Loteplain-M™ Eye Drops

1. Generic Name

Moxifloxacin Hydrochloride and Loteprednol Etabonate Ophthalmic Suspension.

2. Qualitative and Quantitative Composition

Moxifloxacin Hydrochloride IP Equivalent to Moxifloxacin	..... 0.5% w/v
Loteprednol Etabonate	..... 0.5%w/v
Sterile aqueous buffered vehicle	..... q.s

3. Dosage form and strength

Topical Ophthalmic Suspension containing Moxifloxacin Hydrochloride 0.5% w/v and Loteprednol Etabonate 0.5% w/v.

4. Clinical particulars

4.1 Therapeutic indication

- Post Operative Inflammation and Pain.
- Bacterial and Allergic Conjunctivitis, Blepharitis, Uveitis.

4.2 Posology and method of administration

Always use this medicine exactly as directed by the doctor. The recommended dose is to instil one drop in the affected eye 3 times a day.

Method of administration

For ocular use. Shake the bottle vigorously before using the eye drops. This product is sterile when packaged. Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the suspension. The bottle should be closed immediately after use.

4.3 Contraindication

Moxifloxacin

- Contraindicated in patients with a history of hypersensitivity to Moxifloxacin, to other quinolones, or to any of the components in this medication.

Loteprednol

- If you are allergic to loteprednol or any of the other ingredients of this medicine.
- If you have been allergic to any other corticosteroid.
- If you have eye diseases caused by viruses such as herpes simplex virus, vaccinia and varicella.
- If you have eye diseases caused by mycobacterium and fungi.
- If you are breast-feeding.

4.4 Special warnings and precautions for use

For Ocular Use Only. Not for injections.

Moxifloxacin

- Hypersensitivity Reactions: In patients receiving systemically administered quinolones, including moxifloxacin, 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 oedema), airway obstruction, dyspnoea, urticaria and itching. If an allergic reaction to moxifloxacin occurs, discontinue the drug. Serious acute hypersensitivity may require immediate emergency treatment. Oxygen and airway management should be administered as clinically indicated.

- Growth of Resistant Organisms with Prolonged Use: 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 judgement dictates, the patient should be examined with the aid of magnification, such as slit-lamp biomicroscopy and where appropriate, fluorescein staining.

- Avoidance of Contact Lens Wear: Patients should be advised not to wear contact lenses if they have signs or symptoms of bacterial conjunctivitis.

- Tendon Swelling and rupture have happened in people taking oral or intravenous fluoroquinolones, particularly in older patients and in those treated concurrently with corticosteroids. Stop taking Moxifloxacin 0.5% w/v eye drops, if you develop pain or swelling on the tendons (tendinitis)

- Moxifloxacin should not be used for the prophylaxis or empirical treatment of gonococcal conjunctivitis, including gonococcal ophthalmia neonatorum, because of the prevalence of fluoroquinolone-resistant Neisseria gonorrhoeae. Patients with eye infections caused by Neisseria gonorrhoeae should receive appropriate systemic treatment.

Loteprednol

- Inform the doctor if you already have glaucoma.
- Contact your doctor if you have experienced blurred vision or other visual disturbances.
- Contact your doctor if pain develops, or if redness, itching, or inflammation gets worse.
- See your doctor if your symptoms do not get better within 2 days. The doctor may want to re-evaluate your condition.
- You should not use Loteprednol for longer than 10 days without having intraocular pressure in your eye checked by your doctor.
- Long-term use of Loteprednol or other eye drops that contain steroids, may result in glaucoma or raised pressure in the eye, which can cause damage to the optic nerve, problems with vision, and cataracts.
- Long-term use of Loteprednol or other eye drops that contain steroids may lower your ability to fight infections and may increase your chance of getting an eye infection including herpes simplex.
- Using steroid eye drops like Loteprednol may make viral diseases of the eye worse and last longer.

4.5 Drug interactions

- Drug-drug interactions studies have not been conducted with Moxifloxacin and Loteprednol ophthalmic suspension. 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 drugs metabolized by these cytochrome P450 isozymes.
- Loteprednol: Please inform your doctor if you are taking or have recently taken other medicines, including medicines obtained without a prescription.
- Especially tell your doctor if you use: Medicines known as anticholinergics (used to treat a variety of conditions, e.g. gastrointestinal cramps, muscular spasms, urge incontinence or asthma).
- Eye drops for the treatment of high pressure in the eye.
- Some medicines may increase the effects of Loteprednol and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

4.6 Use in special population

- Paediatric: The safety and effectiveness of Moxifloxacin and Loteprednol Etabonate ophthalmic eye drops in infants below 1 year of age has not been established. Loteplain-M eye drops should not be used in children and adolescents without doctor's consultation.
- Geriatric: No overall differences in safety and effectiveness have been observed between elderly and adult patients.
- Liver impairment: No data found.
- Renal failure: No data found.
- Pregnancy and breast-feeding: There are no adequate or well-controlled studies in pregnant women.

