



Composition:

Lifitear Ophthalmic Solution: Each ml contains Lifitegrast INN 50 mg.

Preservative:

Sodium Perborate BP 0.01%.

Pharmacology:

Lifitegrast is a novel lymphocyte function associated antigen 1 (LFA-1) antagonist. It acts by inhibiting LFA-1 interaction with the intercellular adhesion molecule (ICAM)-1 on the T-cell surface, inhibiting T-cell adhesion, migration, activation and subsequent cytokine release and thereby inhibiting subsequent T-cell-mediated inflammation associated with Dry Eye Disease.

Indications:

Lifitegrast is approved by USFDA for the treatment of the signs and symptoms of Dry Eye Disease (DED).

Dosage & administration:

Instill one drop in the affected eye(s) twice daily (approximately 12 hours apart).

Contraindications:

Lifitegrast ophthalmic solution is contraindicated in patients who are hypersensitive to any component of this product.

Adverse effects:

The most common adverse reactions were instillation site irritation, dysgeusia and decreased visual acuity.

Precautions:

- For ophthalmic use only
- To avoid possible contamination of the drops, do not touch the dropper tip or to any surface
- If more than one topical ophthalmic drug is being used, the drugs should be administered at least five (5) minutes between applications
- Contact lenses should be removed prior to the administration of Lifitegrast and may be reinserted 15 minutes following administration

Use in special group:

Use in pregnancy: There are no adequate data and well-controlled studies in pregnant women. Lifitegrast ophthalmic solution should be used during pregnancy unless the potential benefit justifies the potential risk to the fetus.

Use in lactation: It is not known whether Lifitegrast is excreted in human milk. Caution should be exercised while giving this ophthalmic solution to a nursing mother.

Use in children: Safety and efficacy in pediatric patients below the age of 17 years have not been established.

Use in geriatric patients: No overall differences in safety or effectiveness have been observed between elderly and younger adult patients.

Storage:

- Store at below 25°C, keep away from light, cool & dry place
- Do not use longer than 30 days after first opening
- Keep out of the reach of children

Packing:

Lifitear Ophthalmic Solution: Each LDPE dropper bottle contains 5 ml sterile & pyrogen free ophthalmic solution.



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