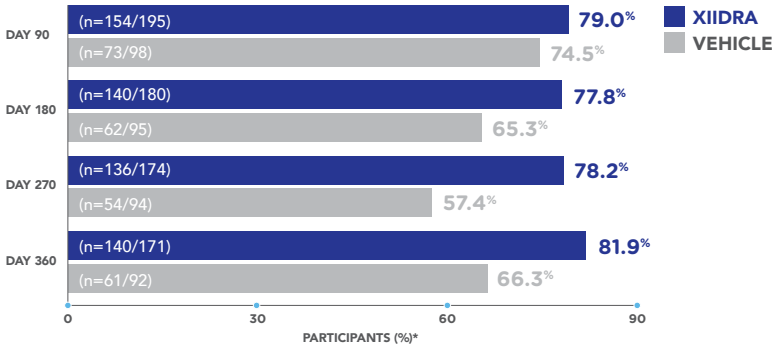
FOR SOME PATIENTS, ARTIFICIAL TEARS MAY NOT BE ENOUGH[1,2]

xiidra® (lifitegrast ophthalmic solution)5%

In the12-month SONATA study, nearly **8 out of 10** patients treated with Xiidra **did not use artificial tears** at day 90[3]

Participants (%) who did not report using artificial tears with Xiidra (n=220) and vehicle (n=111) since prior visit[3]



The 1-year, multicenter, randomized, prospective, double-masked, placebo-controlled, phase 3 SONATA study evaluated the safety of Xiidra compared to vehicle in 331 adult patients who had a self-reported history of dry eye disease. The most common treatment-emergent adverse reactions (>5%) in either treatment group were instillation-site irritation, instillation-site reaction, reduced visual acuity, dry eye, and dysgeusia.[3]

Artificial tear use in the SONATA safety study was assessed as an exploratory end point.[3]

After day 14 (visit 3), the use of artificial tears (≤4 times daily) was allowed as needed. The question about artificial tear use (Yes/No) was asked beginning at day 90 (visit 4). Participants with any artificial tear use during the study: vehicle=43/98 (43.9%); Xiidra=64/195 (32.8%).[3]

Vehicle=placebo.

*Based on number of participants in the safety population with data at the visit.[3]

Pivotal trial data:

Lasting relief that can start as early as 2 weeks[4†‡]

†In some patients with continued daily use. One drop in each eye, twice daily (approximately 12 hours apart).[4]

‡Xiidra is an LFA-1 antagonist for the treatment of dry eye disease. 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. **Use of artificial tears was not allowed during the studies.** The study end points included assessment of signs (based on Inferior fluorescein Corneal Staining Score [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).[4]

Effects on symptoms of dry eye disease: A larger reduction in EDS favoring Xiidra was observed in all studies at day 42 and day 84. Xiidra reduced symptoms of eye dryness at 2 weeks (based on EDS) compared to vehicle in 2 out of 4 clinical trials.[4]

Effects on signs of dry eye disease: At day 84, a larger reduction in ICSS favoring Xiidra was observed in 3 of the 4 studies.[4]

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.

Please see additional Important Safety Information on reverse and Full Prescribing Information in pocket.

NOVARTIS

NEW SAVINGS FOR PATIENTS

xiidra® (lifitegrast ophthalmic solution)5%

First Prescription Upon Enrollment for commercially insured patients*	Subsequent Prescriptions for commercially insured patients*
$0 for 90 days (or 30 days)	Pay as little as $0 Patients save up to: $750 per fill on a 90-day prescription $250 per fill on a 30-day prescription

On average, patients paid $45 for 90 days (or $15 per month) for OTC artificial tears.[5†]

Go to Xiidra.com for cost and affordability resources that can help your patients start and stay on Xiidra

*Limitations apply. Eligible, commercially insured patients using the Co-pay Card pay $0 for their first prescription of Xiidra for 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.

†Based on average dollars per month spent on over-the-counter dry eye products by patients active in both the IQVIA LRx and OTC databases (n=2,258,782). Eligible patients must have at least one record of prescription activity (from any market) in the LRx database prior to the look-back period and at least one record of OTC activity. Calculation was completed by IQVIA based on a study period from November 2018 to October 2019.

OTC=over-the-counter.

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.

Please see additional Important Safety Information on reverse and Full Prescribing Information in pocket.

References: 1. US Food and Drug Administration. Code of Federal Regulations, Title 21, Volume 5 (21CFR349). Accessed April 17, 2020. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=349&showFR=1 **2.** Jones L, Downie LE, Korb D, et al. TFOS DEWS II Management and Therapy Report. *Ocul Surf.* 2017;15(3):575-628. **3.** 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;35(6):741-748. **4.** Xiidra [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2020. **5.** Data on file. IQVIA Dry Eye OTC Analysis, November 2018 to October 2019. Novartis Pharmaceuticals Corp; April 2020.

Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936-1080

6/20

T-XIA-1388857