Indication

Tyrvaya® (varenicline solution) nasal spray is indicated for the treatment of the signs and symptoms of dry eye disease.

Important Safety Information

The most common adverse reaction reported in 82% of patients was sneezing. Events that were reported in 5-16% of patients were cough, throat irritation, and instillation-site (nose) irritation.

Please click here for full Prescribing Information.

TEAM tyrvaya™ PATIENT SUPPORT

Go to Tyrvaya-pro.com to discover our free patient support program made up of people who are dedicated to helping your patients.

MOST DRY EYE PATIENTS WOULD EMBRACE AN OCULAR SURFACE-SPARING NASAL SPRAY

According to a 2023 survey of over 200 dry eye patients:

>7 out of 10

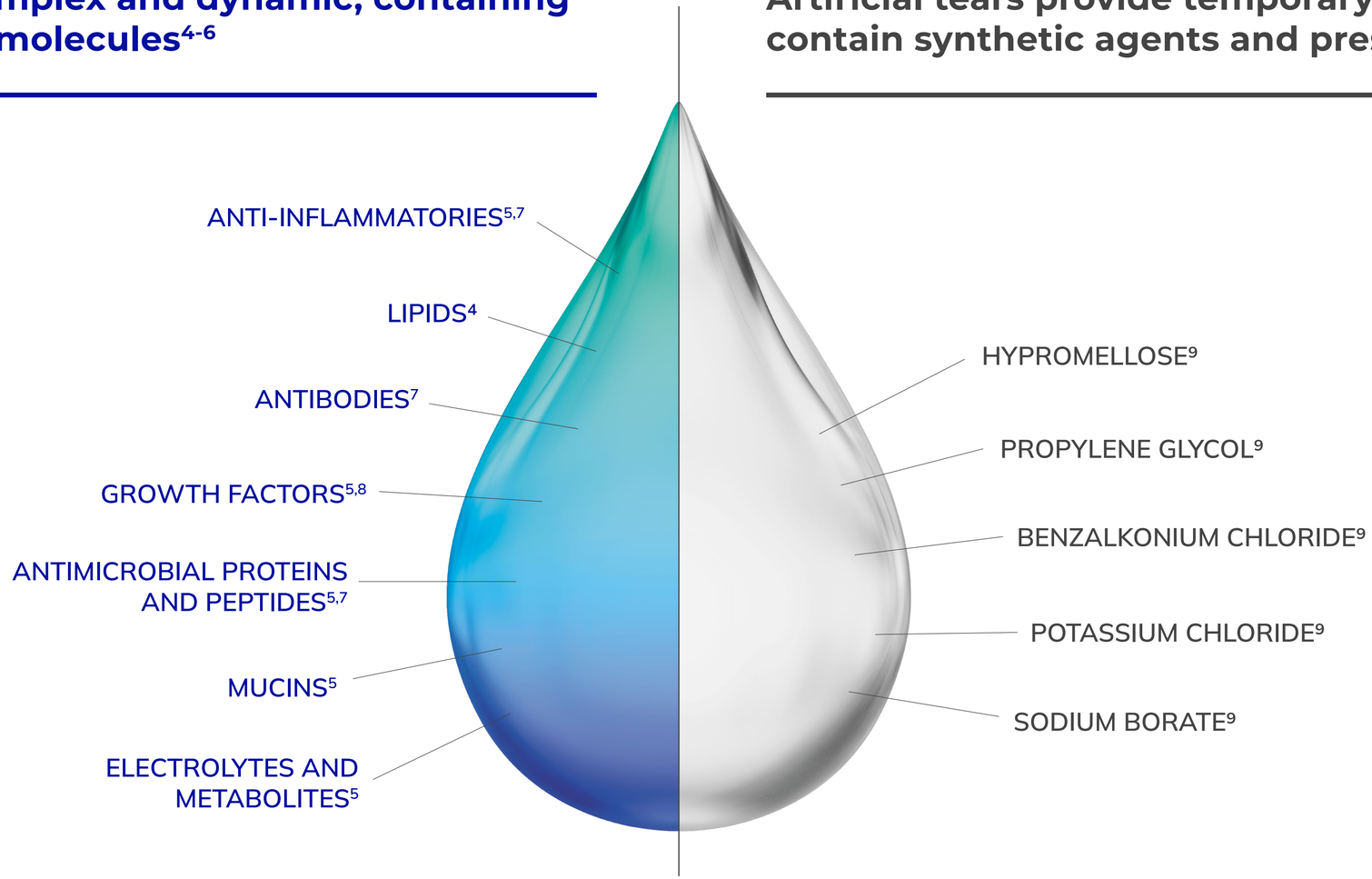
patients agree they would use a dry eye nasal spray, if effective.[2]*

