

EYEMOX

(Moxifloxacin HCl)

Sterile Ophthalmic Solution 0.5%

COMPOSITION:

Each ml contains:
Moxifloxacin Hydrochloride equivalent to Moxifloxacin 5mg.
USP Specifications

DESCRIPTION:

Eyemox (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 and Gram-negative ocular pathogens.

ACTION:

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

Gram-positive microorganisms

- Corynebacterium species
- Microbacterium species
- Staphylococcus aureus
- Staphylococcus epidermidis
- Staphylococcus haemolyticus
- Micrococcus luteus
- Staphylococcus pneumoniae
- Staphylococcus viridans

Gram-negative microorganisms

- Acinetobacter Species
- Haemophilus influenzae
- Klebsiella pneumoniae
- Moraxella catarrhalis.
- Pseudomonas aeruginosa.

Other Microorganism

- Chlamydia trachomatis.

INDICATIONS & USAGE:

Eyemox Ophthalmic Solution is indicated for the treatment of bacterial infections caused by the susceptible strains of the above-mentioned organisms.

CONTRA-INDICATIONS:

Eyemox 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 receiving systemic quinolones, 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 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 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 bio-microscopy and where appropriate, Fluorescein staining.

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

To keep medicine as germ free as possible, do not touch the dropper 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, and enhance the effects of the oral anti coagulant warfarin and its derivatives, and has been associated with transient increase in serum creatinine in patients receiving systemic cyclosporin concomitantly.

USE IN PREGNANCY:

There are no adequate and well-controlled studies in pregnant women. Moxifloxacin should be used during pregnancy only if the potential benefit justifies 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 neonates. 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 and younger patients.

ADVERSE REACTIONS:

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

DOSAGE & ADMINISTRATION:

Instill one drop in the affected eye(s) three times a day for 7 days.

PRESENTATION:

Pack of 5ml in sterile Dropper Bottle.

STORAGE AND PRECAUTIONS:

Store below 30°C.

Protect from heat and sunlight.

Keep out of the reach of children.

Use the solution within four weeks after first opening the bottle

خوراک: ڈاکٹر کی ہدایات کی مطابق استعمال کریں۔

ہدایات: دو کو دو چھپ اور گرمی سے بچائیں۔

• ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

تمام ادویات بچوں کی پہنچ سے دور رکھیں۔

بہلی دفعہ بوتل کھولنے کے بعد دو کو چار ہفتوں تک استعمال کیا جاسکتا ہے۔



Manufactured by:

Vega Pharmaceuticals (Pvt.) Ltd.

30 Km, Multan Road, Lahore, Pakistan.