

Trevox[®]

Levofloxacin

COMPOSITION

Trevox[®] 500: Each film coated tablet contains Levofloxacin USP 500 mg as Levofloxacin Hemihydrate.

Trevox[®] 750: Each film coated tablet contains Levofloxacin USP 750 mg as Levofloxacin Hemihydrate.

Trevox[®] Oral Solution: Each 5 ml oral solution contains Levofloxacin USP 125 mg as Levofloxacin Hemihydrate.

PHARMACOLOGY

Levofloxacin is a synthetic, broad-spectrum, third generation fluoroquinolone derivative antibacterial drug for oral administration. Chemically Levofloxacin is a chiral fluorinated carboxyquinolone.

INDICATION

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 cararrhalis*, *Chlamydia pneumoniae*, *Legionella pneumophila*, or *Mycoplasma pneumoniae*
- Nosocomial Pneumonia
- Complicated urinary tract infections due to *Escherichia coli*, *Klebsiella pneumoniae*, or *Staphylococcus saprophyticus*.
- Uncomplicated UTI
- Acute pyelonephritis caused by *Escherichia coli*
- Chronic bacterial prostatitis
- 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*

DOSAGE AND ADMINISTRATION

- Acute sinusitis, 500 mg once daily for 10-14 days
- Exacerbation of chronic bronchitis, 250-500 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
- Complicated urinary-tract infections and acute pyelonephritis, 250 mg daily for 7-10 days
- Uncomplicated UTI, 250 mg once daily for 3 days
- Pyelonephritis, 250 mg once daily for 10 days
- Chronic bacterial prostatitis, 500 mg once daily for 28 days
- Uncomplicated skin and soft-tissue infections, 500 mg once daily for 7-10 days
- Complicated skin and soft-tissue infections, 750 mg once daily for 7-14 days

Children dosage:

Children 6 months to <5 years: 10 mg/kg every 24 hours

Children > 5 years: 20 mg/kg every 24 hours

CONTRAINDICATION & PRECAUTION

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

The following measures should be taken during administration of Levofloxacin:

- While taking Levofloxacin, adequate amount of water should be taken to avoid concentrated form of urine.
- Levofloxacin oral solution should be taken 1 hr before or 2 hr after eating
- Dose adjustment should be exercised during Levofloxacin ingestion in presence of renal insufficiency.

SIDE EFFECT

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 very rarely include tremors, depression, anxiety, confusion etc.

DRUG INTERACTION

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

ADVERSE DRUG REACTION

Risk of Retinal detachment.

USE IN PREGNANCY AND LACTATION

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

STORAGE CONDITION

Keep away from light and moisture, store below 30⁰ C. Keep away from the reach of children.

HOW SUPPLIED

Trevox[®] 500: Box contains 30 tablets in blister pack.

Trevox[®] 750: Box contains 20 tablets in blister pack.

Trevox[®] Oral Solution: Each bottle contains 100 ml oral solution and a measuring cup.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH