

**Composition : Levoflox-500** : Each film coated tablet contains Levofloxacin 500mg as Levofloxacin Hemihydrate USP.

**Levoflox-750** : Each film coated tablet contains Levofloxacin 750mg as Levofloxacin Hemihydrate USP.

**Pharmacology** : Levofloxacin is a member of the fluoroquinolone class of antibacterial agents. Levofloxacin is rapidly and essentially completely absorbed after oral administration. Peak plasma concentrations are usually attained one to two hours after oral dosing. Levofloxacin undergoes limited metabolism in humans and is primarily excreted as unchanged drug in the urine.

**Indications** : Levofloxacin is indicated for the treatment of mild, moderate, and severe infections caused by susceptible strains of the designated micro-organisms in the condition listed below: 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*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae*.

Uncomplicated & complicated urinary tract infections due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*. Acute pyelonephritis caused by *Escherichia coli*. Uncomplicated & complicated skin and soft tissue infections including abscesses, cellulitis, furuncles, impetigo, pyoderma, wound infections, due to *Staphylococcus aureus*, *Streptococcus pyogenes*, *Proteus mirabilis* or *Enterococcus faecalis*. Enteric infections caused by *Enterobacter sp.*, *Escherichia coli*, *Campylobacter sp.*, *Vibrio cholerae*, *Shigella sp.*, *Salmonella sp.*

**Dosage & administration** : Acute sinusitis: 500mg once daily for 10-14 days or 750mg once daily for 5 days. Exacerbation of chronic bronchitis: 500mg once daily for 7 days, or 750mg once daily for 3 days (Uncomplicated), 750mg once daily for 5 days (Complicated). Community-acquired pneumonia: 500mg once daily for 7-14 days, or 750mg once daily for 5 days. Uncomplicated urinary-tract infections: 250mg once daily for 3 days. Complicated urinary-tract infections and acute pyelonephritis: 250mg once daily for 7-10 days. Uncomplicated skin and soft-tissue infections: 500mg once daily for 7-10 days. Complicated skin and soft-tissue infections: 750mg once daily for 7-14 days. Enteric fever: 500mg once daily for 7-14 days. Diarrhea, cholera, shigellosis & enteritis: Mild to moderate case: 500mg (single dose), Moderate to severe case: 500mg once daily for 3 days. Or, as directed by the registered physician.

**LEVOFLOX**

Tablet



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

**Precautions** : The following measures should be taken during administration of Levofloxacin : While taking Levofloxacin, adequate amount of water should be taken. Dose adjustment should be exercised during Levofloxacin ingestion in presence of renal insufficiency.

**Side effects** : Levofloxacin 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 vary rarely include tremors, depression, anxiety, confusion etc.

**Use in pregnancy and lactation** : There are however, no adequate and well-controlled studies in pregnant women. Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It can be presumed that Levofloxacin will be excreted in human milk. Because of the potential for serious adverse reaction from Levofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

**Use in Child** : There is no data available.

**Drug interactions** : Antacids, Iron and Adsorbents : reduce absorption of Levofloxacin. NSAID : may increase the risk of CNS stimulation. Warfarin : may increase the risk of bleeding.

**Overdose** : Symptoms of overdose include ataxia, dyspnea, prostration, tremors and convulsions.

**Storage** : Store below 30°C in a dry place.

**Packing** : **Levoflox-500** : Each box contains 2 x 10's tablets in blister pack.

**Levoflox-750** : Each box contains 2 x 5's tablets in blister pack.