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

Moxifloxacin & Loteprednol Etabonate Ophthalmic Suspension

Moxisight LP™

Eye Drops

Composition :

Moxifloxacin Hydrochloride IP eq. to Moxifloxacin	0.5%w/v
Loteprednol Etabonate	0.5%w/v
Benzalkonium Chloride Solution IP (As Preservatives)	0.02% v/v
Sterile Aqueous buffered Vehicle	q.s.

PHARMACOLOGY :

PHARMACODYNAMICS

Moxifloxacin, a fourth-generation fluroquinolone, inhibits the DNA gyrase and topoisomerase IV required for bacterial DNA replication, repair and recombination. 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.

Corticosteroids suppress the inflammatory response to inciting agents of mechanical, chemical or immunological nature. No generally accepted explanation of this steroid property has been advanced. Loteprednol etabonate is a new class of corticosteroid with potent anti-inflammatory activity designed to be active at the site of action. Its anti-inflammatory activity is similar to the most powerful steroid used in ophthalmology but with less intraocular pressure.

PHARMACOKINETIC

Following topical ocular administration moxifloxacin was absorbed into the systemic circulation. Plasma concentrations of moxifloxacin were measured in 21 male and female subjects who received bilateral topical ocular doses of the medicinal product 3 times a day for 4 days. The mean steady-state C_{max} and AUC were 2.7 ng/ml and 41.9 ng.hr/ml, respectively. These exposure values are approximately 1,600 and 1,200 times lower than the mean C_{max} and AUC reported after therapeutic 400 mg oral doses of moxifloxacin. The plasma half-life of moxifloxacin was estimated to be 13 hours.

Results from oral and ocular administration of loteprednol in normal volunteers have shown that there are low or undetectable concentrations of either unchanged material or the metabolite. Results from a bioavailability study established that plasma concentrations of loteprednol etabonate following ocular administration of one drop in each eye of loteprednol eight times daily for 2 days or four times daily for 42 days were below the limit of quantitation(1 ng/mL) and detection (500 pg/mL) at all sampling times. In the same study, plasma cortisol concentrations were measured and no evidence of adrenal cortex suppression was observed. All cortiol measurement were within normal range. This study suggests that limited, if any, systemic absorption occurs with loteprednol

INDICATION

Bacterial Conjuctivitis, Blepharitis, Allergic Conjuctivitis, Uveitis and Bacterial Keratitis.

APPLICATION AND ADMINISTRATION

Instill one drop in the affected eye 3 times a day or as directed by the Physician.

CONTRAINDICATION

Moxifloxacin and Loteprednol solution is contraindicated in patients with a history of hypersensitivity to moxifloxacin, to other quinolones Loteprednol or to any of the components in this medication.

WARNING & PRECAUTIONS

In patients receiving systemically administered formulation, serious and occasionally fatal hypersensitivity (analphylactic) 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 oedema), airway obstruction, dyspnoea, urticaria, and itching.

If an allergic reaction occurs, discontinue use of the medicinal product. Serious acute hypersensitivity reactions may require immediate emergency treatment. Oxygen and airway management should be administered where clinically indicated. Tendon Inflammation and rupture may occur particularly in older patients and those treated concurrently with corticosteroids. Following ophthalmic administration plasma concentrations are much lower than after therapeutic oral doses. However, caution should be exercised and treatment should be discontinued at the first sign of tendon inflammation. Prolonged use may result in ocular hypertension or glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Steroids should be used with caution in the presence of glaucoma. Prolonged use may suppress the host response and may increase the possibility of secondary ocular infections. In those diseases causing thining of the cornea or sclera, perforations have been known to occur with the use of topical steroids. In acute purulent conditions of the eye, steroids may mask infection or enhance existing infection.

DRUG INTERACTION

No specific interaction studies have been performed. Given the low systemic concentration of formulation following topical ocular administration of the medicinal product, drug interactions are unlikely to occur.
However, the low potential of eye drops is to increase the intraocular pressure may be adversely affected by syetemically administered medicinal products with anticholinergic activity. In patients receiving concomitant ocular hypotensive therapy, may increase intraocular pressure and decrease the apparent ocular hypotensive effect of these medicinal products.

PREGNANCY AND LACTATION

Pregnancy
There are no adequate data from the use of combination in pregnant women. However, no effects on pregnancy are anticipated since the systemic exposure is negligible. The medicinal product can not be used in pregnancy unless clearly necessary.
Lactation
It is not known whether combination is excreted in human milk. Excretion in breast milk has not been investigated in animal studies. Therefore, the use is containdicated in lactating women.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Combination 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.

SIDE EFFECTS

Eye pain, Eye irritation Corneal defect, Eye discharge, Ocular discomfort, Dry eye, Epiphora, Foreign body sensation in eyes, Conjunctival hyperaemia, Ocular itching, Headache.

OVERDOSE

The limited holding capacity of the conjunctival sac for ophthalmic products practically precludes any overdosing of the medicinal product.

DIRECTION FOR USE

Use the suspension within one month after opening the vial. keep medicine out of reach of children. NOT FOR INJECTION. FOR EXTERNAL USE ONLY. SHAKE WELL BEFORE USE.

STORAGE

Store in a cool dark place.

PRESENTATION

Moxisight LP Eye Drops is available in a 5ml.

Mfg. Lic No.: S-MB/12/135
Manufactured in India by : HANUCHEM LABORATORIES
Plot No. 13, Ind. Area, Sector-5, Parwanoo, Distt.-Solan (H.P.)
(WHO-GMP Certified Unit)

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