

## DISCLAIMER

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**INDICATIONS AND USAGE**  
These highlights do not include all the information needed to use LEVOFLOXACIN Injection safely and effectively. See full prescribing information for LEVOFLOXACIN Injection.

**LEVOFLOXACIN 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 Injection, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred in patients with and without risk factors. These reactions include:
  - Tendinitis and tendon rupture (5.1), including:
    - Peripheral neuropathy (5.3)
    - Central nervous system effects (5.4)

Discontinue Levofloxacin Injection immediately and avoid the use of fluoroquinolones, including Levofloxacin Injection, in patients who experience any of these serious adverse reactions (5.1).

- Fluoroquinolones, including Levofloxacin Injection, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid Levofloxacin Injection in patients with a known history of myasthenia gravis (see **Warnings and Precautions (5.5)**).
- Because fluoroquinolones, including Levofloxacin Injection, have been associated with serious adverse reactions, including tendonitis, tendinitis, tendon rupture, peripheral neuropathy, and central nervous system effects, avoid the use of fluoroquinolones, including Levofloxacin Injection, 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 Injection and other antibacterial drugs, Levofloxacin 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 Indications and Usage (1) 06/2016  
Dosage and Administration (2) 06/2016  
Warnings and Precautions (5) 06/2016

**INDICATIONS AND USAGE**

Levofloxacin 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)
- 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)

System/Infection Class	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	750 mg	7 to 14
Uncomplicated SSTI (1.5)	500 mg	7 to 10
Chronic Bacterial Prostatitis (1.6)	500 mg	28
Inhalational Anthrax (Post-Exposure) (1.7)	500 mg	60
Adults and Pediatric Patients >50 kg of age	8 mg/kg BID (not to exceed 250 mg/dose)	

**CONTRAINDICATIONS**

Known hypersensitivity to levofloxacin 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 dysfunction (see **Warnings and Precautions (5.1)**).
- Hepatoxicity: 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 (5.9).
- Prolongation of the QT interval and isolated cases of torsade de pointes have been reported. Avoid use in patients with known prolongation, those with hypokalemia, and with other drugs that prolong the QT interval (5.10, 8.5).

**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 (see **Warnings and Precautions (5.1)**).
- Pediatrics:** Musculoskeletal disorders (arthralgia, arthritis, tendinopathy, and gait abnormality) seen in more Levofloxacin Injection-treated patients than in placebo-treated patients. In pediatric patients, treatment with Levofloxacin Injection may cause arthropathy and osteochondrodysplasia in juvenile animals (5.11, 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, 14.9).

**See 17 for PATIENT COUNSELING INFORMATION Medication Guide.**

**FULL PRESCRIBING INFORMATION: CONTENTS\***

**WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS**  
Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects

- 1. INDICATIONS AND USAGE
- 1.1 Nosocomial Pneumonia
- 1.2 Community-Acquired Pneumonia: 7- to 14-day Treatment Regimen
- 1.3 Community-Acquired Pneumonia: 5-day Treatment Regimen
- 1.4 Complicated Skin and Skin Structure Infections
- 1.5 Uncomplicated Skin and Skin Structure Infections
- 1.6 Chronic Bacterial Prostatitis
- 1.7 Inhalational Anthrax (Post-Exposure)
- 1.8 Plague
- 1.9 Complicated Urinary Tract Infections: 5-day Treatment Regimen
- 1.10 Complicated Urinary Tract Infections: 10-day Treatment Regimen
- 1.11 Acute Pyelonephritis: 5- or 10-day Treatment Regimen
- 1.12 Uncomplicated Urinary Tract Infections
- 1.13 Acute Bacterial Exacerbation of Chronic Bronchitis
- 1.14 Acute Bacterial Sinusitis: 5-day and 10- to 14-day Treatment Regimens

**2. DOSAGE AND ADMINISTRATION**

- 2.1 Dosage in Adult Patients with Normal Renal Function
- 2.2 Dosage in Pediatric Patients
- 2.3 Dosage Adjustment in Adult Patients with Renal Impairment
- 2.4 Drug Interaction with Chelation Agents: Antacids, Sucralfate, Metal Cations, Multivitamins

