in 5% Dextrose Injection?

- Levofloxacin in 5% Dextrose 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 Levofloxacin in 5% Dextrose Injection affects you.
- Avoid sunlamps, tanning beds, and try to limit your time in the sun. Levofloxacin 5% Dextrose 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 you take Levofloxacin in 5% Dextrose 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 Levofloxacin in 5% Dextrose Injection?

Levofloxacin in 5% Dextrose Injection can cause serious side effects, including:

- See **"What is the most important information I should know about Levofloxacin in 5% Dextrose Injection?"**
- **Serious allergic reactions**
  Allergic reactions can happen in people taking fluoroquinolones, including Levofloxacin in 5% Dextrose Injection, even after only 1 dose. Stop taking Levofloxacin in 5% Dextrose Injection and get emergency medical help right away if you have 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
  - skin rash
  Skin rash may happen in people taking Levofloxacin in 5% Dextrose Injection, even after only 1 dose. Stop taking Levofloxacin in 5% Dextrose 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 Levofloxacin in 5% Dextrose Injection.
- **Liver damage (hepatotoxicity):** Hepatotoxicity can happen in people who take Levofloxacin in 5% Dextrose Injection. Call your healthcare provider right away if you have unexplained symptoms such as:
  - nausea or vomiting
  - stomach pain
  - fever
  - weakness
  - abdominal pain or tenderness
  - itching
  - unusual tiredness
  - loss of appetite
  - light colored bowel movements
  - dark colored urine
  - yellowing of your skin or the whites of your eyes

Stop taking Levofloxacin in 5% Dextrose Injection and tell your healthcare provider right away if you have 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 Levofloxacin in 5% Dextrose Injection (a liver problem).

- **Aortic aneurysm and dissection**
  Tell your healthcare provider if you have ever been told that you have an aortic aneurysm, a swelling of the large artery that carries blood from the heart to the body. Get emergency medical help right away if you have sudden chest, stomach, or back pain.

- **Intestine infection (Pseudomembranous colitis)**
  Pseudomembranous colitis can happen with many antibiotics, including Levofloxacin in 5% Dextrose Injection. 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 finished your antibiotic.

- **Serious heart rhythm changes (QT prolongation and torsades 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. Levofloxacin in 5% Dextrose 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 happening 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)

- **Joint Problems**
  Increased chance of problems with joints and tissues around joints in children can happen. Tell your child's healthcare provider if your child has any joint problems during or after treatment with Levofloxacin in 5% Dextrose Injection.

- **Changes in blood sugar**
  People who take Levofloxacin in 5% Dextrose Injection 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 Levofloxacin in 5% Dextrose Injection, stop taking Levofloxacin in 5% Dextrose Injection 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 Levofloxacin in 5% Dextrose Injection?"**
  The most common side effects of Levofloxacin in 5% Dextrose Injection include:
  - nausea
  - headache
  - diarrhea
  - insomnia
  - constipation
  - dizziness

In children 6 months and older who take Levofloxacin in 5% Dextrose Injection to treat anthrax disease or plague, vomiting is also common.

Low blood pressure can happen when Levofloxacin in 5% Dextrose Injection is given too fast by IV injection. Tell your healthcare provider if you feel dizzy or faint during a treatment with Levofloxacin in 5% Dextrose Injection.

Levofloxacin in 5% Dextrose Injection may cause false-positive urine screening results for opiates when testing is done with some commercially available kits. A positive result should be confirmed using a more specific test.

These are not all the possible side effects of Levofloxacin in 5% Dextrose Injection. 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 Levofloxacin in 5% Dextrose Injection?
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Avoid excessive heat and protect from freezing and light.

Keep Levofloxacin in 5% Dextrose Injection and all medicines out of the reach of children.

General Information about the safe and effective use of Levofloxacin in 5% Dextrose Injection

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Levofloxacin in 5% Dextrose Injection for a condition for which it is not prescribed. Do not give Levofloxacin in 5% Dextrose Injection 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 Levofloxacin in 5% Dextrose Injection. If you would like more information about Levofloxacin in 5% Dextrose Injection, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Levofloxacin in 5% Dextrose Injection that is written for healthcare professionals.

For more information call Fresenius Kabi USA, LLC at 1-800-551-7176.

What are the ingredients in Levofloxacin in 5% Dextrose Injection?

Levofloxacin in 5% Dextrose Injection Premix in Single-Use Flexible Containers:

Active ingredient: levofloxacin

Inactive ingredients: Dextrose (D5W). Solutions of hydrochloric acid and sodium hydroxide may have been added to adjust the pH.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Manufactured for:

FRESENIUS KABI

Lake Zurich, IL 60047

Made in Norway

www.fresenius-kabi.com/us

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