



Xiidra™ (lifitegrast) – New Drug Approval

- On July 12, 2016, the [FDA announced](#) the approval of [Shire's Xiidra \(lifitegrast\)](#) for the treatment of the signs and symptoms of dry eye disease (DED).
- DED includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. When severe and left untreated, this condition can lead to pain, ulcers or scars on the cornea. Dry eye can make it more difficult to perform some activities, such as using a computer or reading for an extended period of time, and it can decrease tolerance for dry environments, such as the air inside an airplane.
 - DED affects approximately 16 million U.S. adults: 5% aged 30 – 40 years and 10 – 15% > 65 years, and is more common among women.
- Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonists.
- The safety and efficacy of Xiidra were based on 4 placebo-controlled, double-blind clinical studies conducted for 12 weeks in 1,181 patients. Assessment of symptoms was based on change from baseline in patient reported eye dryness score (EDS; 0 - 100 visual analogue scale). Assessment of signs was based on inferior corneal staining score (ICSS; 0 - 4 scale).
 - In all 4 studies, a larger reduction in EDS was observed with Xiidra at 6 and 12 weeks.
 - In 2 of the 4 studies, an improvement in EDS was seen with Xiidra at 2 weeks.
 - At week 12, a larger reduction in ICSS favoring Xiidra was observed in 3 of the 4 studies.
- The most common adverse events (5 - 25%) with Xiidra use were instillation site irritation, dysgeusia and decreased visual acuity.
- The recommended dose of Xiidra is 1 drop twice daily in each eye (approximately 12 hours apart).
 - Contact lenses should be removed prior to the administration of Xiidra and may be reinserted 15 minutes following administration.
- Shire plans to launch Xiidra in the third quarter of 2016. Xiidra will be available as a 5% (50 mg/mL) ophthalmic solution.



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