xiidra® (lifitegrast ophthalmic solution)5%

Robust Clinical Trial Data

LARGEST, MOST COMPREHENSIVE TRIAL PROGRAM IN DRY EYE DISEASE IN SUPPORT OF AN INVESTIGATIONAL PRODUCT

5 clinical trials; more than **2,500** patients[1-6]

PHASE 2 - Efficacy/safety of three concentrations (0.1%, 1.0%, 5.0%)[1,2]

230	5	12	Primary endpoint:
patients	sites	week trial	Effect on ocular signs

OPUS-1 - Phase 3 efficacy/safety trial[2,3]

588	13	12	Primary endpoints:
patients	sites	week trial	Effect on ocular signs and symptoms

OPUS-2 - Phase 3 efficacy/safety trial[2,4]

718	30	12	Primary endpoints:
patients	sites	week trial	Effect on ocular signs and symptoms

OPUS-3 - Phase 3 efficacy/safety trial[2,5]

711	41	12	Primary endpoint:
patients	sites	week trial	Effect on ocular symptoms

SONATA - Phase 3 safety trial[2,6]

331	22	1	Primary endpoint:
patients	sites	year trial	Adverse events

COMMITTED TO DRY EYE INNOVATION

~10 years from compound to U.S. FDA approval[7]

1st and only Rx treatment for dry eye signs and symptoms

1st U.S. FDA-approved Tx in more than a decade

INDICATION

Xiidra® (lifitegrast ophthalmic solution) 5% is indicated for the treatment of signs and symptoms of dry eye disease (DED).

IMPORTANT SAFETY INFORMATION

In clinical trials, the most common adverse reactions reported in 5-25% of patients were instillation site irritation, dysgeusia and reduced visual acuity. Other adverse reactions reported in 1% to 5% of the patients were blurred vision, conjunctival hyperemia, eye irritation, headache, increase lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

To avoid the potential for eye injury or contamination of the solution, patients should not touch the tip of the single-use container to their eye or to any surface.

Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.

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

For additional safety information, click here for Full Prescribing Information.

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References:
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2. Xiidra [Prescribing Information]. Lexington, MA: Shire US.
3. Sheppard JD, Torkildsen GL, Lonsdale JD, et al. Lifitegrast ophthalmic solution 5.0% for treatment of dry eye disease: results of the OPUS-1 phase study. *Ophthalmology.* 2014;121:475-83.
4. Tauber J, Karpecki P, Latkany R, et al. Lifitegrast ophthalmic solution 5.0% versus placebo for treatment of dry eye disease: results of the randomized phase III OPUS-2 study. *Ophthalmology.* 2015;122:2423-31.
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6. Donnenfeld ED, Karpecki PM, Majmudar PA, et al. 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.
7. Paton DM. Lifitegrast: First LFA-1/ICAM-1 antagonist for treatment of Dry Eye Disease. Drugs of Today. 2016; 52(9): 485-493.