*Based on 30-minute, online, quantitative surveys with 205 US dry eye patients (≥21 years of age) commissioned by Viatris Inc. Patients had a confirmed diagnosis of dry eye disease, at least 2 dry eye symptoms, and met 1 of the following criteria: currently using over-the-counter artificial tears and have never tried a prescription dry eye treatment, currently using a prescription dry eye treatment, or previously used a prescription dry eye treatment. Seventy-eight percent of patients in the survey had a response of >50 for their level of agreement with the following statement on a 0-100 scale, with 100 indicating the highest level of agreement: “I would take a treatment that would involve nasal spray delivery for Dry Eye Disease if it were effective.”

THERE IS NO SUBSTITUTE FOR YOUR PATIENTS' OWN REAL TEARS[3]

Real tears are complex and dynamic, containing more than 2000 molecules[4-6]

Artificial tears provide temporary relief & may contain synthetic agents and preservatives[9,10]



Increasing production of real tears can REDUCE the signs and symptoms of dry eye disease [11]

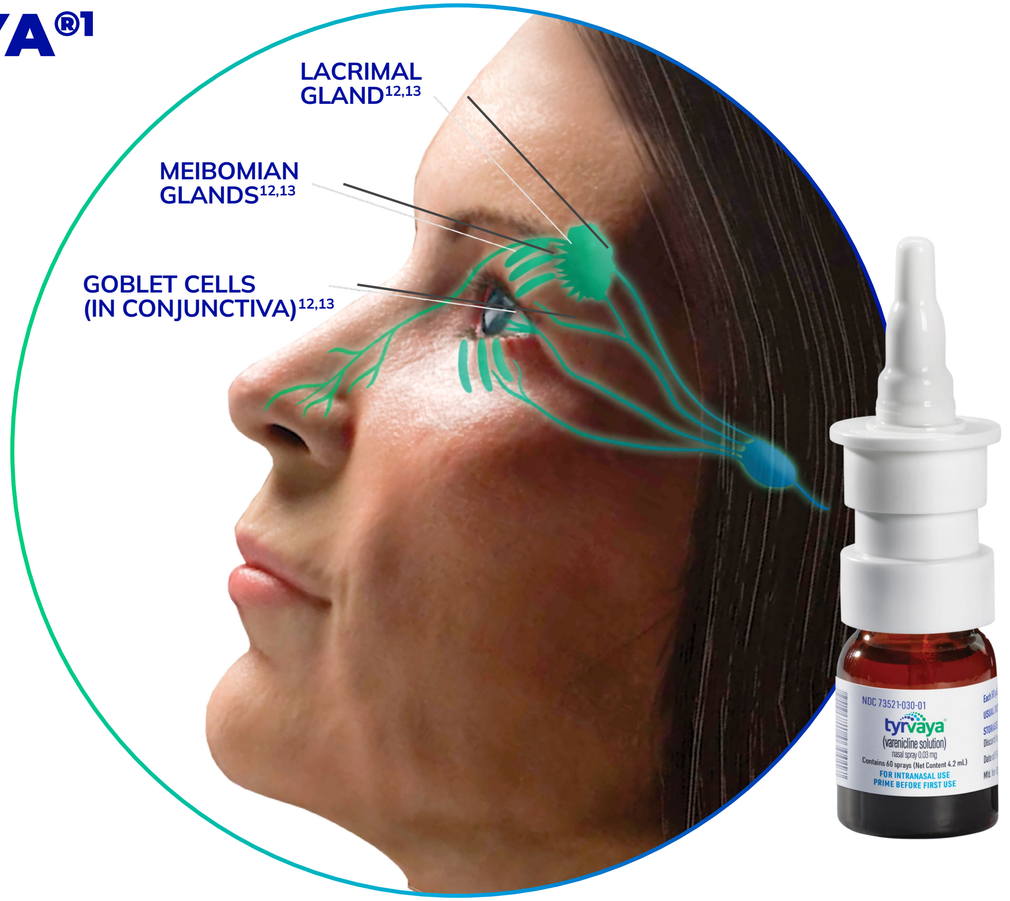
ACTIVATE REAL TEARS WITH TYRVAYA®[1]

Tyrvaya is believed to work by activating the trigeminal parasympathetic pathway via the nose to help increase the production of patients' own basal tears[1]

- The trigeminal parasympathetic pathway **innervates the lacrimal gland, meibomian glands, and goblet cells**[10,12,13]
- These glands and cells are **involved in the production of the 3 components vital to a healthy tear film:** aqueous, lipid, and mucin[10,12,13]

The exact mechanism of action is unknown.

