SANOLEVOX

LEVOFLOXACIN AS (HEMIHYDRATE)

OPHTHALMIC SOLUTION 1.5%

1- DESCRIPTION

Sanolevox (levofloxacin ophthalmic solution) 1.5% is a sterile topical ophthalmic solution. Levofloxacin is a fluoroquinolone antibacterial active against a broad spectrum of Gram-positive and Gram-negative ocular pathogens.

Contains:

Active Ingredients:

Levofloxacin hemihydrate 15.36 mg/ml equivalent to 15 mg levofloxacin.

Inactive Ingredients:

PEG, propylene glycol , Sodium Chloride, Citric acid anhydrous, sodium hydroxide /HCL As PH Adjusting ,Water for injection.

2- CLINICAL PHARMACOLOGY

1- Mechanism of Action

Levofloxacin is a member of the fluoroquinolone class of anti-microbial drug .

2- Pharmacokinetics

Levofloxacin concentration in plasma was measured in 14 healthy adult volunteers during a 16 day course of treatment with Sanolevox solution. The dosing schedule was 1-2 drops per eye once in the morning on Days 1 and 16; 1-2 drops per eye every two hours Days 2 through 8; and 1-2 drops per eye every four hours Days 9 through 15. The mean levofloxacin concentration in plasma 1 hour post dose ranged from 3.13 ng/mL on Day 1 to 10.4 ng/mL on Day 16.

Maximum mean levofloxacin concentrations increased from 3.22 ng/mL on Day 1 to 10.9 ng/mL on Day 16, which is more than 400 times lower than those reported after standard oral doses of levofloxacin.

Levofloxacin concentration in tears was measured in 100 healthy adult volunteers at various time points following instillation of 2 drops of Sanolevox solution. Mean tear concentration measured 15 minutes after instillation was 757 mcg/mL.

3- INDICATIONS AND USAGE

Sanolevox solution is indicated for the treatment of corneal ulcer caused by susceptible strains of the following bacteria:

GRAM-POSITIVE BACTERIA:

*Efficacy for this organism was studied in fewer than 10 infections.

Corynebacterium species*

Staphylococcus aureus

Staphylococcus epidermidis
Streptococcus pneumoniae
Viridans group streptococci*

GRAM-NEGATIVE BACTERIA:
Pseudomonas aeruginosa
Serratia marcescens*

*Efficacy for this organism was studied in fewer than 10 infections

4- DOSAGE AND ADMINSTRATION

Days 1 through 3:
Instill one to two d rops in the affected eye(s) every 30 minutes to 2 hours while awake and approximately 4 and 6 hours after retiring.
Day 4 through treatment completion:
Instill one to two drops in the affected eye(s) every 1 to 4 hours while awake.

5- DOSAGE FORMS AND STRENGTHS

Bottle filled with 5 mL sterile ophthalmic solution of levofloxacin, 1.5%.

6- CONTRAINDICATION:

Sanolevox solution is contraindicated in patients with a history of hypersensitivity to levofloxacin, to other quinolones, or to any of the components in this medication.

7- WARNINGS AND PRECAUTIONS:

1- Hypersensitivity Reactions

In patients receiving systemically administered quinolones, including levofloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported, some following the first dose. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, angioedema, (including laryngeal, pharyngeal or facial edema), airway obstruction, dyspnea, urticaria and itching. If an allergic reaction to levofloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

2- Growth of Resistant Organisms with Prolonged Use

As with other anti-infectives, prolonged use may result in overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue use and institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy, and where appropriate, fluorescein staining.

3- Avoidance of Contact Lens Wear

Patients should be advised not to wear contact lenses if they have signs and symptoms of corneal ulcer.

8- PATIENT COUNSELING INFORMATION

1- Avoid Contamination of the Product

Advise patients to avoid contaminating the applicator tip with material from the eye, finger, or
other source.

2- Avoid Contact Lens Wear

Advise patients not to wear contact lenses if they have signs and symptoms of corneal ulcer.

3- Hypersensitivity Reactions Systemically administered quinolones, including levofloxacin, have been associated with hypersensitivity reactions, even following a single dose. Advise patients to discontinue use immediately and contact their physician at the first sign of a rash or allergic reactions.

9- ADVERSE REACTIONS:

The most frequently reported adverse events in the overall study population were headache and a taste disturbance following instillation. These events occurred in approximately 8-10% of patients. Adverse events occurring in approximately 1-2% of patients included decreased/blurred vision, diarrhea,dyspepsia, fever, infection, instillation site irritation/discomfort, ocular infection, nausea, ocular pain/discomfort, and throat irritation.Other reported ocular reactions occurring in less than 1% of patients included chemosis, corneal erosion,corneal ulcer, diplopia, floaters, hyperemia, lid edema, and lid erythema.

10- USE IN SPECIFIC POPULATIONS

1- Pregnancy

Pregnancy Category C Teratogenic Effects: Levofloxacin at oral doses of 810 mg/kg/day in rats caused decreased fetal body weight and increased fetal mortality. No teratogenic effect was observed when rabbits were dosed orally as high as 50 mg/kg/day, at which systemic exposure was estimated to be 250 times that observed at the maximum recommended human ophthalmic dose, or when dosed intravenously as high as 25 mg/kg/day, at which systemic exposure was estimated to be 120 times that observed at the maximum recommended human ophthalmic dose.

There are, however, 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.

2- Nursing Mothers Levofloxacin has not been measured in human milk. Based on data from ofloxacin, it can be presumed that levofloxacin is excreted in human milk. Caution should be exercised when Sanolevox is administered to a nursing mother.

3- Pediatric Use Safety and effectiveness in children below the age of six years have not been established. Oral administration of systemic quinolones has been shown to cause arthropathy in immature animals. There is no evidence that the ophthalmic administration of levofloxacin has any effect on weight bearing joints.

4- Geriatric Use No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

11- HOW SUPPLIED/STORAGE HANDLING

Sanolevox (levofloxacin ophthalmic solution) 1.5% is supplied in carton box contains sterile opaque white LDPE plastic bottle contains 5ml solution with HDPE nozzle and white PP plastic cap +insert leaflet .

Storage: Store not exceed than 30^{o}c and be use after opening for just 30 days at room temperature under protection from light.

Shelf life : 2 years .

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