

PRESCRIBING INFORMATION: For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Moxifloxacin Eye Drops IP 0.5% w/v

LUMIMOX™

Eye Drops

लुमिमाक्स

Composition:

Moxifloxacin Hydrochloride IP
Eq. to Moxifloxacin 0.5% w/v
Sterile aqueous base q.s.

DESCRIPTION: -

LUMIMOX is Moxifloxacin Hydrochloride ophthalmic solution is a yellow coloured sterile solution. Moxifloxacin is 8-methoxy fluoroquinolone anti-infective for topical use.

MECHANISM OF ACTION: -

Moxifloxacin is an 8-methoxyfluoroquinolone with a diazabicyclononyl ring at C7 position. The antibacterial action of Moxifloxacin results from inhibition of the topoisomerase II (DNA Gyrase) and topoisomerase IV which is an essential enzyme that is involved in the replication, transcription and repair of bacterial DNA.

INDICATIONS: -

LUMIMOX is indicated in the treatment of bacterial conjunctivitis and keratitis caused by susceptible strains of the following organisms.

AEROBIC GRAM POSITIVE MICROORGANISMS: -

Corynebacterium species*
Micrococcus luteus*
Staphylococcus aureus
Staphylococcus epidermidis
Staphylococcus haemolyticus
Staphylococcus hominis
Staphylococcus warneri*
Streptococcus pneumonia
Streptococcus viridans group

AEROBIC GRAM-NEGATIVE MICROORGANISMS: -

Acinetobacter lwoffii*
Haemophilus influenzae
Haemophilus parainfluenzae*

OTHER MICROORGANISMS: -

Chlamydia trachomatis

*Efficacy for this organism was studied in fewer than 10 infections

PRECAUTIONS:

General: As with other anti-infective, prolonged use may result in overgrowth of non-susceptible organisms including fungi. If super infection 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 bio microscopy, and where appropriate fluorescein staining.

INFORMATION FOR PATIENTS:

Avoid contaminating the applicator tip with material on the eye, fingers or other sources.

DRUG INTERACTION:

Drug-drug interaction studies have not been conducted with **LUMIMOX** eye drop. In vitro studies indicates that Moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19; OR CYP1A2 indicating that Moxifloxacin is unlikely to alter the pharmacokinetics of drug metabolised by these cytochrome P450 isozymes.

PREGNANCY LACTATION:

There are no adequate well controlled studies in pregnant women; therefore, Moxifloxacin ophthalmic solution should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Moxifloxacin has not been measured in human milk. Although it is presumed to be excreted in human milk. Caution should be exercised when Moxifloxacin ophthalmic solution is administered.

GERIATRIC USE:

No overall differences in safety and effectiveness have been observed between elderly and younger patients.

ADVERSE REACTIONS:

The most frequently reported ocular adverse events were conjunctivitis, decreased visual acuity, dry eye, keratitis, ocular discomfort, ocular hyperaemia, ocular pain, ocular pruritus, subconjunctival haemorrhage, and tearing. These events occurred in approximately 1-6% of patients.

CONTRAINDICATIONS: -

It is contraindicated in patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, or to any of the component of this formulation.

WARNING:

LUMIMOX eye drop should not be injected subconjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

DOSAGE: As directed by the Physician

STORAGE: Store in a cool and dark place. Protected from light, Do not freeze.

Keep container out of reach of children.

PRESENTATION: -

LUMIMOX is Available in 5 ml.

Precautions:

Do not swallow the eye drop solution.
Close the bottle immediately after the use.
Do not use after the expiry date marked on the product.
Do not use the bottle if the tamper proof seal on the bottle neck is broken before your first use.
Avoid contamination, do not touch the bottle tip to any surface and avoid direct contact with the eye.
Do not use the if allergic to any of its ingredients.
Retain the carton with the bottle for future reference.
Allow 5 minutes between the administration of other ophthalmic products.

Mfg. Lic No. Q20/1520

Manufactured by:



SEARON HEALTHCARE (SHE) LIMITED
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Marketed by:



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