What would **activating their own real tears** mean for your patients with dry eye?



GO TO TYRVAYA-PRO.COM TO SEE TYRVAYA IN ACTION.

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tyrvaya®
(varenicline solution)
nasal spray 0.03 mg
FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

CLINICAL TRIALS DESIGNED WITH REAL-WORLD USE IN MIND[1,6,14-17]

Two randomized, vehicle-controlled, double-masked studies in which adults aged ≥22 years diagnosed with dry eye disease received 1 spray of either active drug or vehicle in each nostril twice daily. The patient population was 74% female with a mean age of 61 years.[1,14-17]

- Enrollment not limited by baseline Eye Dryness Score (EDS) (range, 2-100 mm)[1,17]
- Use of artificial tears was allowed in both the Tyrvaya and vehicle groups[1,17]
- Studies did not include a placebo run-in period[1,17]

Patients with **mild, moderate, or severe** dry eye were enrolled[1,6,14-17]

Real tear production was measured by anesthetized Schirmer's Test Score (STS), which reduces irritation that causes reflex tearing.[1,18,19]

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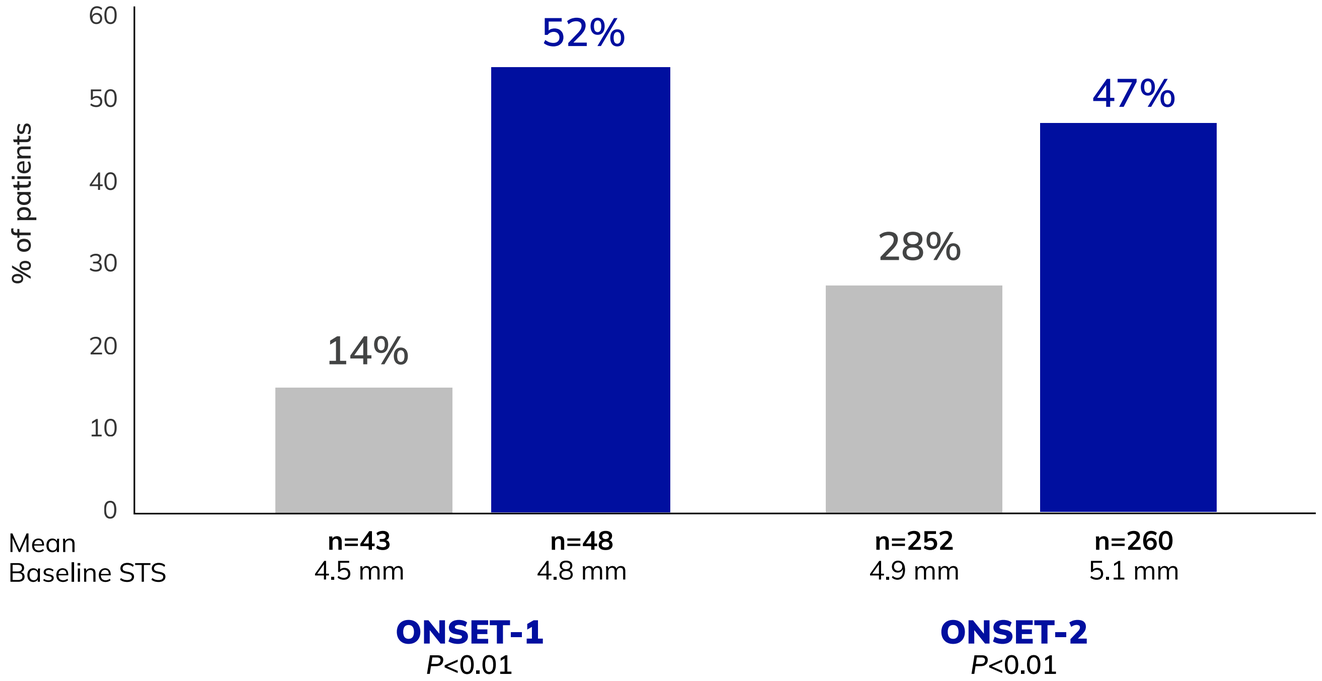
PROVEN TO INCREASE TEAR PRODUCTION BY 4 WEEKS[1,14,15]

