Trevox® 500 IV

Levofloxacin 0.5% w/v

COMPOSITION

Trevox® 500 IV : Each 100 ml solution contains Levofloxacin 500 mg as Levofloxacin Hemihydrate INN.

PHARMACOLOGY

Levofloxacin is a synthetic, broad-spectrum, third generation fluoroquinolone derivative antibacterial agent for oral and intravenous administration. Chemically Levofloxacin is a chiral fluorinated carboxyquinolone. The mechanism of action of Levofloxacin involves inhibition of bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerases), enzymes required for DNA replication, transcription, repair and recombination.

INDICATION

Levofloxacin infusion is indicated for the treatment of mild, moderate and severe infections caused by susceptible strains of the designated microorganisms in the conditions listed below-

- Pneumonia: Nosocomial and community acquired
- Acute bacterial sinusitis
- Acute bacterial exacerbation of chronic bronchitis
- Skin and skin structure infections: Complicated and uncomplicated
- Chronic bacterial prostatitis
- Urinary tract infections: Complicated and uncomplicated
- Acute pyelonephritis
- Inhalational anthrax, post-exposure (not tested in humans for post-exposure prevention of inhalational anthrax; plasma concentrations are likely to predict efficacy).

DOSAGE AND ADMINISTRATION

The usual dose of Levofloxacin infusion is 250 mg or 500 mg administered by slow intravenous infusion over 60 minutes every 24 hours or 750 mg administered by slow infusion over 90 minutes every 24 hours. Because the **Trevox**® 500 IV is for single-use only, any unused portion should be discarded.

Type of Infection	Dose Every 24 hours	Duration (days)
Nosocomial Pneumonia	750 mg	7-14
Community Acquired Pneumonia	500 mg or 750 mg	7-14 or 5
Acute Bacterial Sinusitis	500 mg or 750 mg	7-14 or 5
Acute Bacterial Exacerbation of Chronic Bronchitis	500 mg	7
Complicated Skin and Skin Structure Infections	750 mg	7-14
Uncomplicated Skin and Skin Structure Infections	500 mg	7-10
Chronic Bacterial Prostatitis	500 mg	28
Complicated Urinary Tract Infection or Acute Pyelonephritis	250 mg or 750 mg	10 or 5
Uncomplicated Urinary Tract Infection	250 mg	3

In each case, sequential therapy (intravenous to oral) may be instituted at the discretion of the physician.

USE IN PREGNANCY AND LACTATION

There are 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. Based on data on other fluoroquinolones and very limited data on Levofloxacin, it can be presumed that Levofloxacin will be excreted 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 importance of the drug to the mother.

SIDE EFFECT

Levofloxacin is generally well tolerated. However few side effects can usually be seen. Common (>1%) side effects include headache, nausea, vomiting, diarrhea, constipation, abdominal pain, dyspepsia, edema and injection site reaction. Less common (0.1 to 1%) side effects include allergic reaction, hyperglycemia, hypoglycemia, anxiety, agitation, tremor, palpitation, abnormal hepatic function, tendonitis etc.

CONTRAINDICATION

Levofloxacin is contraindicated in persons with known hypersensitivity to Levofloxacin or other quinolone antibacterials.

DRUG INTERACTION

There are no data concerning an interaction of intravenous fluoroquinolones with oral antacids, sucralfate, multivitamins, didanosine, or metal cations. However, no fluoroquinolone should be co-administered with any solution containing multivalent cations, e.g., magnesium, through the same intravenous line. Levofloxacin may enhance the effect of warfarin. Elevations of the prothrombin time in the setting of concurrent warfarin and Levofloxacin use have been associated with episodes of bleeding. Disturbances of blood glucose, including hyperglycemia and hypoglycemia, have been reported in patients treated concomitantly with fluoroquinolones and an anti-diabetic agent. The concomitant administration of a non-steroidal anti-inflammatory drug with a fluoroquinolone, including Levofloxacin, may increase the risk of CNS stimulation and convulsive seizures.

PRECAUTION

Trevox® 500 IV should be administered by slow infusion over a period of 60 minutes. Local IV site reactions have been reported with the intravenous administration of levofloxacin. These reactions are more frequent if infusion time is 30 minutes or less or if small veins of the hand are used.

INSTRUCTION FOR THE USE OF Trevox® 500 IV

1. Check the bottle for minute leaks by squeezing the bottle firmly. If leaks are found, or if seal is not intact, discard the solution.
2. Do not use if the solution is cloudy or a precipitate is present.
3. Do not use in series connections.
4. Close flow control clamp of administration set.
5. Insert piercing pin of administration set into port with a twisting motion until the pin is firmly seated.
6. Suspend bottle from hanger.
7. Squeeze and release drip chamber to establish proper fluid level in chamber during infusion of **Trevox**® 500 IV.
8. Open flow control clamp to expel air from set. Close clamp.
9. Regulate the rate of administration with flow control clamp.

STORAGE

Store below 25° C and protect from light. Avoid extreme heat and freezing. Keep out of reach of children.

HOW SUPPLIED

Trevox® 500 IV: Each box contains 1 bottle of 100 ml of Levofloxacin solution for intravenous infusion.

Manufactured by
SQUARE
PHARMACEUTICALS LTD.
Kaliakoir, Bangladesh