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

MOSI

(Moxifloxacin Ophthalmic Solution 0.5% w/v)

Strength of Active Substance

Moxifloxacin Hydrochloride equivalent to Moxifloxacin base .....0.545% w/v ≡ 0.5%w/v

Product Description

Clear, yellow coloured solution

Pharmacodynamics

Moxifloxacin has *in vitro* activity against a wide range of Gram-positive and Gram-negative microorganism. Moxifloxacin inhibits the topoisomerase II (DNA gyrase) and topoisomerase IV required for bacterial DNA replication, transcription, repair and recombination. The C8-methoxy moiety of moxifloxacin also lessens the selection of resistant mutants of Gram-positive bacteria compared to the C_8-methoxy moiety found in the older fluoroquinolones. Moxifloxacin's bulky C_7 substituent group interferes with the quinolone efflux pump mechanism of bacteria. Moxifloxacin is often bacteriacidal at concentrations equal to or slightly greater than the inhibitory concentrations. Fluoroquinolones, including moxifloxacin is differ in chemical structure and mode of action from β-lactam antibiotics, macrolides and aminoglycosides, and therefore may be active against bacteria resistant to β-lactam antibiotics, macrolides and aminoglycosides. Therefore, organism resistant to these drugs may be susceptible to moxifloxacin. *In-vitro* resistance to moxifloxacin develops slowly via multiple-step mutations and occurs at a general frequency between 10^{-9} to 10^{-11} for Gram-positive bacteria.

Moxifloxacin has been shown to be active against most strains of the following microorganisms, both *in vitro* and in clinical infections:

Gram-positive bacteria:

Corynebacterium sp.
Microbacterium sp.
Micrococcus luteus [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains]
Staphylococcus aureus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus epidermidis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus haemolyticus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus hominis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus warneri [including erythromycin resistant strains]
Streptococcus mitis [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]
Streptococcus pneumoniae [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains]
Streptococcus viridans [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant]

Gram-negative bacteria:

Actinetobacter sp.
Haemophilus "alconae" [including ampicillin resistant strains]
Haemophilus influenzae [including ampicillin resistant strains]
Klebsiella pneumoniae
Moraxella catarrhalis
Pseudomonas aeruginosa

Other microorganisms:

Chlamydia trachomatis

Moxifloxacin has been shown to be active *in vitro* against most strains of the following organisms; however, the significance of these data is unknown.

Gram-positive bacteria:

Arthrobacter sp.
Bacillus cereus
Bacillus thuringensis
Corynebacterium accolens
Corynebacterium amycolatum
Corynebacterium bovis
Corynebacterium macginleyi
Corynebacterium propinquum
Corynebacterium pseudodiptheriticum
Enterococcus faecalis
Exiguobacterium sp.
Kocuria kristinae
Kocuria :lindaea"
Kocuria rhizophila
Listeria monocytogenes
Microbacterium "harmaniae"
Microbacterium "otitidis"
Rothia mucilaginosus
Staphylococcus arlettae
Staphylococcus capitis
Staphylococcus caprae
Staphylococcus cohnii
Staphylococcus lugdunesis
Staphylococcus pasteuri
Staphylococcus saprophyticus
Staphylococcus sciuri
Streptococcus agalactiae
Streptococcus "conjunctiviae"
Streptococcus cristatus
Streptococcus dysgalactiae
Streptococcus mitis
Streptococcus Groups C, G and F
Streptococcus "ocularis"
Streptococcus oralis
Streptococcus parasanguinis
Streptococcus pyrogenes
Streptococcus salivarius
Streptococcus sanguis
Streptococcus "schlechii"

Gram-negative bacteria:

Achromobacter xylosoxidans
Acinetobacter baumannii
Acinetobacter calcoaceticus
Acinetobacter johnsonii
Acinetobacter junii
Acinetobacter lwoffi
Acinetobacter "mumbaiae"
Acinetobacter schindleri
Acinetobacter ursingii
Aeromonas caviae
Chryseobacterium indologenes
Chryseobacterium sp.
Citrobacterkoseri
Enterobacter aerogenes
Enterobacter hormaechei
Escherichia coli
Klebsiella oxytoca
Moraxella osloensis
Morganella morganii
Neisseria gonorrhoeae
Pantoea agglomerans
Proteus mirabilis
Proteus vulgaris
Pseudomonas orzyihabitans
Pseudomonas stutzeri
Serratia liquefaciens
Serratia marcescens
Stenotrophomonas maltophilia
Citrobacter Freundii

Anaerobic microorganisms:

Clostridium perfringens
Fusobacterium sp.
Porphyromonas sp.
Prevotella sp.
Propionibacterium acnes

Other Organisms:

Atypical Mycobacterium
Chlamydia pneumoniae
Mycobacterium avium
Legionella pneumophila
Mycobacterium marinum
Mycoplasma pneumoniae

Pharmacokinetics:

Following topical ocular administration of ***MOSI***, moxifloxacin was absorbed into the systemic circulation. Study on the plasma concentration of moxifloxacin had taken placed and the mean steady state C_{max} and AUC were 2.7 ng/ml and 41.9 ng.hr/ml respectively. The plasma half-life of moxifloxacin was estimated to be 13 hours

Indications

MOSI is indicated for treatment of patients 1 year of age and older with bacterial conjunctivitis caused by susceptible strains of the following organisms:

Gram-positive bacteria:

Corynebacterium sp.
Microbacterium sp.
Micrococcus luteus [including erythromycin, gentamicin, tetracycline, and/or trimethoprim resistant strains]
Staphylococcus aureus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus epidermidis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus haemolyticus [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus hominis [including methicillin, erythromycin, gentamicin, ofloxacin, tetracycline and/or trimethoprim resistant strains]
Staphylococcus warneri [including erythromycin resistant strains]
Streptococcus mitis [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]
Streptococcus pneumoniae [including penicillin, erythromycin, gentamicin, tetracycline and/or trimethoprim resistant strains]
Streptococcus viridans [including penicillin, erythromycin, tetracycline and/or trimethoprim resistant strains]

Gram-negative bacteria:

Acinetobacter sp.
Haemophilus "alconae" [including ampicillin resistant strains]
Haemophilus influenza [including ampicillin resistant strains]
Klebsiella pneumoniae
Moraxella catarrhalis
Pseudomonas aeruginosa

Other microorganisms:

Chlamydia trachomatis

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

Recommended Dose

Route of Administration: Ocular

Instill one drop in the affected eye 3 times a day for 7 days.

