YOU CAN HELP SET PATIENTS UP FOR SUCCESS

xiidra® (lifitegrast ophthalmic solution)5%

Discussing these key areas with patients can help them have a positive treatment experience[1]:

1. How their treatment works and how it may differ from other options[1]
2. What results they may see with their treatment and when[1]
3. The most common side effects associated with their treatment[2]
4. How they may be able to save on their treatment and find additional resources[2]

1 WHY XIIDRA

Xiidra helps to treat the signs and symptoms of dry eye disease[3]

- Artificial tears typically work by lubricating the eyes and may provide temporary relief[4]
- **Xiidra works differently, targeting a source of inflammation** that can cause dry eye disease[3,5]

2 EFFICACY

Xiidra can offer lasting relief from symptoms in as little as 2 weeks[3]*

- Some patients saw improvement as soon as 2 weeks in 2 of the 4 studies, with **improvements also observed at 12 weeks in all 4 studies[3†]**
- It may take more than 2 weeks for some patients to notice improvements in symptoms[3]
- Notable improvements in signs of dry eye disease: in 3 out of 4 studies, a larger reduction in Inferior fluorescein Corneal Staining Score (ICSS) favoring Xiidra was observed at 12 weeks[3]

*In some patients with continued daily use. One drop in each eye, twice daily (approximately 12 hours apart).[3]
†The safety and efficacy of Xiidra were assessed in four 12-week, randomized, multicenter, double-masked, vehicle-controlled studies (N=2133). Patients were dosed twice daily. The mean age was 59 years (range, 19-97 years). The majority of patients were female (76%). **Use of artificial tears was not allowed during the studies.** The study end points included assessment of signs (based on ICSS on a scale of 0 to 4) and symptoms (based on patient-reported Eye Dryness Score [EDS] on a visual analogue scale of 0 to 100). A larger reduction in EDS favoring Xiidra was observed in all studies at day 42 and day 84.[3]

Indication

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

Important Safety Information

- Xiidra is contraindicated in patients with known hypersensitivity to lifitegrast or to any of the other ingredients.
- 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, increased lacrimation, eye discharge, eye discomfort, eye pruritus and sinusitis.

For additional safety information, see accompanying Full Prescribing Information in pocket.

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3 TOLERABILITY

xiidra® (lifitegrast ophthalmic solution)5%

The most common adverse reactions (reported in 5%-25% of patients) were[3]*:

- Eye irritation
- Discomfort or blurred vision
- Unusual taste sensation

*In 5 clinical studies of dry eye disease with lifitegrast ophthalmic solution, 1401 patients received at least 1 dose of lifitegrast (1287 of whom received Xiidra). The majority of patients (84%) had up to 3 months of treatment exposure. 170 patients were exposed to Xiidra for approximately 12 months.[3]

The comfort of Xiidra can improve over time

- Numerical improvements in drop comfort scores were seen in the phase 3 OPUS 1-3 studies from day 14 through day 84 at 3 minutes post instillation[6-9†]
- Drop comfort was measured based on patient-reported scores from 0 (very comfortable) to 10 (very uncomfortable)[6-9]

†The safety and efficacy of Xiidra were assessed in 4 multicenter, randomized, prospective, double-masked, placebo-controlled studies (one phase 2 study, and 3 phase 3 studies [OPUS-1, OPUS-2, and OPUS-3]). The 4 studies evaluated the safety and efficacy of Xiidra compared to vehicle in 2133 patients. **Results from OPUS-1 day 0 did not show drop comfort score improvement at the 3-minute mark compared to baseline.** Drop comfort was evaluated at day 0 in the phase 2 study and numerical improvement in drop comfort was seen at the 3-minute mark compared to baseline.[6-9]

4 SAVINGS

There are several ways to save, including the Xiidra Savings Program

- Over 80% of patients on the Xiidra **Savings Program** pay **as little as $0 for a 90-day (or 30-day) prescription‡**
- Encourage patients to **visit Xiidra.com** for more information and to register for the **Xiidra Co-pay Card**

‡Limitations apply. Eligible, commercially insured patients using the Co-pay Card pay $[0] for their first prescription of Xiidra of up to 90 days. After the first fill, eligible, commercially insured patients may pay as little as $[0] for prescriptions of Xiidra, subject to a maximum monthly savings of $[250] for a 30-day prescription and $[750] for a 90-day prescription. Offer not valid under Medicare, Medicaid, or any other federal or state program. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions for details.

Important Safety Information (cont)

- 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, see accompanying Full Prescribing Information in pocket.

References: 1. Akpek EK, Amescua G, Farid M, et al; American Academy of Ophthalmology Preferred Practice Pattern Cornea and External Disease Panel. Dry Eye Syndrome Preferred Practice Pattern®. *Ophthalmology*. 2019;126(1):286-334. **2.** Neiman AB, Ruppar T, Ho M, et al. CDC: Grand Rounds: Improving medication adherence for chronic disease management-innovation and opportunities. *MMWR Morb Mortal Wkly Rep*. 2017;66(45):1248-1251. **3.** Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2020. **4.** US Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 5 (21CFR349). Accessed December 9, 2020. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=349&showFR=1 **5.** Bron AJ, de Paiva CS, Chauhan SK, et al. TFOS DEWS II Pathophysiology Report. *Ocul Surf*. 2017;15(3):438-510. **6.** Nichols KK, Donnenfeld ED, Karpecki PM, et al. Safety and tolerability of lifitegrast ophthalmic solution 5.0%: pooled analysis of five random controlled trials in dry eye disease. *Eur J Immunol*. 2019;29(4)394-401. **7.** Data on file. 1118-KCS-200. OPUS-1 Clinical Study Report. Novartis Pharmaceuticals Corp; December, 2013. **8.** Data on file. 1118-DRY-300. OPUS-2 Clinical Study Report. Novartis Pharmaceuticals Corp; March, 2014. **9.** Data on file. SHP606-304. OPUS-3 Clinical Study Report. Novartis Pharmaceuticals Corp; December, 2015.

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