**3. CONTRAINDICATIONS**

- 3.1 Hypersensitivity to Levofloxacin or Other Quinolones

**4. WARNINGS AND PRECAUTIONS**

- 4.1 Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects
- 4.2 Tendinitis and Tendon Rupture
- 4.3 Peripheral Neuropathy
- 4.4 Central Nervous System Effects
- 4.5 Exacerbation of Myasthenia Gravis
- 4.6 Other Serious and Sometimes Fatal Adverse Reactions
- 4.7 Hepatoxicity
- 4.8 *Clostridium difficile*-Associated Diarrhea
- 4.9 Prolongation of the QT Interval
- 4.10 Musculoskeletal Disorders in Pediatric Patients and Arthropathic Effects in Animals
- 4.11 Blood Glucose Disturbances
- 4.12 Photosensitivity/Phototoxicity
- 4.13 Development of Drug-Resistant Bacteria

**5. ADVERSE REACTIONS**

- 5.1 Serious and Other Important Adverse Reactions
- 5.2 Central Nervous System Effects
- 5.3 Postmarketing Experience

**FULL PRESCRIBING INFORMATION**

**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, 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)**), including:
    - Peripheral neuropathy (see **Warnings and Precautions (5.3)**)
    - Central nervous system effects (see **Warnings and Precautions (5.4)**)
- Discontinue Levofloxacin Injection immediately and avoid the use of fluoroquinolones, including levofloxacin, in patients who experience any of these serious adverse reactions (see **Warnings and Precautions (5.1)**).
- Fluoroquinolones, including levofloxacin, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid levofloxacin Injection in patients with a known history of myasthenia gravis (see **Warnings and Precautions (5.5)**).
- Because fluoroquinolones, including levofloxacin, have been associated with serious adverse reactions, including tendonitis, tendinitis, tendon rupture, peripheral neuropathy, and central nervous system effects, avoid the use of fluoroquinolones, including levofloxacin, 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 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.

- Fluoroquinolones, including levofloxacin, 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)**), including:
    - Peripheral neuropathy (see **Warnings and Precautions (5.3)**)
    - Central nervous system effects (see **Warnings and Precautions (5.4)**)

**1.1 Nosocomial Pneumonia**

Levofloxacin 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*. Adjuvantive therapy should be used as clinically indicated. When *Pseudomonas aeruginosa* is a documented or presumptive pathogen, combination therapy with an anti-pseudomonal  $\beta$ -lactam is recommended (see **Clinical Studies (14.9)**).

**1.2 Community-Acquired Pneumonia: 7- to 14-day Treatment Regimen**

Levofloxacin is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.1)**).

**1.3 Community-Acquired Pneumonia: 5-day Treatment Regimen**

Levofloxacin is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.1)**).

**1.4 Complicated Skin and Skin Structure Infections**

Levofloxacin is indicated for the treatment of complicated skin and skin structure infections due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.4)**).

**1.5 Uncomplicated Skin and Skin Structure Infections**

Levofloxacin is indicated for the treatment of uncomplicated skin and skin structure infections due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.5)**).

**1.6 Chronic Bacterial Prostatitis**

Levofloxacin is indicated for the treatment of chronic bacterial prostatitis due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.6)**).

**1.7 Inhalational Anthrax (Post-Exposure)**

Levofloxacin is indicated for the treatment of inhalational anthrax (post-exposure) in adults and pediatric patients ≥50 kg of age (see **Indications and Usage (1.7)**).

**1.8 Plague**

Levofloxacin is indicated for the treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (see **Indications and Usage (1.8)**).

**1.9 Complicated Urinary Tract Infections: 5-day Treatment Regimen**

Levofloxacin 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 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 **Indications and Usage (1.10)**).

**1.11 Acute Pyelonephritis: 5- or 10-day Treatment Regimen**

Levofloxacin is indicated for the treatment of uncomplicated urinary tract infections (mild to moderate) due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*.

**1.12 Uncomplicated Urinary Tract Infections**

Levofloxacin is indicated for the treatment of uncomplicated urinary tract infections (mild to moderate) due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*.

**1.13 Acute Bacterial Exacerbation of Chronic Bronchitis**

Levofloxacin is indicated for the treatment of acute bacterial sinusitis (ABS) due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis* (see **Clinical Studies (14.4)**).

**1.14 Acute Bacterial Sinusitis**

Levofloxacin is indicated for the treatment of acute bacterial sinusitis (ABS) due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis* (see **Clinical Studies (14.4)**).

**2. DOSAGE AND ADMINISTRATION**

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

**2.1 Dosage in Adult Patients with Normal Renal Function**

The usual dose of Levofloxacin Injection is 250 mg or 500 mg administered by slow intravenous infusion over 60 minutes every 24 hours or 750 mg administered by slow intravenous infusion over 90 minutes every 24 hours, as indicated by infection and described in Table 1.

**2.2 Dosage in Pediatric Patients**

These recommendations apply to patients with creatinine clearance ≥50 mL/min. For patients with creatinine clearance <50 mL/min, adjustments to the recommended dosage are required (see **Dosage and Administration (2.2)**).

