



Levofloxacin USP 1.5%

# COMPOSITION

Trevox® Ear Drops: Each ml contains Levofloxacin Hemihydrate USP equivalent to Levofloxacin 15 mg.

### PHARMACOLOGY

Levofloxacin is a synthetic, broad-spectrum, third generation fluoroquinolone antibacterial agent. It works by the inhibition of bacterial topoisomerase IV and DNA gyrase enzymes required for DNA replication, transcription, repair and recombination.

#### INDICATION

This drug is indicated for the treatment of Otitis externa, otitis media caused by susceptible strains of the following bacteria: Staphylococcus, Streptococcus, Pneumococcus, Moraxella (Branhamella) catarrhalis, Klebsiellapneumoniae, Enterobacter, Serratia, Haemophilus influenzae, Pseudomonas aeruginosa, Acinetobacter.

### DOSAGE AND ADMINISTRATION

The usual dosage is 6 to 10 drops in the ear twice a day. After applying the ear drops, perform an ear bath for about 10 minutes. The number of doses may be increased or decreased as appropriate depending on the symptoms.

#### CONTRAINDICATION

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

### **DRUG INTERACTION**

Sucralfate, didanosine, multivitamins, antacids, or other drugs or supplements that contain magnesium, aluminum, iron, or zinc may reduce levels of levofloxacin.

### SIDE EFFECTS

Fungal otitis externa, vertigo, dizziness, diarrhoea, ear pain to the administration site are the common side effects that may occur.

## **PRECAUTION & WARNINGS**

As a guideline, administration is for 4 weeks, and continued administration thereafter should be done carefully to prevent the development of fungi and the development of bacterial resistance due to long-term administration, so as not to administer the drug carelessly.

#### **OVER DOSE**

Levofloxacin overdose may cause severe dizziness, liver problems, including hepatitis.

# PREGNANCY AND LACTATION

It should be administered to pregnant or potentially pregnant women and during lactation only if the therapeutic benefit outweighs the risk.

#### Storage

Protect from light. Store below 30° C. Keep out of reach of children.

# How supplied

Trevox® Ear Drops: Each Plastic dropper bottle contains 10 ml of Levofloxacin otic solution.

