# Levomax®

Levofloxacin film coated tablet

## DESCRIPTION

**Levomax**® is a preparation of Levofloxacin. It is a synthetic, broad spectrum, third generation fluoroquinolone derivative antibacterial agent for oral administration. Chemically Levofloxacin is a chiral fluorinated carboxyquinolone.

## INDICATIONS

**Levomax**® is indicated for the treatment of following infections:

- Acute maxillary sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Community-acquired pneumonia
- Nosocomial pneumonia
- Complicated and uncomplicated urinary tract infections
- Acute pyelonephritis
- Chronic bacterial prostatitis
- Complicated and uncomplicated skin and soft tissue infections
- Typhoid fever

## DOSAGE AND ADMINISTRATION

**Levomax**® Dosing Guideline of patients with Normal Renal Function

| Indication | Due to | Dosing Regimen |
|---|---|---|
| Acute bacterial sinusitis | *S pneumoniae, H influenzae* or *M catarrhalis* | 750 mg/once daily/ 5 days<br>500 mg/once daily/ 10-14days |
| Acute bacterial exacerbation of chronic bronchitis | *Methicillin-susceptible S aureus, S pneumoniae, H influenzae, H parainfluenzae,* or *M catarrhalis* | 500 mg/once daily/ 7 days |
| Community-acquired pneumonia | *Methicillin-susceptible S aureus, S pneumoniae (including multidrugresistant S pneumoniae), H influenzae, H parainfluenzae, K pneumoniae, M catarrhalis, C pneumoniae, L pneumophila,* or *M pneumoniae* | 750 mg/once daily/ 5 days<br>500 mg/once daily/ 7-14 days |
| Nosocomial pneumonia | *Methicillin-susceptible S aureus, P aeruginosa, S marcescens, E coli, K pneumoniae, H influenzae,* or *S pneumoniae* | 750 mg/once daily/ 7-14 days |
| Uncomplicated urinary tract (mild to moderate) | *E coli, K pneumoniae,* or *S saprophyticus* | 250 mg/once daily/ 3 days |
| Complicated urinary tract (mild to moderate) | *E faecalis, E cloacae, E coli, K pneumoniae, P mirabilis,* or *P aeruginosa* | 750 mg/once daily/ 5 days<br>250 mg/once daily/ 10 days |
| Acute pyelonephritis | *E coli, including cases with concurrent bacteremia* | 750 mg/once daily/ 5 days<br>250 mg/once daily/ 10 days |
| Chronic bacterial prostatitis | *E coli, E faecalis,* or *methicillin-susceptible S epidermidis* | 500 mg/once daily/ 28 days |
| Uncomplicated skin and skin structure (mild to moderate) | *Methicillin-susceptible S aureus,* or *S pyogenes* | 500 mg/once daily/ 7-10 days |
| Complicated skin and skin structure | *Methicillin-susceptible S aureus, E faecalis, S pyogenes,* or *P mirabilis* | 750 mg/once daily/ 7-14 days |
| Typhoid fever | *Salmonella Typhi* | 500 mg/once daily/ 7-14 days |

**Levomax**® Dosing Guideline of Patients with Renal Impairment

| Dosage in Normal Renal Function Every 24 h | Creatinine Clearance 20 to 49 mL/min | Creatinine Clearance 10 to 19 mL/min | Hemodialysis or Chronic Ambulatory Peritoneal Dialysis (CAPD) |
|---|---|---|---|
| 750 mg | 750 mg every 48 h | 750 mg initial dose, then 500 mg every 48 h | 750 mg initial dose, then 500 mg every 48 h |
| 500 mg | 500 mg initial dose, then 250 mg every 24 h | 500 mg initial dose, then 250 mg every 48 h | 500 mg initial dose, then 250 mg every 48 h |

## CONTRAINDICATION

**Levomax**® is contraindicated in patients with a history of hypersensitivity to Levofloxacin or other quinolone antimicrobial agents.

## WARNINGS

The safety and efficacy of Levofloxacin in paediatric patients, adolescents (under the age of 18 years), pregnant women and nursing mothers have not been established.

## PRECAUTIONS

Levofloxacin should be used with caution in the presence of renal insufficiency. In patients with impaired renal function (creatinine clearance <50ml/min), adjustment of the dosage is necessary to avoid the accumulation of Levofloxacin due to decreased clearance.

## USE IN PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant women. **Levomax**® should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. Levofloxacin has not been measured in human milk. Because of the potential for serious adverse reactions from Levofloxacin in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the benefit of the drug to the mother.

## SIDE-EFFECTS

Serious and occasionally fatal hypersensitivity and anaphylactic reactions have been reported in patients receiving therapy with quinolones, including Levofloxacin. These reactions often occur following the first dose. Some reactions have been accompanied by cardiovascular collapse, hypotension, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat or facial edema), airway obstruction (including bronchospasm, shortness of breath, and acute respiratory distress), dyspnea, tinnitus, urticaria, tremor, vertigo, itching and abnormal hepatic function.

## PHARMACEUTICAL PRECAUTION

Keep away from light & moisture. Keep out of reach of children.

## PACKAGING

**Levomax**® 500 mg tablet : Box containing 2 strips of 10 tablets each. Each film coated tablet contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 500 mg.

**Levomax**® 750 mg tablet : Box containing 1 strip of 10 tablets . Each film coated tablet contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 750 mg.

SK+F
Manufactured by
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