

FARMOX Eye Drops

Moxifloxacin 0.5%

فارموکس
آنکھوں کے لئے قطرے جراثیم سے پاک

STERILE OPHTHALMIC SOLUTION

Composition:

Each ml contains:

Moxifloxacin (as Moxifloxacin HCl).....5.0mg

DESCRIPTION:

Farmox (Moxifloxacin Ophthalmic Solution 0.5%) is a sterile topical ophthalmic solution. Moxifloxacin is a 4th Generation fluoroquinolone antibacterial; active against a broad spectrum of Gram-positive & Gram-negative ocular pathogens it is more soluble in water at natural pH. The pH is approx. 6.8.

Each ml of Farmox ophthalmic solution contains: Moxifloxacin Methyl Cellulose, Sodium Chloride, and Purified Water. This product is self preserved.

Action:

Moxifloxacin inhibits bacterial topoisomerase IV and DNA gyrase (both of which are type II topoisomerase). Enzymes required for DNA replication, transcription, repair & recombination. On the basis of different chemical structure & mode of action from Beta lactam antibiotic & amino glycosides it may be active against bacterial resistant to Beta lactate and amino glycosides. Moxifloxacin has been shown to be active against most strains of the following microorganism, both in vitro and in clinical infections.

Gram-Positive microorganism

- Corynebacterium species
- Microbacterium species
- Staphylococcus aureus
- Staphylococcus epidermidis
- Staphylococcus haemolyticus
- Micrococcus luteus
- Staphylococcus pneumonia
- Staphylococcus viridians

Gram-Negative microorganism

- Acinetobacter species
- Haemophilus influenza
- Klebsiella pneumonia
- Moraxella catarrhalis
- Pseudomonas aeruginosa

Other Microorganism

- Acinetobacter species

Indications & Usage:

Farmox ophthalmic solution is indicated for the treatment of bacterial infections caused by the susceptible strains of the above mentioned organisms.

Contra-Indications:

Farmox ophthalmic solution is contra-indicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

In patients a receiving systemic quinolones, serious & 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 & itching. If an allergic reaction to moxifloxacin occurs, discontinue the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment Oxygen and airway management should be administered as clinically indicated.

Precautions

As with other anti-infectives, prolonged use may result in overgrowth of non —susceptible organism, including fungi. If super infection occurs, discontinue use & institute alternative therapy. Whenever clinical judgment dictates, the patient should be examined with the aid of magnification, such as slit-lamp bio-microscopy & where appropriate, Fluorescein staining. Patients should be advised not to wear contact lenses if they have signs & symptoms of bacterial infection.

To keep medicine as germ free as possible, do not touch the applicator tip to any surface (including eye).

Drug interactions:

Systemic administration of some quinolones has been shown to elevate plasma concentrations of theophylline, interfere with the metabolism of caffeine & enhance the effects of the oral anti coagulant warfarin & its derivatives & has been associated with transient elevations in serum creatinine in patients receiving systemic cyclosporine concomitantly.

Use in Pregnancy:

There are no adequate & well controlled studies in pregnant women. Moxifloxacin should be used during pregnancy only if the potential benefits the potential risk to the fetus.

Nursing Mothers:

Moxifloxacin has not been measured in human milk. Based upon data from ofloxacin, it can be presumed that Moxifloxacin is excreted in human milk. Caution should be exercised when Moxifloxacin is administered to a nursing mother.

Pediatric use:

Moxifloxacin has been shown to be safe & effective in pediatric patients including neonate, despite of that oral administration of quinolones has been shown to cause arthropathy in immature animals, there is no evidence that the ophthalmic administration of Moxifloxacin has any effect on weight bearing joints.

Geriatric use:

No overall differences in safety or effectiveness have been observed between elderly & other adult patients.

Adverse Reactions:

The most frequently reported adverse events in the overall study population were transient decreased vision, fever, foreign body sensation, headache, transient ocular burning, ocular pain or discomfort pharyngitis & photophobia. Other reported reactions occurring in less than 1% of patients included allergic reactions, lid edema ocular dryness & ocular itching.

Dosage & administration:

For Adult & Children one year of age: 1 - 2 drops in the affected eye(s) three to four times a day for 7 — 14 days. For Children up to 1 year of age: Use & dose must be determined by the doctor.

Storage:

Store between 15 to 25°C. Protect from light. Keep all medicines out of the reach of children.

Presentation:

Farmox is available 5ml sterile ophthalmic solution in plastic dropper bottles.

مقدار اور طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق۔ ۱۵ سے ۲۵ ڈگری سینٹی گریڈ کے درمیان رکھیں۔

روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

بوتل کھولنے کے بعد ۳ دن سے زائد استعمال نہ کریں۔

Manufactured by:

Elko Organization (Pvt.) Ltd.
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Karachi, Pakistan.



MARKETED BY:
LUMEN
PHARMA
Karachi-Pakistan.