% of Patients With ≥10-mm Increase From Baseline in STS at Week 4*



50% OF PATIENTS

Real tears, real fast: rapid increase in tear film production

Treatment Group

- Vehicle
- Tyrvaya®

A score of ≤10 mm represents abnormal tear production.[20]

*Cochran-Mantel-Haenszel (CMH) test controlling for study site, baseline STS, and baseline EDS. All randomized and treated patients were included in the analysis and missing data were imputed using last-available data.[1]

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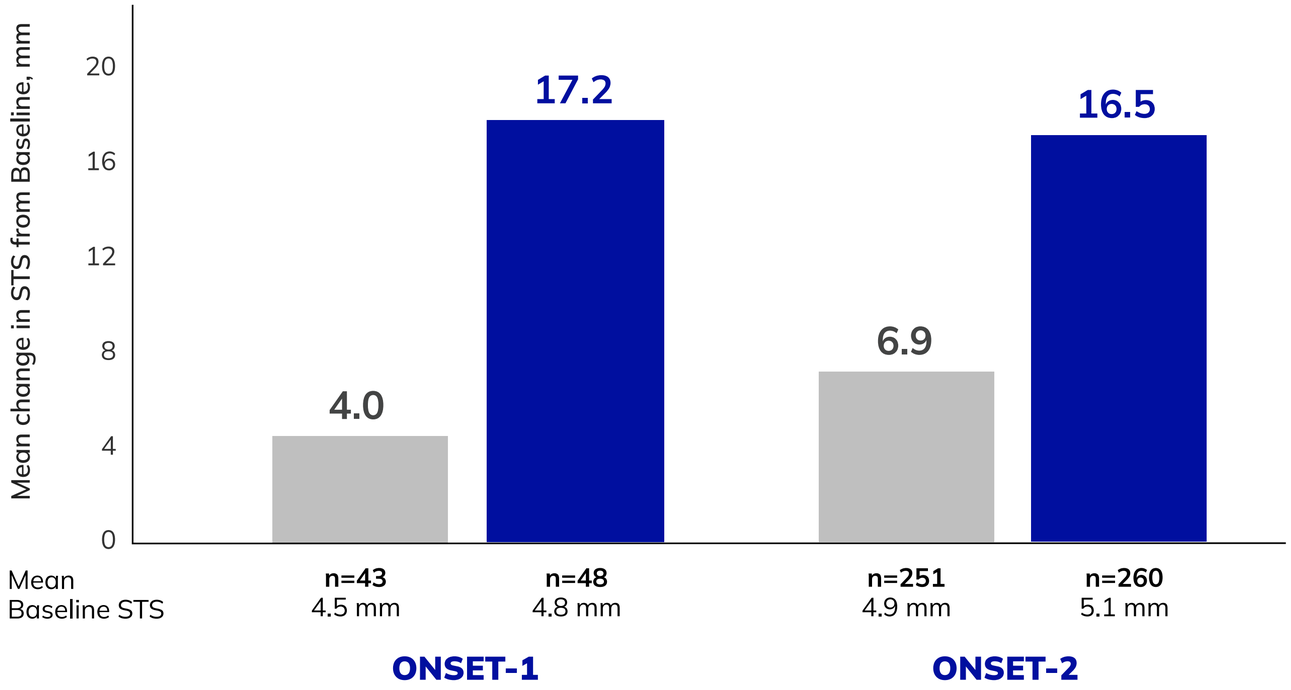
FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

ONSET OF ACTION MEASURED AS EARLY AS ~5 MINUTES FOLLOWING FIRST DOSE[16,17]

Mean change in Schirmer's Test Score (STS) ~5 minutes after first administration



~5 MIN

On average, Tyrvaya® increased real tear production **after just 1 dose**

Treatment Group

- Vehicle
- Tyrvaya®

Limitation: Not a prespecified endpoint.

