

# LEVERO 750/500/250 TABLETS

## COMPOSITION

### LEVERO 250

Each film-coated tablet contains:

Levofloxacin Hemihydrate IP equivalent to Levofloxacin .....250 mg

Colours: Red Oxide of Iron & Titanium Dioxide

### LEVERO 500

Each film-coated tablet contains:

Levofloxacin Hemihydrate IP equivalent to Levofloxacin .....500 mg

Colours: Red Oxide of Iron & Titanium Dioxide

## INDICATIONS

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Levofloxacin and other antibacterial drugs, Levofloxacin 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. Levofloxacin tablets are indicated for the treatment of adults ( $\geq 18$  years of age) with mild, moderate and severe infections caused by susceptible strains of the designated microorganisms in the conditions listed in this section.

### 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*. Adjunctive therapy should be used as clinically indicated. Where *Pseudomonas aeruginosa* is a documented or presumptive pathogen, combination therapy with an anti-pseudomonal beta-lactam is recommended.

### Community-Acquired Pneumonia: 7–14 days Treatment Regimen

Levofloxacin is indicated for the treatment of community-acquired pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae* (including multi-drug-resistant *Streptococcus pneumoniae* [MDRSP]), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Chlamydomphila pneumoniae*, *Legionella pneumophila* or *Mycoplasma pneumoniae*.

### Community-Acquired Pneumonia: 5-day Treatment Regimen

Levofloxacin is indicated for the treatment of community-acquired pneumonia due to *Streptococcus pneumoniae* (excluding multi-drug-resistant strains [MDRSP]), *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Mycoplasma pneumoniae* or *Chlamydomphila pneumoniae*.

### Acute Bacterial Sinusitis: 5-day and 10–14 days Treatment Regimens

Levofloxacin is indicated for the treatment of acute bacterial sinusitis due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*.

### Acute Bacterial Exacerbation of Chronic Bronchitis

Levofloxacin is indicated for the treatment of acute bacterial exacerbation of chronic bronchitis due to methicillin-susceptible *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae* or *Moraxella catarrhalis*.

### 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*, *Enterococcus faecalis*, *Streptococcus pyogenes* or *Proteus mirabilis*.

## Uncomplicated Skin and Skin Structure Infections

Levofloxacin is indicated for the treatment of uncomplicated skin and skin structure infections (mild to moderate), including abscesses, cellulitis, furuncles, impetigo, pyoderma and wound infections, due to methicillin-susceptible *Staphylococcus aureus* or *Streptococcus pyogenes*.

## Chronic Bacterial Prostatitis

Levofloxacin is indicated for the treatment of chronic bacterial prostatitis due to *Escherichia coli*, *Enterococcus faecalis* or methicillin-susceptible *Staphylococcus epidermidis*.

## 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*.

## 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*.

## Acute Pyelonephritis: 5 or 10-day Treatment Regimen

Levofloxacin is indicated for the treatment of acute pyelonephritis caused by *Escherichia coli*, including cases with concurrent bacteremia.

## 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*.

## Inhalational Anthrax (Post-Exposure)

Levofloxacin is indicated for inhalational anthrax (post-exposure) to reduce the incidence or progression of the 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 has not been tested in humans for the post-exposure prevention of inhalation anthrax. The safety of Levofloxacin 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 therapy should only be used when the benefit outweighs the risk.

## DOSAGE AND ADMINISTRATION

### Dosage in Adult Patients with Normal Renal Function

The usual dose of Levofloxacin tablets is 250 mg, 500 mg or 750 mg administered orally every 24 hours, as indicated by the infection and as described in Table 1.

