

#### COMPOSITION:

Levo 500 Tablet: Each film coated tablet contains Levofloxacin INN 500 mg as Levofloxacin Hemihydrate.

#### PHARMACOLOGY:

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

#### INDICATIONS:

Levofloxacin is indicated for the treatment of adults (18 years of age) with 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, or Moraxella catarrhalis, Chlamydia 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 urinary tract infections. Acute pyelonephritis caused by Escherichia coli. Bacterial prostatitis. Uncomplicated & complicated skin and soft tissue infections (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 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, Acute pyelonephritis caused by Escherichia coli, 250 mg daily for 10 days, Bacterial prostatitis, 500 mg once daily for 28 days, Uncomplicated skin and soft-tissue infections, 250 mg once daily for 7-10 days, Complicated skin and soft-tissue infections, 750 mg once daily for 7-14 days.

## CONTRAINDICATION AND PRECAUTION:

Levofloxacin is contraindicated in patients with a history of hypersensitivity to Levofloxacin, quinolone 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. Take levofloxacin oral solution at least 1 hour before or 2 hours after a meal. Dose adjustment should be exercised during Levofloxacin administration 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 very rarely include tremors, depression, anxiety, confusion etc.

## DRUG INTERACTION:

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

# USE IN PREGNANCY AND 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:

Not recommended for children.

## HOW SUPPLIED:

Levo 500 mg tablet: Box contains 2 x 3 tablets in alu pvc blister strip.

Manufactured by:

