

*Only for the use of medical professionals*

# **Leflox<sup>®</sup>**

Levofloxacin

**Presentation:** Leflox<sup>®</sup> 500mg & 750mg Tablet: Light yellow colored, oval shaped, film coated tablets, one side engraved with 'ACI' and other side with a break-line; each tablet contains Levofloxacin Hemihydrate INN equivalent to Levofloxacin 500mg & 750mg respectively.

**Uses:** Leflox<sup>®</sup> is indicated for the treatment of adults (>16 years of age) with mild, moderate, and severe infections caused by susceptible strains of the designated micro-organisms in the condition listed below: Respiratory Tract Infections; 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*, or *Moraxella catarrhalis*. Community-acquired pneumonia due to *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae*. Urinary Tract Infections; Complicated urinary tract infections due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*. Acute pyelonephritis caused by *Escherichia coli*. Skin & Soft tissue Infections; Uncomplicated & complicated skin & skin structure infections including abscesses, cellulitis, furuncles, impetigo, Pyoderma, wound infections, due to *Staphylococcus aureus*, *Streptococcus pyogenes*, *Proteus mirabilis* or *Enterococcus faecalis*.

**Dosage and administration:** Acute sinusitis: 500 mg once daily 10-14 days, 750 mg once daily 5 days, Acute exacerbation of chronic bronchitis: 500 mg once daily 7 days, Severe COPD: 750 mg once daily 7 days, Mild to moderate COPD: 500 mg once daily 7 days, Community-acquired pneumonia: 500 mg once 7-14 days, 750 mg once daily 5 days, Complicated urinary tract infections or Acute pyelonephritis: 750 mg once daily 5 days, 250 mg once daily 10 days, Uncomplicated urinary-tract infections: 250 mg once daily 3 days, Uncomplicated skin and soft tissue infections: 500 mg once daily 7-10 days, Complicated skin and soft-tissue infections: 750 mg once daily 7-14 days.

**Contra-indications, warnings, etc.:** Contra-indication: Patients with a history of hypersensitivity to Leflox<sup>®</sup> other quinolones or any other components of this product. Precautions: Adequate amount of water should be drunk while taking Leflox<sup>®</sup> to avoid concentrated form of urine. In case of renal insufficiency; Dose adjustment should be exercised.

**Side-effects:** Leflox<sup>®</sup> is generally well tolerated. However, a few side effects can usually be seen. Side effects include: nausea, vomiting, diarrhea, 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:** Leflox<sup>®</sup> is not recommended for use during pregnancy and nursing, as the effects on the unborn child or nursing infant are unknown. Use in children: Not recommended for children. Drug interactions; Antacids, Iron and adsorbents-reduce absorption of Leflox<sup>®</sup>. NSAID may increase the risk of CNS stimulation. Warfarin may increase the

risk of bleeding.

**Overdosage:** Leflox® 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 precautions:** Store in a cool dry place. Protect from light.

**Package quantities:** Leflox® 500 tablet: Cartons of 20 tablets in strips.  
Leflox® 750 tablet: Cartons of 10 tablets in strips.

® Registered Trade Mark



**ACI Limited**