Observed data.
On Day 1 in clinical studies, a baseline anesthetized Schirmer's test was performed. Tyrvaya was then administered concurrently with Schirmer's test. Schirmer's test results were measured at ~5 minutes. STS measures tear film production on a paper strip placed in the lower lid margin for 5 minutes. Score is measured from 0-35 millimeters.[1,14-17]

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FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

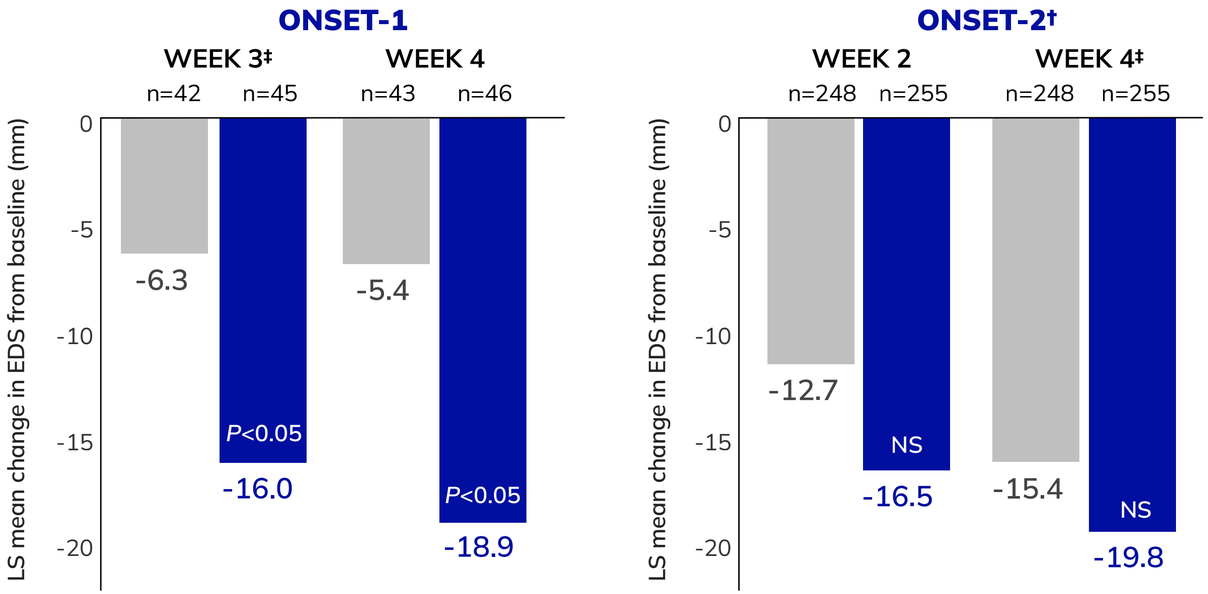
IN THE CLINIC

DELIVERED RAPID SYMPTOM IMPROVEMENT REGARDLESS OF DISEASE SEVERITY[14-17]

Symptoms of dry eye disease were measured by mean change from baseline in Eye Dryness Score (EDS) in the clinic.

Statistically significant improvement at Week 3 in ONSET-1

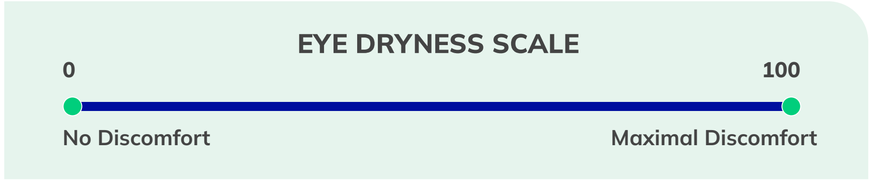
IN THE CLINIC: Mean change from baseline in EDS[14-17]*



Treatment Group

- Vehicle
- Tyrvaya®

The baseline EDS ranges for patients in ONSET-1 and ONSET-2 were 2-100 mm, representing patients with mild, moderate and severe dry eye disease[1]



EDS was rated by patients using a visual analogue scale, with a greater reduction indicating symptom relief. In ONSET-1, Tyrvaya baseline EDS range was 27–98 mm.

*ANCOVA model with treatment, site, baseline STS, and baseline EDS as covariates. Average ONSET-1 baseline EDS values: Tyrvaya 63.7 mm, vehicle 65.2 mm.[16] Average ONSET-2 baseline EDS values: Tyrvaya 58.5 mm, vehicle 58.1 mm.[17]

†Observed data.

