

# EVO<sup>®</sup>

Levofloxacin  
Tablet/Oral Solution

## Description

Levofloxacin is a synthetic, broad-spectrum antibacterial agent. Chemically Levofloxacin is a chiral fluorinated carboxyquinolone.

## Indications

- Acute maxillary sinusitis due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*.
- Acute bacterial exacerbation of chronic bronchitis due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae* or *Moraxella catarrhalis*.
- Nosocomial pneumonia due to methicillin-susceptible *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Serratia marcescens*, *Escherichia coli*, *Klebsiella pneumoniae*, *Haemophilus influenzae*, or *Streptococcus pneumoniae*.
- Community acquired pneumonia due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila* or *Mycoplasma pneumoniae*.
- Uncomplicated urinary tract infections due to *E. coli*, *Klebsiella pneumoniae* or *Staphylococcus saprophyticus*.
- Complicated urinary tract infections due to *Enterococcus faecalis*, *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, or *Pseudomonas aeruginosa*.
- Acute pyelonephritis caused by *E. coli*.
- Uncomplicated & complicated skin and skin structure infections including abscesses, cellulitis, furuncles, impetigo, and pyoderma, wound infections, due to *Staphylococcus aureus*, *Streptococcus pyogenes*, *Proteus mirabilis* or *Enterococcus faecalis*.
- Chronic bacterial prostatitis due to *Escherichia coli*, *Enterococcus faecalis*, or *Staphylococcus epidermidis*.

## Dosage and Administration

Acute sinusitis: 500 mg once daily for 10-14 days

Acute sinusitis: 750 mg once daily for 5 days

Exacerbation of chronic bronchitis: 500 mg once daily for 7 days

Community acquired pneumonia: 500 mg once daily for 7-14 days

Community acquired pneumonia: 750 mg once daily for 5 days

Nosocomial pneumonia: 750 mg once daily for 7-14 days

Uncomplicated urinary tract infections: 250 mg once daily for 3 days

Complicated urinary tract infections and acute pyelonephritis: 250 mg once daily for 10 days

Complicated urinary tract infections and acute pyelonephritis: 750 mg once daily for 5 days

Uncomplicated skin and skin structure infections: 500 mg once daily for 7-10 days

Complicated skin and skin structure infections: 750 mg once daily for 7-14 days

Chronic bacterial prostatitis: 500 mg once daily for 28 days

### **Contraindication**

Levofloxacin is contraindicated in patients with a history of hypersensitivity to Levofloxacin, quinolone antimicrobial agents, or any other components of this product.

### **Precautions**

The following measures should be taken during administration of Levofloxacin:

While taking Levofloxacin adequate amount of water should be drunk to avoid risk of crystalluria.

Dose adjustment should be exercised during Levofloxacin ingestion in presence of renal insufficiency & hepatic insufficiency.

### **Side Effects**

Levofloxacin is generally well tolerated. However, a few side effects can usually be seen. Side effects include: nausea, vomiting, diarrhoea, abdominal pain, flatulence and rare occurrence of phototoxicity (0.1%). Side effects that may be seen very rarely include tremors, depression, anxiety, confusion etc.

### **Use in Pregnancy & Lactation**

Levofloxacin is not recommended for use during pregnancy or nursing, as the effects on the unborn child or nursing infant are unknown.

#### **Use in Children**

From clinical studies, it is evident that Levofloxacin can be used in children aged as low as 6 months.

The usual dose for children in community acquired pneumonia (CAP) is Children aged 6 months to less than 5 years: 10 mg/kg b.i.d. (up to 500 mg per day) for 10 days.

Children aged 5 years to 16 years: 10 mg/kg q.d. (up to 500 mg per day) for 10 days.

The usual dose for children in recurrent or persistent Acute Otitis Media (AOM) is Children aged 6 months to less than 5 years: 10 mg/kg per day (maximum dose: 500 mg/day) given twice daily for 10 days.

### **Drug Interactions**

Antacids, Iron and Absorbents – reduce absorption of Levofloxacin

NSAIDs – may increase risk of CNS stimulation

Warfarin – may increase the risk of bleeding.

### **Overdosage**

Levofloxacin exhibits a low potential for acute toxicity. However, in the events of an acute overdosage, the stomach should be emptied. The patients should be kept under observation and appropriate hydration should be maintained.

### **Pharmaceutical Precaution and Storage condition**

Store in a cool & dry place, protected from light. Keep out of the reach of children.

### **Commercial Pack**

Evo® 250 Tablet: Box containing 30 tablets in 3x10's blister strips. Each film coated tablet contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 250 mg.

Evo® 500 Tablet: Box containing 20 tablets in 2x10's blister strips. Each film coated tablet contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 500 mg.

Evo® 750 Tablet: Box containing 10 tablets in 1x10's blister strip. Each film coated tablet contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 750 mg.

Evo® Oral Solution: Bottle contains 100 ml oral solution. Each 5 ml contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 125mg.

Manufactured by

Beximco Pharmaceuticals Ltd.

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