

Lotepred[®] Plus

Loteprednol Etabonate INN 0.5%
& Tobramycin USP 0.3%
Ophthalmic Suspension

Composition:

Lotepred[®] Plus Ophthalmic Suspension: Each ml contains Loteprednol Etabonate INN 5 mg and Tobramycin USP 3 mg.

Preservative: Sodium Perborate BP 0.01%.

Vehicle: Polyvinyl Alcohol USP 1% & HPMC USP 0.25%.

Pharmacology:

Loteprednol is a corticosteroid which is thought to act by the induction of phospholipase A2 inhibitory proteins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor arachidonic acid. Tobramycin is a member of aminoglycoside which shows bactericidal activity by inhibiting protein synthesis of bacteria.

Indications:

Lotepred[®] Plus is indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists. It is also effective in post-operative inflammation.

Dosage & application:

Instill 1 drop of **Lotepred[®] Plus** into the conjunctival sac of the eye(s) every 4 to 6 hours.

Contraindications:

Contraindicated in most viral diseases of the cornea and conjunctiva. Also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

Side effects:

Increased intraocular pressure, burning & stinging upon instillation, vision disorders, discharge, itching, photophobia, headache and other unspecified eye disorders may occur.

Precautions:

- For ophthalmic use only.
- If this product is used for 10 days or longer, intraocular pressure should be monitored.
- Fungal infections of the cornea are particularly prone to develop coincidentally with long-term use of steroid topically.
- Prolonged use may result in overgrowth of nonsusceptible organisms including fungi. If superinfection occurs, appropriate therapy should be initiated.
- Cross-sensitivity to other aminoglycoside antibiotics may occur.

Use in special group:

Use in pregnancy: There are no adequate and well-controlled studies in pregnant women. **Lotepred[®] Plus** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation: Caution should be exercised when **Lotepred[®] Plus** is administered to a nursing mother.

Use in children: Safety and effectiveness in pediatric patients have not been established.

Storage:

- Store below 30°C temperature in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of the children.

Packing:

Lotepred[®] Plus Ophthalmic Suspension: Each LDPE dropper bottle contains 5 ml Sterile Eye Drops.



Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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