Type of Infection <sup>1</sup>	Dosed Every 24 hours	Duration (days) <sup>2</sup>
<sup>1</sup> Due to the designated pathogens [see INDICATIONS].		
<sup>3</sup> Due to methicillin-susceptible <i>Staphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> (including multi-drug-resistant strains [MDRSP]), <i>Haemophilus influenzae</i> , <i>Haemophilus parainfluenzae</i> , <i>Klebsiella pneumoniae</i> , <i>Moraxella catarrhalis</i> , <i>Chlamydomydia pneumoniae</i> , <i>Legionella pneumophila</i> or <i>Mycoplasma pneumoniae</i> .		
<sup>4</sup> Due to <i>Streptococcus pneumoniae</i> (excluding multi-drug-resistant strains [MDRSP]), <i>Haemophilus influenzae</i> , <i>Haemophilus parainfluenzae</i> , <i>Mycoplasma pneumoniae</i> or <i>Chlamydomydia pneumoniae</i> .		
<sup>5</sup> This regimen is indicated for complicated urinary tract infection (cUTI) due to <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> and <i>Proteus mirabilis</i> , and acute pyelonephritis (AP) due to <i>Escherichia coli</i> , including cases with concurrent		

bacteremia.

<sup>6</sup> This regimen is indicated for cUTI due to *Enterococcus faecalis*, *Enterococcus cloacae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis* and *Pseudomonas aeruginosa*; and for AP due to *Escherichia coli*.

<sup>7</sup> Drug administration should begin as soon as possible after suspected or confirmed exposure to aerosolized *Bacillus anthracis*. This indication is based on a surrogate endpoint. Levofloxacin plasma concentrations achieved in humans are reasonably likely to predict clinical benefit.

<sup>8</sup> The safety of Levofloxacin in adults for duration 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. Prolonged Levofloxacin therapy in adults should only be used when the benefit outweighs the risk.

Nosocomial pneumonia	750 mg	7–14
Community-acquired pneumonia <sup>3</sup>	500 mg	7–14
Community-acquired pneumonia <sup>4</sup>	750 mg	5
Acute bacterial sinusitis	750 mg	5
Acute bacterial exacerbation of chronic bronchitis	500 mg	10-14
Acute bacterial exacerbation of chronic bronchitis	500 mg	7
Complicated skin and skin structure infections	750 mg	7–14
Uncomplicated skin and skin structure infections	500 mg	7–10
Chronic bacterial prostatitis	500 mg	28
cUTI or Acute Pyelonephritis (AP) <sup>5</sup>	750 mg	5
cUTI or Acute Pyelonephritis (AP) <sup>6</sup>	250 mg	10
Uncomplicated urinary tract infection	250 mg	3
Inhalational anthrax (post-exposure), adult and pediatric patients >50 kg and ≥6 months of age <sup>7,8</sup>	500 mg	60 <sup>8</sup>
Pediatric patients <50 kg and ≥ 6 months of age <sup>7,8</sup>	Table 2 below	60 <sup>8</sup>

### 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 <sup>1</sup>	Dose	Frequency Once Every	Duration <sup>2</sup>
<sup>1</sup> Due to <i>Bacillus anthracis</i> .			
<sup>3</sup> Drug administration should begin as soon as possible after suspected or confirmed exposure to aerosolized <i>Bacillus anthracis</i> . This indication is based on a surrogate endpoint. Levofloxacin plasma concentrations achieved in humans are reasonably likely to predict clinical benefit.			
<sup>4</sup> The safety of Levofloxacin in pediatric patients for duration 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. Prolonged Levofloxacin therapy should only be used when the benefit outweighs the risk.			
Inhalational anthrax (post-exposure) <sup>3,4</sup>			
Pediatric patients >50 kg and ≥6 months of age	500 mg	24 hours	60 days <sup>4</sup>
Pediatric patients <50 kg and ≥ 6 months of age	8 mg/kg (not to exceed 250 mg per dose)	12 hours	60 days <sup>4</sup>

### Dosage Adjustment in Adults with Renal Impairment

Administer Levofloxacin with caution in the presence of renal impairment. Careful clinical observation and appropriate laboratory studies should be performed prior to and during therapy since elimination of Levofloxacin may be reduced.

### Administration Instructions

#### Food and Levofloxacin Tablets

Levofloxacin tablets can be administered without regard to food.

### CONTRAINDICATIONS

Levofloxacin is contraindicated in individuals with a known hypersensitivity to Levofloxacin or other quinolone antibacterials.

### PACKAGING INFORMATION

**LEVERO-250** Tablets .....Blister pack of 10 Tablets  
**LEVERO-500** Tablets .....Blister pack of 10 Tablets  
**LEVERO-750** Tablets .....Blister pack of 10 Tablets