Review Article

Lifitegrast Ophthalmic solution – A review

ABSTRACT:

Introduction: Lifitegrast reduces the swelling in the eye tissues. Carcinogenesis – Studies have not been conducted in the animals to assess the carcinogenicity. Lifitegrast was not found to be mutagenic invitro assay. **Methods:** Totally 1181 patients were recruited for the safety and efficacy of lifitegrast for the treatment of dry eyes. The study was conducted for four 12 weeks, randomized, multi-centre, double blinded trial. **Result:** The average baseline Eye Dryness Score was between 40 and 70. A larger reduction in EDS favouring lifitegrast was observed in all studies at Day 42 and Day 84. **Conclusion:**Lifitegrast ophthalmic solution 5% provides a new option for the treatment of dry eyes.

Keywords:*Lifitegrast; Eye dryness; Drug complication.*

1

Comment [URG1]: The TM symbol mus t be appointed because someone else patented the name

Comment [URG2]: Should read: Inflammation

Comment [URG3]: This is confusing. The word four should be deleted

INTRODUCTION:

It is used to treat signs and symptoms of the dry disease. It belongs to lymphocyte associated antigen-1 (LAP-1) antagonist. Lifitegrastreduces the swelling in the eye tissues.

Comment [URG4]: Space

Indications: It is indicated in treatment of dry eye disease.

Dosage forms: Ophthalmic solution containing lifitegrast 5% (50 mg/mL).

Mechanism of Action: A cell surface protein found on leucocytes which is an integrin lymphocyte function-associated antigen-1 (LFA-1). Lifitegrast binds to LFA-1 and blocks the interaction of LFA-1 with its ICAM-1(intracellular adhesion molecule-1). Interaction of LFA-1/ICAM-1 leads to formation of an immunological synapse resulting in T-cell activation and migration to target tissues[1].

Comment [URG5]: ligand

Nonclinical Toxicology: Carcinogenesis – Studies have not been conducted in the animals to assess the carcinogenicity.

Mutagenicity –Lifitegrast was not found to be mutagenic invitro assay.

Impaired fertility – Lifitegrast had no effect on fertility and reproduction in male and female treated rats after administering i.v. doses of lifitegrast at 30mg/kg/day.

Adverse effects: The most common adverse effects commonly reported in a study with 1401 patients 5-25% of them had instillation site irritation, reduced visual acquity and dysgeusia. Other 1-5% of patients experienced head ache, blurring of vision, eye pruritis,sinusitis[2].

Uses in specific population:Pregnancy – There are no data available for studies related to pregnant women. Lifitegrast administered to rats during their gestational period did not produce any embryofetal defects[3]. When given to pregnant rabbits there were increased incidence of omphalocele at the lowest dose tested, 3mg/kg/day[1].

Lactation – There are no reliable data available on presence of lifitegrast in breast milk.

Pediatric- Use Safety and efficacy in pediatric patients below the age of 17 years have not been established[1].

Geriatric - Use No overall differences in safety or effectiveness have been observed between elderly and younger adult patients[1].

Clinical studies: Totally 1181 patients were recruited for the safety and efficacy of lifitegrast for the treatment of dry eyes. The study was conducted for four 12 weeks, randomized, multi-centre, double blinded trial. Use of artificial tears was not allowed. Patients were randomization to the drug group or placebo in a 1:1 ratio and dosed twice a day.

Eye dryness Score (EDS) was assessed by patients using a visual analogue scale (VAS) (0 = no discomfort, 100 = maximal discomfort) during each study visit. The average baseline EDS was between 40 and 70. A larger reduction in EDS favouring lifitegrast was observed in all studies at Day 42 and Day 84[4].

Conclusion: Lifitegrast ophthalmic solution 5% provides a new option for the treatment of dry eyes.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

Reference:

1) Pflugfelder SC, Stern M, Zhang S, Shojaei A. LFA-1/ICAM-1 Interaction as a Therapeutic Target in Dry Eye Disease. J OculPharmacolTher. 2017 Jan/Feb;33(1):5-12. doi: 10.1089/jop.2016.0105. Epub 2016 Dec 1. PMID: 27906544; PMCID: PMC5240001.
2) Donnenfeld ED, Karpecki PM, Majmudar PA, Nichols KK, Raychaudhuri A, Roy M, Semba CP. Safety of Lifitegrast Ophthalmic Solution 5.0% in Patients With Dry Eye Disease: A 1-Year, Multicenter, Randomized, Placebo-Controlled Study. Cornea. 2016 Jun;35(6):741-8. doi: 10.1097/ICO.0000000000000803. PMID: 27055211; PMCID: PMC4859202.
3) Chung MK, Yu WJ, Lee JS, Lee JH. Embryotoxicity and toxicokinetics of the antimalarial artesunate in rats. Toxicol Res. 2013 Mar;29(1):27-34. doi: 10.5487/TR.2013.29.1.027. PMID: 24278626; PMCID: PMC3834439.
4) Keating GM. Lifitegrast ophthalmic solution 5%: a review in dry eye disease. Drugs. 2017 Feb 1;77(2):201-8.