EyeKare KH

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

MOXIEYE-K™

Preservative Free

Moxifloxacin & Ketorolac Tromethamine Ophthalmic Solution

COMPOSITION

Moxifloxacin Hydrochloride IP equivalent to Moxifloxacin 0.5% w/v, Ketorolac Tromethamine IP 0.5% w/v, Water for Injections IP q.s

It contains HPMC solution as lubricant

DOSAGE FORM : Ophthalmic Solution.

DESCRIPTION : MOXIEYE-K is a sterile multidose topical anti-inflammatory NSAID and antibiotic combination for ophthalmic use. MOXIEYE-K contains Moxifloxacin HCl 0.5% w/v and Ketorolac Tromethamine 0.5% w/v.

Moxifloxacin is an 8-methoxy fluoroquinolone anti-infective for topical ophthalmic use.

Ketorolac is a member of the pyrrolopurrole group of nonsteroidal anti-inflammatory drugs (NSAIDS).

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.

PHARMACOLOGY

Moxifloxacin:

Microbiology : The antibacterial action of moxifloxacin results inhibition of the Topoisomerase II (DNA gyrase) and topoisomerase IV. DNA gyrase is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA. Topoisomerase IV is an enzyme known to play a key role in the partitioning of the chromosomal DNA during bacterial cell division. Cross resistance has been observed between systemic moxifloxacin and some other quinolones. *In vitro* resistance to moxifloxacin develops via multiple-step mutations.

Moxifloxacin has been shown to be active against most strains of the following microorganisms.

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

Aerobic Gram-negative microorganisms:
Acinetobacter lwoffii
Haemophilus influenzae
Haemophilus parainfluenzae

Other microorganisms:
Chlamydia trachomatis

Ketorolac Tromethamine : Ketorolac Tromethamine is a nonsteroidal anti-inflammatory drug which, when administered systemically, has demonstrated analgesic, anti-inflammatory, and antipyretic activity. The mechanism of its action is thought to be due to its ability to inhibit prostaglandin biosynthesis. Prostaglandins have been shown in many animal models to be mediators of certain kinds of intraocular inflammation. In studies performed in animal eyes, prostaglandins have been shown to produce disruption of the blood-aqueous humor barrier, vasodiliation, increased vascular permeability, leukocytosis, and increased intraocular pressure.
Prostaglandins also appear to play a role in the miotic response produced during ocular surgery by constricting the iris sphincter independently of cholinergic mechanisms. Ocular administration of ketorolac tromethamine reduces, Prostaglandin E2 (PGE2) levels in aqueous humor.

INDICATIONS:

- NSAID responsive inflammatory ocular conditions for which a NSAID is indicated and where superficial bacterial ocular infection or the risk of bacterial ocular infection exists and where the inherent risk of NSAID use in certain infective conjunctivitis is accepted to obtain a diminution in edema and inflammation.
- Topical NSAID like ketorolac tromethamine is indicated for the treatment of postoperactive inflammation in patients who have undergone cataract extraction.
- The use of a combination drug with an anti-infective component is indicated where the risk of superficial ocular infection is high or where there is an expectation that potentially dangerous numbers of bacteria will be present in the eye.

DOSAGE AND ADMINISTRATION : Instill one drop in the affected eye 3 times a day or as directed by the physician.

CONTRAINDICATIONS : MOXIEYE-K is contraindicated in patients with a history of hypersensitivty to moxifloxacin, to other quinolones, ketorolac or to any of the components in this medication.

WARNING AND PRECAUTIONS : NOT FOR INJECTION.
MOXIEYE-K solution should not be injected subconjunctivaly, nor should it be introduced directly into the anterior chamber of the eye.
In patients receiving systemically administered quinolones, including moxifloxacin, serious and occasionally fatal hypersensitivity (anaphylactic) reations 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 incidiacted.
General : 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 judgement dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy and where appropriate, fluorescein staining. Patients should be advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

MOXIEYE-K contains ketorolac which has the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery.

All topical nonsteroidal anti-inflammatory drugs (NSAIDs) may slow or delay healing. Topical corticosteroids are also known to slow or delay healing. Concomitant use of topical NSAIDs and topical steroids may increase the potential for healing problems.

Use of topical NSAIDs may result in Keratitis. In some susceptible patients, continued use of topical NSAIDs may result in epithelial breakdown, corneal thining, corneal Erosion, corneal ulceration or corneal perforation. These events may be sight threatening. Patients with evidence of corneal epithelial breakdown should be closely monitored for corneal health.

Postmarketing experience with topical NSAIDs suggests that patients with complicated ocular surgeries, corneal denervation, corneal epithelial defects, diabetes mellitus, ocular surface diseases (e.g. dry eye syndrome), rheumatoid arthritis, or repeat ocular surgeries within a short period of time may be at increased risk for corneal adverse events which may become sight threatening. Topical NSAIDs should be used with caution in these patients.

Postmarketing experience with topical NSAIDs also suggests that use more than 24 hours prior to surgery or use beyond 14 days post-surgery may increase patients risk for the occurrence and severity of corneal adverse events.

Information for Patients : MOXIEYE-K ophthalmic solution should not be administered while wearing contact lenses.

Avoid contaminating the applicator tip with material from the eye, fingers or other source. Systemically administered quinolones including moxifloxacin have been associated with hypersensitivity reactions, even following a single dose. Discontinue use immediately and contact your physician at the first sign or a rash or allergic reaction.

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

Lactation: Caution should be exercised when MOXIEYE-K is administered to a nursing mother.

Pediatric Use : Not recommended below 3 years of age.

Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

UNDESIRABLE EFFECTS

Moxifloxacin: The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye keratitis, ocular discomfort, ocular hyperemia, ocular pain, ocular pruritus, subconjunctival hemorrhage, and tearing. These events occured 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.

Ketorolac Tromethamine: The most frequent adverse events reported with the use of ketorolac tromethamine ophthalmic solution have been transient stinging and burning on instillation. These events were reported by up to 40% of patients participating in clinical trials.

Other adverse events occuring approximately 1% to 10% of the time during treatment with ketorolac tromethamine ophthalmic solution included allergic reactions, corneal edema, iritis, ocular inflammation, ocular irritation, superficial keratitis and superficial ocular infections.

PACKING : MOXIEYE-K Eye Drops are available in 5ml in ***lyondellbasel Purell*** low density polyethylene dispensing system consisting of plastic bottle with good flexibility. Tamper evidence ring around the closure and neck area of the bottle.

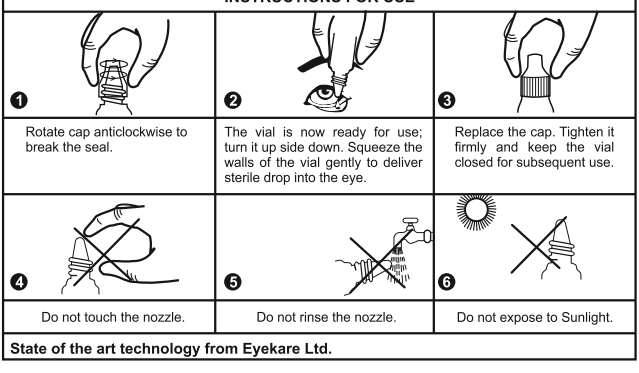
STORAGE INSTRUCTIONS : Store at temperature not exceeding 25°C and protect from light.

Keep out of reach of children.

Use the solution within one month after opening the container.

For external use only.

INSTRUCTIONS FOR USE



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