‡ONSET-2 was conducted during the coronavirus disease 2019 pandemic. Data in the Controlled Adverse Environment (CAE®) had potential study limitations due to restricted use of the CAE chamber (i.e., data was restricted for ~30% of the study population due to social distancing restrictions and the enclosed close-proximity chamber environment).[17]

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tyrvaya® (varenicline solution) nasal spray 0.03 mg

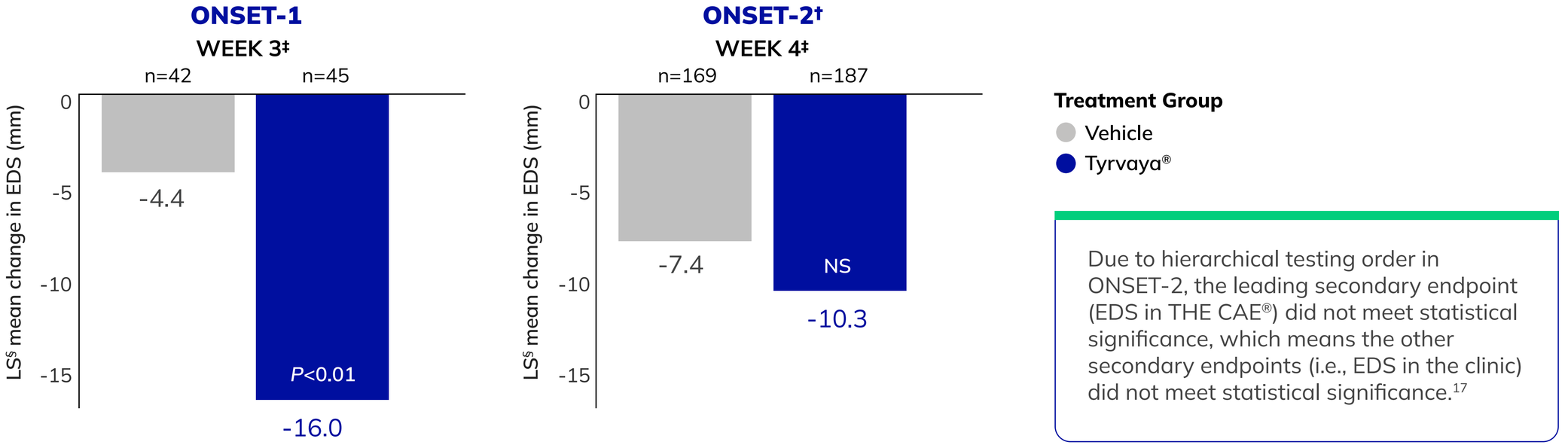
FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

IN THE CONTROLLED ADVERSE ENVIRONMENT (CAE®)

DELIVERED RAPID SYMPTOM IMPROVEMENT REGARDLESS OF DISEASE SEVERITY[14-17]

Symptoms of dry eye disease were also measured by mean change from baseline in EDS in the CAE®.[14-17]

IN THE CAE®: Mean change from baseline in EDS[14-17]*



Due to hierarchical testing order in ONSET-2, the leading secondary endpoint (EDS in THE CAE®) did not meet statistical significance, which means the other secondary endpoints (i.e., EDS in the clinic) did not meet statistical significance.[17]

Observed data.

*ANCOVA model with treatment, site, baseline STS, and baseline EDS as covariates. Average ONSET-1 baseline EDS values: Tyrvaya 63.7 mm, vehicle 65.2 mm. Average ONSET-2 baseline EDS values: Tyrvaya 58.5 mm, vehicle 58.1 mm.[17]

†Observed data.

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§Least square.