4.7 Effects on ability to drive and use machine.

Moxifloxacin and Loteprednol Etabonate Ophthalmic Suspension can cause your vision to be blurred. This usually passes quickly. Do not drive or use machines until your vision is clear.

4.8 Undesirable effects

Moxifloxacin

Common: eye pain, eye irritation

Uncommon: punctate keratitis, dry eye, conjunctival haemorrhage, ocular hyperaemia

Rare: eye pruritis, eyelid oedema, ocular discomfort

Not known : corneal epithelium defect, corneal disorder, conjunctivitis, blepharitis, eye swelling, conjunctival oedema, vision blurred, visual acuity reduced, asthenopia, erythema of eyelid endophthalmitis, ulcerative keratitis, corneal erosion, corneal abrasion, intraocular pressure increased, corneal opacity, corneal erosion, corneal infiltrates, corneal deposits, eye allergy, keratitis, corneal oedema, photophobia, eyelid oedema, lacrimation increased, eye discharge, foreign body sensation in the eyes.

Loteprednol

Common: Corneal defect**,** eye discharge, ocular discomfort, dry eye, tearing, foreign body sensation in eyes, eye redness, ocular itching, burning sensation at the site of instillation and rise intra-ocular pressure.

Uncommon: abnormal vision, conjunctiva swelling, conjunctivitis, eye irritation, eye pain, fine elevations on the conjunctiva, light sensitivity, ocular inflammation, inflammation of the cornea and conjunctiva, ocular infection and lens opacification.

4.9 Overdose

There is limited experience of overdose with Moxifloxacin and Loteprednol Etabonate ophthalmic suspension. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

If you forget to use Loteplain-M eye drops

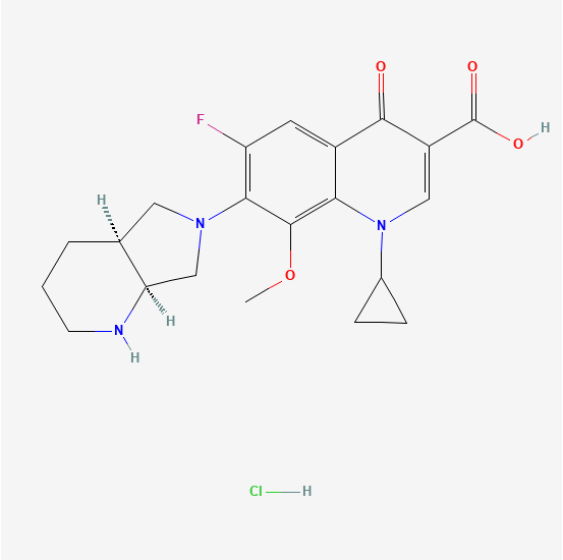
Do not take a double dose to make up for a forgotten dose.
Wait until the next dose and then continue as before.

If you stop using Loteplain-M eye drops

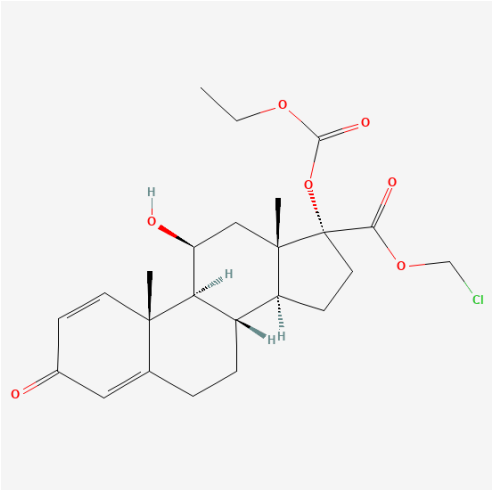
Always use this medicine exactly as directed by the physician. Do not use these eye drops without speaking to your doctor first.
If you have any further questions on the use of this medication, ask your doctor or pharmacist.

