

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

Moxifloxacin and Dexamethasone Eye Drops

MOXIVISC™-DM

मॉक्सिविस्क - डीएम

COMPOSITION:

Each ml contains:

Moxifloxacin Hydrochloride IP eq. to Moxifloxacin	5 mg
Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate	1 mg
Aqueous buffered vehicle	q.s.
(Preservative Free)	

PHARMACEUTICAL FORM : Eye Drops

PHARMACODYNAMIC PROPERTIES :

MOXIFLOXACIN :

The antibacterial action of moxifloxacin results from 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.

Moxifloxacin has been shown to be active against most strains of the following microorganisms and is indicated for the treatment of bacterial conjunctivitis 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 pneumoniae

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.)

DEXAMETHASONE :

Dexamethasone is a highly potent and long-acting glucocorticoid. It has an approximately 7 times greater anti-inflammatory potency than prednisolone, another commonly prescribed corticosteroid. Corticosteroids inhibit phospholipase A2 thereby preventing the generation of substances which mediate inflammation, such as prostaglandins. Corticosteroids also retard epithelial regeneration, diminish post-inflammatory neovascularization and reduce towards normal levels the excessive permeability of inflamed capillaries.

PHARMACOKINETIC PROPERTIES :

MOXIFLOXACIN: Following application to both eyes of Moxifloxacin 0.5% ophthalmic solution in healthy adults, the mean steady-state C_{max} (2.7 ng/mL) and the estimated AUC (45 ng·hr/mL) values were 1,600 and 1,000 times lower respectively, than the values reported after therapeutic 400 mg oral doses of moxifloxacin.

DEXAMETHASONE: When given topically to the eye, dexamethasone is absorbed into the aqueous humour, cornea, iris, choroid, ciliary body and retina. Systemic absorption occurs but may be significant only at higher dosages or in extended paediatric therapy.

DRUG INTERACTIONS :

The risk of increased intraocular pressure associated with prolonged corticosteroid therapy may be more likely to occur with concomitant use of anticholinergics, especially atropine and related compounds, in patients predisposed to acute angle closure.

The risk of corneal deposits or corneal opacity may be more likely to occur in patients presenting with compromised cornea and receiving polypharmacy with other phosphate containing eye medications.

THERAPEUTIC INDICATIONS :

Moxivisc-DM is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where bacterial infection or a risk of bacterial ocular infection exists. The combination can also be used for post-operative inflammation and any other ocular inflammation associated with infection.

APPLICATION AND ADMINISTRATION :

One or two drops instilled into the conjunctival sac(s), every 4 to 6 hours or as directed by the Physician. During the initial 24 to 48 hours, the dosage may be increased to 1 or 2 drops every two hours. Frequency must be decreased gradually or warranted by improvement in clinical signs. Care should be taken not to discontinue the therapy prematurely.

Use the solution within one month after opening the container.

NOT FOR INJECTION. FOR EXTERNAL USE ONLY.

CONTRAINDICATIONS :

Contraindicated in epithelial herpes simplex keratitis, vaccinia, varicella, and in many other viral diseases of the conjunctiva and cornea. Also contraindicated in Mycobacterial infection of the eye and fungal diseases of ocular structures and in individuals hypersensitive to any of the components of the medication.

SPECIAL WARNINGS AND PRECAUTIONS :

Prolonged use of steroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior sub-capsular cataract formation.

PREGNANCY AND LACTATION :

There are no adequate studies of Moxivisc-DM administration in pregnant women. Hence it should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus, according to the Physician.

In Nursing Mothers, it is not known whether this drug combination or their metabolites are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Moxivisc-DM is administered to a nursing woman.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES :

Eyesight may become blurred for a short time following the use of Moxivisc-DM. You must not drive or operate hazardous machinery until your eyesight has returned to normal.

UNDESIRABLE EFFECTS :

Conjunctival irritation, increased lacrimation, keratitis and papillary conjunctivitis have been reported as undesirable effects.

STORAGE :

Store below 30°C. Protect from light & moisture. Do not freeze.

Keep out of reach of children.

PRESENTATION :

Moxivisc-DM is available in 5 ml pack.

Manufactured in India by :
Akums Drugs & Pharmaceuticals Ltd.
2,3,4 & 5, Sector-6B, I.I.E., SIDCUL,
Haridwar - 249 403.

TM : TRADE MARK OF LAVUE



LAVUE

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