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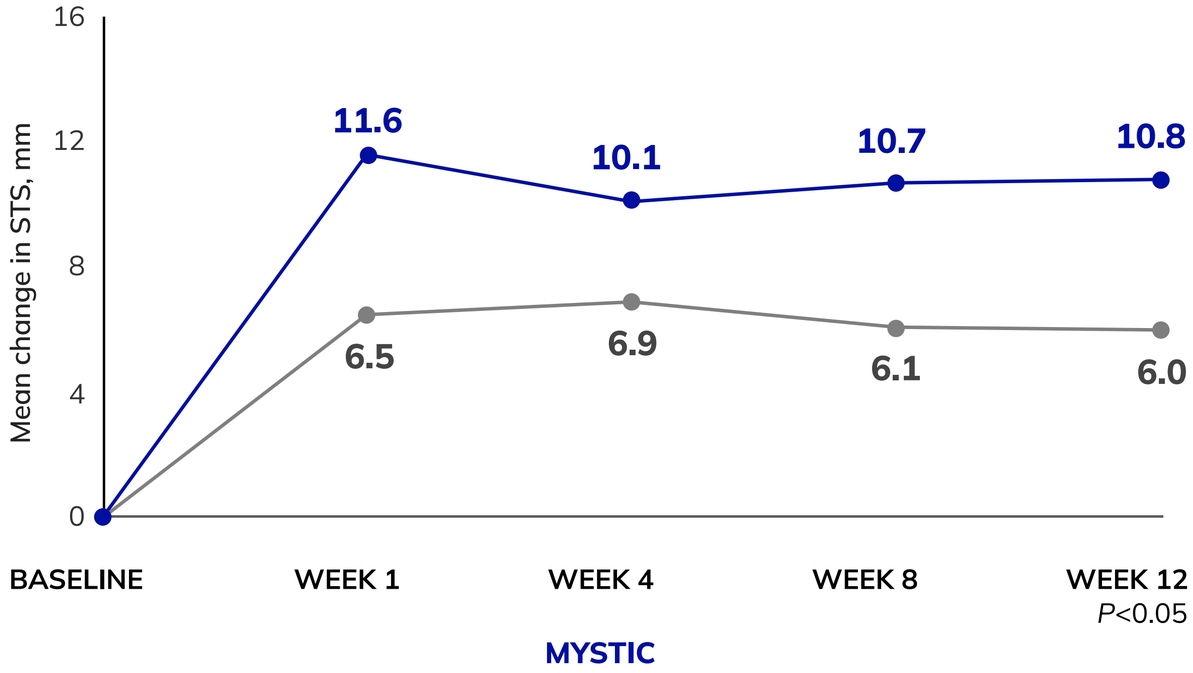
FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

INCREASE IN TEAR PRODUCTION SHOWN OVER 12 WEEKS[6,21]

Mean Change in STS Through Week 12*



12 WEEKS

Tyrvaya® showed an **increase of 10-11 mm in STS** at all measured timepoints

Treatment Group

- Vehicle
- Tyrvaya®

All subjects were Hispanic or Latino. Tyrvaya group mean baseline STS 5.5 mm (n=41); vehicle group mean baseline STS 5.3 mm (n=41).[6]

Limitation: Ex-US, single-center study. Weeks' 1, 4, and 8 were not prespecified endpoints[6]

Study design: Mystic was a phase II randomized, single-site, masked, vehicle-controlled 12-week ex-US study in which 123 adults aged ≥22 years diagnosed with dry eye disease received 1 spray of either active drug or vehicle in each nostril twice daily. The patient population was 81.3% female with a mean age of 53.8. All were Hispanic or Latino.[21]

*All randomized and treated patients were included in the analysis, and missing data were imputed using last-available data[6]

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FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

CONSIDER TYRVAYA® FOR DRY EYE PATIENTS LIKE THESE

Fiona's Challenge

Previously tried Rx dry eye drops but still symptomatic

Olivia's Challenge

Relying on artificial tears >4X/day

Gary's Challenge

Heavy drop burden due to glaucoma

Connie's Challenge

Wears contact lenses and has dry eye symptoms*

NOTE: Actor portrayals. Patient profiles are not based on actual individual patient cases.

*Use of Tyrvaya with contact lenses would be at the discretion of the eyecare professional. Patients with contact lenses were excluded from Tyrvaya clinical trials.

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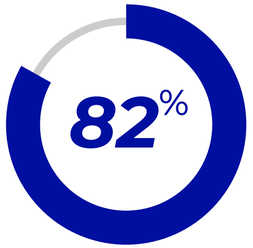
WELL TOLERATED IN CLINICAL STUDIES[1]

Most common adverse reaction[1]:

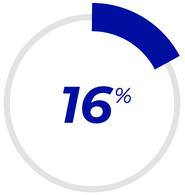


Sneezing
(287/349)

In patients who reported sneezing, the majority rated it as mild (281/287)[16]

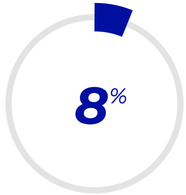
In ONSET-2, 65% of sneezing resolved within 1 minute (159/244)[16]

Other common adverse reactions that were reported in >5% of patients include[1,16,17,21]:



Cough
(55/349)

Throat irritation
(44/349)



Instillation-site (nose) irritation
(27/349)

No patients discontinued Tyrvaya® due to sneezing[16,17,21]

Discontinuation due to all adverse events across all studies was:

2.0% Tyrvaya-treated patients (7/349)[16,17,21]

2.1% Vehicle-treated patients (7/335)[16,17,21]

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FOR THE SIGNS & SYMPTOMS OF DRY EYE DISEASE

A TWICE-A-DAY NASAL SPRAY[1]

1 SPRAY IN EACH NOSTRIL | **2** TIMES A DAY | **~12** HOURS APART

Prime before initial use. Re-prime if not used for more than 5 days. If a dose is missed, patients should resume regular dosing at the next scheduled dose time.