5. Pharmacological properties

Moxifloxacin Hydrochloride is the hydrochloride salt of a fluoroquinolone antibacterial antibiotic. Its chemical name is 7-[(4aS,7aS)-1,2,3,4,4a,5,7,7a-octahydropyrrolo[3,4b] pyridin-6-yl]-1-cyclopropyl-6-fluoro-8-methoxy-4-oxoquinoline-3-carboxylic acid;hydrochloride. The empirical formula and molecular weight are $C_{21}H_{25}ClFN_3O_4$ and 437.9 g/mol.



Loteprednol Etabonate is a topical corticoid anti-inflammatory. Its chemical name is chloromethyl (8S,9S,10R,11S,13S,14S,17R)-17-ethoxycarbonyloxy-11-hydroxy-10,13-dimethyl-3-oxo-7,8,9,11,12,14,15,16-octahydro-6H-cyclopenta[a]phenanthrene-17-carboxylate. The empirical formula and molecular weight are $C_{24}H_{31}ClO_7$ and 466.9 g/mol.



5.1 Mechanism of action

Moxifloxacin: The antibacterial action of Moxifloxacin results from inhibition of 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.

Lotepradenol: 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.

5.2 Pharmacodynamic properties

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. This new class of steroids consists of bioactive molecules whose in-vivo transformation to non-toxic substances can be predicted from their chemistry and knowledge of enzymatic pathways in the body. Cortienic acid is an inactive metabolite of hydrocortisone and analogs of cortienic acid are also devoid of corticosteroid activity. Loteprednol etabonate is an ester derivative of one of these analogs, cortienic acid etabonate.

Moxifloxacin is a quinolone/fluoroquinolone antibiotic. Moxifloxacin can be used to treat infections caused by the following bacteria: Aerobic Gram-positive microorganisms: Corynebacterium species, Micrococcus luteus, Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus warneri,

Streptococcus pneumoniae, and Streptococcus viridans group. Aerobic Gramnegative microorganisms: Acinetobacter lwoffii, Haemophilus influenzae, and Haemophilus parainfluenzae. Other microorganisms: Chlamydia trachomatis.

Moxifloxacin is bactericidal and its mode of action depends on blocking of bacterial DNA replication by binding itself to an enzyme called DNA gyrase, which allows the untwisting required to replicate one DNA double helix into two. Notably the drug has 100 times higher affinity for bacterial DNA gyrase than for mammalian. Moxifloxacin is a broad-spectrum antibiotic that is active against both Gram-positive and Gram-negative bacteria.

5.3 Pharmacokinetic properties

Moxifloxacin is readily absorbed from the gastrointestinal tract after oral doses with an absolute bioavailability of about 90%. It is widely distributed throughout the body tissues and is about 30 to 50% bound to plasma proteins. Moxifloxacin has an elimination half-life of about 12 hours, allowing once-daily dosing. It is metabolised mainly via sulfate and glucuronide conjugation and is excreted in the urine and the faeces as unchanged drug and as metabolites, the sulfate conjugate primarily in the faeces and the glucuronide exclusively in the urine. Distribution into milk has been found in animals.

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 cortisol measurements were within normal range. This study suggests that limited, if any, systemic absorption occurs with Loteprednol.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology:

Not required

7. Description

Already mentioned and covered in the above points.

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24months

8.3 Packaging Information

Loteplain-M eye drops are available in 5 ml and 3 ml.

8.4 Storage and handling instructions

Store in a dry, well-ventilated place at a temperature not exceeding 30^0C. Preserve in a tight container.

Keep the medicine out of reach of children.

Use within one month after opening the container. If the suspension becomes cloudy or dark brown, it should be discarded.

9. Patient Counselling Information

9.1 Adverse Reactions:

Refer part 4.8

9.2 Drug Interactions:

Refer part 4.5

9.3 Dosage:

Refer part 4.2

9.4 Storage:

Refer part 8.4

9.5 Risk Factors:

Refer part 4.4

9.6 Self-monitoring information:

NA

9.7 Information on when to contact a health care provider or seek emergency help.

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications:

Refer part 4.3

10. Details of the manufacturer:

Manufactured in India by: ABLE PHARMA

Village Gullarwala, Sai Road, Baddi,

Distt. - Solan - 173205 (H.P.), INDIA.

11. Details of permission or license number with date

Mfg.Lic.No.: MB/06/490, Dated - 13-December-2024.

12. Date of revision: December 2025