

Loteplain Eye Drops

1. Loteprednol Etabonate Ophthalmic Suspension

2. Qualitative and Quantitative composition

Loteprednol Etabonate IHS..... 0.5% w/v

Excipients..... q.s.

Sterile Aqueous Buffered Vehicle..... q.s.

3. Dosage form and strength:

Loteprednol Etabonate IHS 0.5% w/v

4. Clinical particulars

4.1 Therapeutic indication

Loteplain is an eye drop suspension. Loteplain is used to treat inflammation of the eye, after surgery. Sometimes the eye may become inflamed (red and painful).

Loteprednol etabonate is one of a group of medicines called corticosteroids. It acts by reducing inflammation and eases the symptoms.

4.2 Posology and method of administration

Always use this medicine exactly as directed by the doctor. The recommended dose for adults and elderly is one to two drops four times daily. Treatment with Loteplain normally begins 24 hours after surgery and continues for two weeks.

Method of administration

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

- If you are allergic to the active substance (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, 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

- Inform the doctor if you are already having glaucoma.
- Contact your doctor if you experience 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 Loteplain longer than 10 days without having the intraocular pressure in your eye checked by your doctor.
- Long-term use of Loteplain 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 Loteplain 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 Loteplain may make viral diseases of the eye worse and last longer.

4.5 Drug interactions

- Please inform your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Especially, tell you 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 Loteplain 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

- **Pregnancy and breast-feeding**

For Loteplain no clinical data on exposed pregnancies are available. Studies in animals have shown reproductive toxicity. The potential risk for humans is unknown and Loteplain should not be used in pregnancy unless clearly necessary.

Loteplain should not be used when breast-feeding.

- **Fertility**

There are no clinical data concerning the loteprednol etabonate influence on the fertility in humans.

- **Use in children and adolescents.**

Loteplain should not be used in children and adolescents without doctors' consultation.

4.7 Effects on ability to drive and use machine.

Eye drops 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

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following symptoms: redness, itching or swelling of the membrane covering the white part of the eye and/or eyelid(s) or general symptoms such as difficulty breathing, difficulty swallowing, flushing or redness of the face and swelling of the face or tongue you should stop using this medicine and seek immediate medical advice. These could be the signs of severe allergic reaction.

4.9 Overdose

No case of overdose has been reported. Acute overdosage is unlikely to occur via the ophthalmic route.

If you forget to use Loteplain

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

Always use this medicine exactly as your doctor has told you. Do not stop using Loteplain without speaking to your doctor first.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. Pharmacological properties

5.1 Mechanism of action

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. Animal studies have shown that loteprednol etabonate has a binding affinity to steroid receptors that is 4.3 times greater than dexamethasone. 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.

5.3 Pharmacokinetic properties

Results from oral and ocular administration of Loteplain 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 Loteplain 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 Lotepain.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

Preclinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity and genotoxicity. Embryotoxicity and teratogenic effects were observed in reproductive toxicity studies in rabbits (delayed ossification, increased incidence of meningocele, abnormal left carotid artery and limb flexures) at oral doses 35 times the maximum daily clinical dose and in rats (decreased foetal body weight and skeletal ossification, absent innominate artery, cleft palate and umbilical hernia) at oral doses greater than 60 times the maximum daily clinical dose. Mild ocular irritation was noted with both the acute and multidose rabbit ocular studies

7. Description Name:

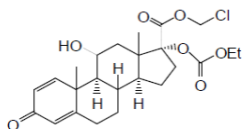
Loteprednol etabonate

Chemical Name: Chloromethyl 17 α -[(ethoxycarbonyl)oxy]-11 β -hydroxy-3-oxoandrost-1,4-diene-17 β -carboxylate

Molecular Formula: C₂₄H₃₁ClO₇

Molecular Weight: 466.96 g/mol

Structure



8. Pharmaceutical particulars

8.1 Incompatibilities: There are no known incompatibilities.

8.2 Shelf-life: Do not use this medicine after the expiry date which is stated on the carton and bottle after expiry. The expiry date refers to the last day of that month. Throw away any solution 28 days after opening.

8.3 Packaging Information: Loteplain is a milky-white eye-drops suspension. Loteplain is available in bottles containing 3ml & 5ml Not all pack sizes may be marketed.

8.4 Storage and handling instructions:

Keep this medicine out of the sight and reach of children.

Store the container in an upright position.

Do not store above 25°C. Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

DO NOT USE IF PROTECTIVE SEAL IS BROKEN

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 3

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 manufacturer: ABLE PHARMA

Village Gullarwala, Sai Road,

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

(WHO-GMP Certified Unit)

11. License number date: MB/06/490 & MNB/06/489

12. Date of revision: April 2024