Forget what you know about other nasal sprays. Teach your patients the Tyrvaya way to spray[1]

Please review the full Instructions for Use with your patients before they use Tyrvaya. Share these tips:

Do not spray into your sinuses
Insert and tilt the tip of the nasal spray just past the nasal opening. Aim the tip out towards your ear on the same side of the nostril you're spraying into.

Ensure proper tongue placement
Press your tongue to the roof of your mouth.

Resist inhaling the mist
Breathe gently as you press down completely and release the applicator, just misting the inside of your nostril. The medication will absorb into the wall of the nose, where the nerve you are aiming for is located.

GO TO TYRVAYA-PRO.COM TO WATCH HOW TO SPRAY THE TYRVAYA WAY.

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PRESCRIBE THE OCULAR SURFACE-SPARING NASAL SPRAY FOR DRY EYE[1]

Avoids application to an already irritated ocular surface [1,22]

Provides a preservative-free alternative to drops[22]

May allow patients to keep contact lenses in during administration*

How to prescribe Tyrvaya®

Tyrvaya 0.03 mg 8.4 mL for 30 days or Tyrvaya 0.03 mg 25.2 mL for 90 days—instill 1 spray in each nostril twice daily (approximately 12 hours apart)

Prime before initial use.
Re-prime if not used for more than 5 days
NDC#: 73521-030-02

*Use of Tyrvaya with contact lenses would be at the discretion of the eyecare professional. Patients with contact lenses were excluded from clinical trials.

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References: 1. Tyrvaya. Prescribing Information. Oyster Point Pharma. 2024. **2.** Viatris. Data on file. Patient ATU & DTC tracking. November 2023. **3.** Vicario-de-la-Torre M, Caballo-González M, Morales-Fernández L, et al. *Polymers (Basel)*. 2018;10(4):1-13. **4.** Lam SM, Tong L, Duan X, et al. *J Lipid Res*. 2014;55(2):289-298. **5.** Willcox MDP, Argüeso P, Georgiev GA, et al. *Ocul Surf*. 2017;15(3):366-403. **6.** Quiroz-Mercado H, Hernandez-Quintela E, Chiu KH, Henry E, Nau JA. *Ocul Surf*. 2022;24:15-21. **7.** McDermott AM. *Exp Eye Res*. 2013;117:53-61. **8.** Klenkler B, Sheardown H, Jones L, et al. *Ocul Surf*. 2007;5(3):228-239. **9.** Jones L, Downie LE, Korb D, et al. *Ocul Surf*. 2017;15(3):575-628. **10.** Rouen PA, White ML. *Home Health Now*. 2018;36(2):74-83. **11.** Nelson JD, Shimazaki J, Benitez-del-Castillo JM, et al. *Invest Ophthalmol Vis Sci*. 2011;52(4):1930-1937. **12**. Bron AJ, de Paiva CS, Chauhan SK, et al. *Ocul Surf*. 2017;15(3):438-510. **13.** Dartt DA, Willcox MDP. *Exp Eye Res*. 2013;117:1-3. **14.** Wirta D, Torkildsen GL, Boehmer B, et al. *Cornea*. 2022;4(10):1207-1216. **15.** Wirta D, Vollmer P, Paauw J, et al. *Ophthalmology*. 2021;0(0):379-387. **16.** Oyster Point Pharma. Data on file. OPP-002 (ONSET-1) Clinical Study Report. August 4, 2019. **17.** Oyster Point Pharma. Data on file. OPP-101 (ONSET-2) Clinical Study Report. October 13, 2020. **18.** Craig JP, Downie LE. Tears and Contact Lenses. In: Phillips A J, Speedwell L, eds. Contact Lenses. 6th ed. *Elsevier*; 2019:97-116. **19.** Aaron M, Solley WA, Broocker G. General Eye Examination. In: Palay DA, Krachmer JH, eds. *Primary Care Ophthalmology*. 2nd ed. Mosby; 2005:1-23. **20.** Akpek EK, Amescua G, Farid M, et al. *Ophthalmology*. 2019;126(1):P286-P334. **21**. Oyster Point Pharma. Data on file. OPP-004 (MYSTIC) Clinical Study Report. March 19, 2020. **22.** Nau J, Wyatt DJ, Rollema H, Crean CS. *Clin Ther*. 2021;43(9):1595-1607.

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