**2.3 Dosage Adjustment in Adult Patients with Renal Impairment**

These recommendations apply to patients with creatinine clearance ≥50 mL/min. For patients with creatinine clearance <50 mL/min, adjustments to the recommended dosage are required (see **Dosage and Administration (2.3)**).

**2.4 Drug Interaction with Chelation Agents: Antacids, Sucralfate, Metal Cations, Multivitamins**

Levofloxacin Injection should not be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line. Treatment order to isolate and identify organisms causing the infection and to determine their susceptibility to levofloxacin (see **Microbiology (12.4)**). Therapy with levofloxacin may be initiated before results of these tests are known; once results become available, appropriate therapy should be selected.

**2.5 Administration Instructions**

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 Injection with other intravenous substances, additives or other medications should not be added to Levofloxacin Injection in Single-Dose Vials, or infusions 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 Injection with a 5% dextrose injection compatible with Levofloxacin Injection and with any other drug(s) administered via this common line.

**2.6 Preparation of Intravenous Solution**

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 Injection with other intravenous substances, additives or other medications should not be added to Levofloxacin Injection in Single-Dose Vials, or infusions 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 Injection with a 5% dextrose injection compatible with Levofloxacin Injection and with any other drug(s) administered via this common line.

**2.7 Hydration for Patients Receiving Levofloxacin Injection**

Adequate hydration of patients receiving intravenous levofloxacin should be maintained to prevent the formation of highly concentrated urine. Crystalluria and cyindruria have been reported in patients receiving levofloxacin (see **Warnings and Precautions (5.10)** and **Warnings and Precautions (5.9)**).

**2.8 Hydration for Patients Receiving Levofloxacin Injection**

Adequate hydration of patients receiving intravenous levofloxacin should be maintained to prevent the formation of highly concentrated urine. Crystalluria and cyindruria have been reported in patients receiving levofloxacin (see **Warnings and Precautions (5.10)** and **Warnings and Precautions (5.9)**).

**3. CONTRAINDICATIONS**

- 3.1 Hypersensitivity to Levofloxacin or Other Quinolones

**4. WARNINGS AND PRECAUTIONS**

- 4.1 Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects
- 4.2 Tendinitis and Tendon Rupture
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**5. ADVERSE REACTIONS**

- 5.1 Serious and Other Important Adverse Reactions
- 5.2 Central Nervous System Effects
- 5.3 Postmarketing Experience

**6. GENERAL INFORMATION**

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

**1. INDICATIONS AND USAGE**

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- Fluoroquinolones, including levofloxacin, 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)**), including:
    - Peripheral neuropathy (see **Warnings and Precautions (5.3)**)
    - Central nervous system effects (see **Warnings and Precautions (5.4)**)

**1.1 Nosocomial Pneumonia**

Levofloxacin 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*. Adjuvantive therapy should be used as clinically indicated. When *Pseudomonas aeruginosa* is a documented or presumptive pathogen, combination therapy with an anti-pseudomonal  $\beta$ -lactam is recommended (see **Clinical Studies (14.9)**).

**1.2 Community-Acquired Pneumonia: 7- to 14-day Treatment Regimen**

Levofloxacin is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.1)**).

**1.3 Community-Acquired Pneumonia: 5-day Treatment Regimen**

Levofloxacin is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.1)**).

**1.4 Complicated Skin and Skin Structure Infections**

Levofloxacin is indicated for the treatment of complicated skin and skin structure infections due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.4)**).

**1.5 Uncomplicated Skin and Skin Structure Infections**

Levofloxacin is indicated for the treatment of uncomplicated skin and skin structure infections due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.5)**).

**1.6 Chronic Bacterial Prostatitis**

Levofloxacin is indicated for the treatment of chronic bacterial prostatitis due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae* (see **Indications and Usage (1.6)**).

**1.7 Inhalational Anthrax (Post-Exposure)**

Levofloxacin is indicated for the treatment of inhalational anthrax (post-exposure) in adults and pediatric patients ≥50 kg of age (see **Indications and Usage (1.7)**).

**1.8 Plague**

Levofloxacin is indicated for the treatment of plague, including pneumonic and septicemic plague, due to *Yersinia pestis* (see **Indications and Usage (1.8)**).

**1.9 Complicated Urinary Tract Infections: 5-day Treatment Regimen**

Levofloxacin 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 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 **Indications and Usage (1.10)**).

**1.11 Acute Pyelonephritis: 5- or 10-day Treatment Regimen**



