For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

MOXIFLOXACIN EYE DROPS IP 0.5% w/v. (Viscosity not less than 250 centipoise)

MOXIEYE™ GEL

COMPOSITION
Each ml contains: Moxifloxacin Hydrochloride IP
Equivalent to Moxifloxacin ..... 0.5% w/v
Sterile Aqueous Base ..... q.s.
Viscosity not less than 250 centipoise

PRESERVATIVE : Product is self preserved.

ACTIVE INGREDIENT : Moxifloxacin.

DESCRIPTION : Moxifloxacin is a fourth-generation 8-methoxy fluoroquinolone antibacterial agent having a broad-spectrum activity with enhanced Gram-positive coverage, maintain Gram-negative activity and also active against a typical microorganisms, Mycobacterium and anaerobes.
The bactericidal action of Moxifloxacin results from inhibition of enzymes DNA gyrase and topoisomerase IV required for bacterial DNA replication, transcription, repair and recombination.
Moxifloxacin has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections as described below

Aerobic Gram-positive microorganisms : Corynebacterium species
Micrococcus luteus*, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri*, Staphylococcus pneumoniae, Staphylococcus viridans group.

Aerobic Gram-Negative microorganisms : Acinetobacter iwoffii*, Haemophilus influenzae, Haemophilus parainfluenzae.

Other microorganisms : Chlamydia trachomatis
*Efficacy for this organism was studied in fewer than 10 infections.

INDICATIONS : Moxieye Gel is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains and post-operative prophylaxis from susceptible strains.

DOSAGE AND ADMINISTRATION : Instill one drop in the affected eye 3 times a day for 7 days or as directed by the ophthalmologist. Moxieye Gel being a viscous liquid is retained on the ocular surface for a longer time, therefore the dosage may be determined by the ophthalmologist, after assessing the therapeutic response and condition of the patient.

CONTRAINDICATIONS : Moxieye Gel is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medication.

WARNING AND PRECAUTIONS : NOT FOR INJECTION.
In patients receiving systemically administered quinolones, including moxifloxacin, 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 use of the drug. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

DRUGS INTERACTIONS : Drug interaction studies have not been conducted with moxifloxacin solution. In vitro studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19 or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drugs metabolized by these cytochrome P450 isoenzymes.

PREGNANCY

Pregnancy Category C : Since there are no adequate and well-controlled studies in pregnant women, moxifloxacin solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

LACTATION : Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercised when moxifloxacin solution is administered to nursing mothers.

PAEDIATRIC USE : The safety and effectiveness of Moxieye Gel solution in infants below 1 year of age have not been established. There is no evidence that the ophthalmic administration of Moxieye Gel has any effect on weight bearing joints.

GERIATRIC USE : No overall difference in safety and effectiveness have been observed between elderly and younger patients.

SIDE EFFECTS : The most frequently reported ocular side effects were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occurred in approximately 1-6% of patients.
Nonocular adverse events reported at a rate of 1-4% were fever, increased cough, infection, otitis media, pharyngitis, rash, and rhinitis.

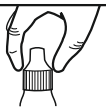
OVERDOSAGE : A topical overdose may be flushed from the eyes with warm tap water.

PRESENTATION : Moxieye Gel solution having visosity not less than 250 centipoise in a container of 5 ml.

STORAGE : Store in cool & dry place. Protect from light. Use the solution within one month after opening the container. For external use only.

MEDICINE : Keep out of reach of children.

INSTRUCTIONS FOR USE

fig. 1	fig. 2	fig. 3
		
Rotate cap anticlockwise to break the seal.	The vial is now ready for use; turn it up side down. Squeeze the walls of the vial gently to deliver sterile drop into the eye.	Replace the cap. Tighten it firmly and keep the vial closed for subsequent use.
fig. 4	fig. 5	fig. 6
		
Do not touch the nozzle.	Do not rinse the nozzle.	Do not expose to Sunlight.

State of the art technology from EYEKARE KILITCH LTD.

TM Trade Mark applied for

EyeKare
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Marketed by:
EYEKARE KILITCH LTD.
902-B, Godrej Coliseum,
Sion (E), Mumbai - 400 022.

Manufactured in India by:
KH KILITCH HEALTHCARE LLP
At: R-905, T.T.C. Industrial Area, M.I.D.C.,
Rabale, Navi Mumbai - 400 701.

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