

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

**Moxifloxacin & Loteprednol Etabonate Ophthalmic Suspension**

**LUMIMOX-LP™**

लुमिमोक्स-एलपी

Eye Drops

**COMPOSITION :**

|                               |        |
|-------------------------------|--------|
| Moxifloxacin Hydrochloride IP |        |
| Equivalent to Moxifloxacin    | 5.0 mg |
| Loteprednol Etabonate         | 5.0 mg |
| Sterile Aqueous Base          | q.s.   |

**DOSAGE FORM:** Ophthalmic Suspension

**CATEGORY:** Antibiotic & Steroid Combination

**DESCRIPTION:**

**LUMIMOX-LP** is a combination of Loteprednol Etabonate an anti-inflammatory corticosteroid and Moxifloxacin Hydrochloride a fluoroquinolone antimicrobial for topical ophthalmic use.

**PHARMACOLOGY:**

**Loteprednol Etabonate:** Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probable dealing or no slow healing. They inhibit the edema, fibrin deposition, capillary dilation, leukocyte migration, fibroblast proliferation, deposition of collagen and scar formation associated with inflammation. There is no generally acceptable explanation for the mechanism of action of ocular corticosteroids. However corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2. Corticosteroids are capable of producing a rise in intraocular pressure.

**Moxifloxacin:** Moxifloxacin is an 8-methoxy fluoroquinolone with a diazabicyclononyl ring at the C7 position for anti-infective topical ophthalmic use. The antibacterial action of Moxifloxacin results from inhibition of the topoisomerase II (DNA Gyrase) and topoisomerase IV. The mechanism of action for quinolones, including Moxifloxacin is different from that of macrolides, aminoglycosides or tetracyclines. Therefore, Moxifloxacin may be active against pathogens that are resistant to these antibiotics. There is no cross resistance between Moxifloxacin and the aforementioned classes of antibiotics. Cross-resistance has been observed between systematic Moxifloxacin and some other quinolones.

**INDICATIONS:**

**LUMIMOX-LP** Ophthalmic Suspension is indicated in the treatment of bacterial conjunctivitis caused by susceptible strains of the Aerobic gram positive micro-organisms and Aerobic gram negative micro-organisms associated with steroid responsive inflammation.

**STORAGE:** Store in cool and dark place.  
Protect from light.

**CONTRA-INDICATIONS:**

**LUMIMOX-LP** Ophthalmic Suspension is contraindicated with known or suspected hypersensitivity in any of the ingredients of this preparation and other corticosteroids. **LUMIMOX-LP** Ophthalmic Suspension is contraindicated in viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (Dendritic keratitis), vaccinia and varicella and also mycobacterial infection of the eye and fungal diseases of ocular structures.

**WARNINGS:**

- Indiscriminate and prolonged use of the preparation may lead to glaucoma, cataract and fungal infections.
- Use the suspension within one month after opening the container.
- Do not use if the suspension changes color or becomes cloudy.
- If eye pain, changes in vision, continued redness or irritation of the eye is experienced, or if the condition worsens or persists for more than 72 hours discontinue use and consult a medical doctor.

**PRECAUTIONS:**

**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 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 conjunctivitis. As with all ophthalmic preparations containing Benzalkonium Chloride, patients should be advised not to wear soft contact lenses when using **LUMIMOX-LP**.

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

**Pediatric Use:** The safety and effectiveness of Moxifloxacin in infants below 1 year of age have not been established. There is no evidence that the ophthalmic administration of Moxifloxacin has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

The safety and effectiveness of Loteprednol Etabonate in pediatric patients have not been established.

**KEEP OUT OF REACH OF CHILDREN.**

**FOR EXTERNAL USE ONLY.**

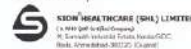
**NOT FOR INJECTION.**

**SHAKE WELL BEFORE USE.**

**PRESENTATION:**

**LUMIMOX-LP** is a sterile suspension supplied in white opaque plastic dropper bottle with a cap, containing 5ml of the suspension.

Mfg. Lic. No.: 0/28/7636  
Manufactured by:



Marketed by:



**LUMIN LABS LLP**  
D2-304, Siyona Pethkar, Punawale,  
Mumbai - Bangalore Highway,  
Pune-411033