Contraindications

MOSI is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the components in this medications.

Warnings

For ocular use only. Not for injection. Moxifloxacin solution should not be injected subconjunctivally or introduced directly into the anterior chamber of the eye.

In patients receiving systemically administered 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, urticarial, 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 administrated as clinically indicated.

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 advised not to wear contact lenses if they have signs and symptoms of bacterial conjunctivitis.

Information for Patients:

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

Carcinogenesis, Mutagenesis , Impairment of Fertility:

Moxifloxacin was not mutagenic in four bacterial strains used in the Ames Salmonella reversion assay. As with other quinolones, the positive response observed with moxifloxacin in strain TA 102 using the same assay may be due to the inhibition of DNA gyrase. Moxifloxacin was not mutagenic in the CHO/HGPRT mammalian cell gene mutation assay. An equivocal result was obtained in the same assay when V79 cells were used. Moxifloxacin was clastogenic in the V79 chromosome aberration assay, but it did not induce unscheduled DNA synthesis in cultured rat hepatocytes. There was no evidence *in vivo* in a micronucleus test or a dominant lethal test in mice.

Exacerbation of myasthenia gravis

Fluoroquinolones have neuromuscular blocking activity and may exacerbate muscle weakness in person with myasthenia gravis. Post marketing serious adverse events, including deaths and requirement for ventilator support have been associated with flouroquinolones use in persons with myasthenia gravis. Avoid flouroquinolones in patients with known history of myasthenia gravis.

Pregnancy and Lactation

Teratogenic Effects.

Pregnancy Category C

Since there are no adequate and well-controlled studies in pregnant woman, ***MOSI*** should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus.

Nursing Mothers:

Moxifloxacin has not been measured in human milk, although it can be presumed to be excreted in human milk. Caution should be exercise when ***MOSI*** is administered to a nursing mother.

Pediatric Use:

Safety and effectiveness in pediatric patients below the age of 1 year have not been established. There is no evidence that the ophthalmic administration of ***MOSI*** has any effect on weight bearing joints, even though oral administration of some quinolones has been shown to cause arthropathy in immature animals.

Geriatric Use:

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

Interactions with Other medicaments:

No serious ophthalmic or systemic adverse reactions related to ***MOSI*** were reported.

Effects on ability to drive and use machines

Moxifloxacin eye drops has no or negligible influence on the ability to drive and use machines, however, as with any eye drops, temporary blurred vision or other visual disturbances may affect the ability to drive or use machines. If blurred vision occurs at instillation, the patient should wait until their vision clears before driving or using machinery.

Adverse Reactions:

Post Marketing Experience

Exacerbation of myasthenia gravis

No serious ophthalmic or systemic adverse reactions related to ***MOSI*** were reported.

Adverse reactions were generally mild and occurred at an incidence similar to placebo (vehicle). The most frequently reported event was transient ocular discomfort (burning/stinging). Other reported events included headache, keratitis, ocular pruritus, ocular hyperemia, pharyngitis and subconjunctival haemorrhage which were reported at an incidence.

Overdosage

No information is available on overdosage in humans. If a topical overdose of Moxifloxacin Ophthalmic Solution occurs, the eye(s) may be flushed with tap water.

Storage:

Storage condition: Preserve in tight containers. Store below 30°C.

Storage condition after first opening: Preserve in tight containers. Store below 30°C.

Shelf-Life

Shelf life: 24 months.

Shelf life after first opening: 28 days.

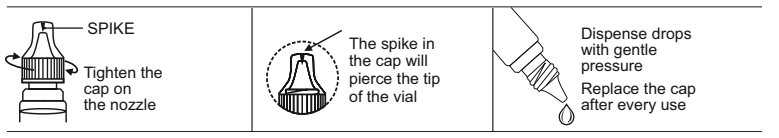
Presentation

5.0ml solution filled in 5.0ml white, translucent, round and labelled LDPE vial with HIPS cap. Labelled vial packed into a carton along with a pack insert.

Revision Date

September 2025

MODE OF USE



Manufactured by :
FDC Limited
B-8, MIDC Industrial Area, Waluj,
Chhatrapati Sambhajinagar - 431 136, Maharashtra.

Product Registration Holder
UNIMED SDN BHD
No. 53, Jalan Tembaga SD 5/2B,
Bandar Sri Damansara, 52200 Kuala Lumpur.

SAP CODE

FDC Limited	LEAFLET	Minipharma Code No.: **Front: 2104 / Back: 3059**
Size	110 (L) x 280(H) mm	
Folded Size	----------	
No. of Folds	----------	
GSM	40 gsm	
Paper	Bible paper	
Colour	Pantone Process Black C	
SAP Code:	Supercedes SAP Code: 2000011966	
Location: Waluj - Malaysia	Prepared On: 29-09-2025	
Reason for Change: Aurangabad word replace with Chhatrapati Sambhajinagar.		