

# Orgalev™

Levofloxacin

## PRESENTATION:

**Orgalev™ 500 Tablet:** Each film coated tablet contains Levofloxacin Hemihydrate INN equivalent to Levofloxacin 500 mg.

## 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 microorganism 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*, *Klebsiella pneumoniae* or *Mycoplasma pneumoniae*.
- 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*.

## 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 or twice daily for 7-14 days
- Complicated urinary tract infections and acute pyelonephritis, 250 mg daily for 7-14 days
- Complicated skin and soft tissue infections, 750 mg daily for 7-14 days
- Uncomplicated skin and soft tissue infections, 500 mg once daily for 7-10 days

## CONTRAINDICATIONS:

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

## PRECAUTIONS:

The following measures should be taken during administration of Levofloxacin.

While taking Levofloxacin adequate amount of water should be drunk to avoid concentrated form of urine. 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 very rarely include tremor, depression, anxiety, confusion etc.

### Risk of retinal detachment.

## USE IN PREGNANCY & LACTATION:

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

## DRUG INTERACTIONS:

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

## OVERDOSE:

Levofloxacin exhibits a low potential for acute toxicity. However, in the events of acute overdose, the stomach should be emptied. The patients should be kept under observation and appropriate hydration should be maintained.

## STORAGE:

Store in a cool and dry place, protected from light. Keep all medicine out of reach of children.

## PACKING:

**Orgalev™ 500 Tablet:** Each box containing 30's tablets in blister strip.

*Manufactured by:*

**Organic Health Care Ltd.**  
Gazipur, Bangladesh.

