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

Moxifloxacin Eye Drops IP MOXIVISC™

मॉक्सीविस्क

COMPOSITION:

Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 0.5% w/v Sterile aqueous vehicle q.s. With Xanthan Gum IP

Preservative:

This product is self preserved.



DESCRIPTION: Moxifloxacin Eye Drops is a yellow coloured sterile solution. Moxifloxacin is an 8-methoxy fluoroguinolone anti-infective for topical ophthalmic use.

MECHANISM OF ACTION:

The antibacterial action of moxifloxacin results from inhibition of bacterial 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 that plays a key role in the partitioning of the chromosomal DNA during bacterial cell division.

INDICATIONS:

Moxifloxacin is indicated for the treatment of bacterial conjunctivitis & 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 pneumoniae

Streptococcus viridans group

Aerobic gram negative microorganisms:

Acinetobacter Iwoffii*

Haemophilus influenzae

Haemophilus parainfluenzae

Other microorganisms:

Chlamydia trachomatis

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

Drug Interaction: Drug - drug interaction studies have not been conducted with Moxivisc solution. In vitro studies indicate that moxifloxacin does not inhibit CYP3A4, CYP2D6, CYP2C9, CYP2C19, or CYP1A2 indicating that moxifloxacin is unlikely to alter the pharmacokinetics of drug metabolized by these cytochrome P450 isozymes. **CONTRAINDICATIONS**: Moxivisc is contra-indicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones, or to any of the component of this formulation.

WARNING:

Moxifloxacin solution should not be injected sub-conjunctivally, nor should it be introduced directly into the anterior chamber of the eye.

PRECAUTIONS:

General: As with other anti-infective, 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 biomicroscopy, and where appropriate, fluoroscein staining.

Information for Patients: Avoid contaminating the applicator tip with material from the eye, fingers or other sources.

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 to a nursing mother.

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 hyperemia, ocular pain, ocular pruritus, subconjunctival haemorrhage and tearing. These events occurred in approximately 1-6% of patients.

APPLICATION AND ADMINISTRATION:

One drop to be administered in the affected eye 3 times a day for 7 days or as directed by the Physician. FOR EXTERNALUSE ONLY, NOT FOR INJECTION.

STORAGE:

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

Use the solution within one month after opening the container. Do not touch the nozzle tip to any surface since this may contaminate the solution.

Keep out of reach of children.

PRESENTATION: Moxivisc Eye Drops is available in 5 ml pack.

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

