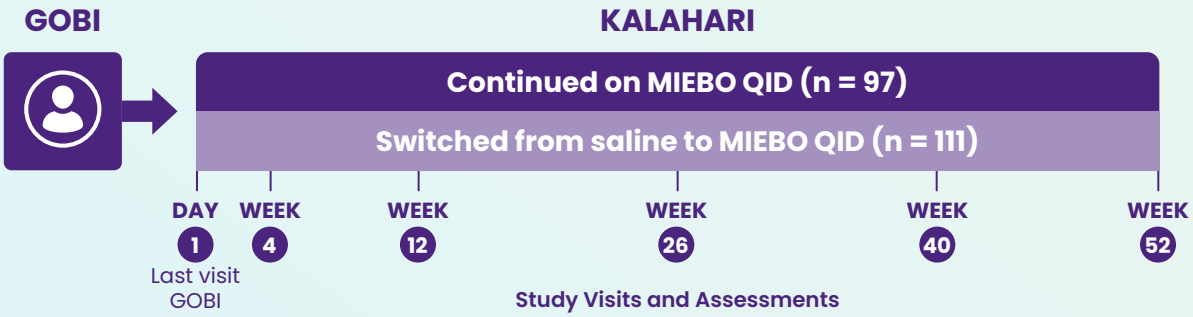
Miebo™ (perfluorohexyloctane ophthalmic solution)

FOR THE SIGNS AND SYMPTOMS OF DRY EYE DISEASE (DED)[1]

Demonstrated efficacy and excellent safety profile over 1 year, reinforcing results from MIEBO pivotal trials[2]

Outcomes from KALAHARI: A 52-week, open-label extension with 208 patients from the phase 3 GOBI study



- **The primary safety endpoint** was the incidence of ocular and non-ocular adverse events (AEs)
  - The **most common ocular AEs** were vitreous detachment (1.9% of patients, none considered treatment-related), allergic conjunctivitis (1.4%), blurred vision (1.4%), and increased lacrimation (1.4%)
  - 51 patients (24.5%) had **≥1 non-ocular AE**; most were mild (12.5%) or moderate (10.1%) in severity*
- **Efficacy endpoints included** investigator-rated corneal fluorescein staining and patient-reported symptom severity (eye dryness or burning/stinging)
  - Patients from GOBI who continued taking MIEBO **maintained the improvements in tCFS and eye dryness (VAS)** observed in GOBI, while patients from GOBI who switched from saline to MIEBO **saw improvements in tCFS and eye dryness at Week 4** that were maintained through Week 52

The results from KALAHARI demonstrated that MIEBO is an efficacious, durable Rx drop with an excellent safety profile for patients with evaporative dry eye disease.

QID, 4 times daily; tCFS, total corneal fluorescein staining; VAS, Visual Analog Scale.
Baseline ocular characteristics for patients in KALAHARI were similar between patients assigned to MIEBO or hypotonic saline control in the GOBI study.

*Only 1 non-ocular AE was considered by the investigators as related to study treatment.[3]

INDICATION

MIEBO® (perfluorohexyloctane ophthalmic solution) is indicated for the treatment of the signs and symptoms of dry eye disease.

IMPORTANT SAFETY INFORMATION

- MIEBO should not be administered while wearing contact lenses. Contact lenses should be removed before use and for at least 30 minutes after administration of MIEBO
- Instruct patients to instill one drop of MIEBO into each eye four times daily

Please see additional Important Safety Information on next page.
Click here for full Prescribing Information for MIEBO.

PHASE 3 GOBI TO KALAHARI

Sustained tolerability and efficacy results for patients with dry eye disease[2]

Excellent safety profile and tolerability over the year-long study

- Fewer than 14% of patients (n = 29) had ≥1 ocular AE. Most ocular AEs were mild in severity. No serious ocular AEs occurred

Continued improvements in the signs and symptoms of DED

- For the MIEBO-to-MIEBO arm, **improvements in tCFS and eye dryness were maintained** throughout KALAHARI
- For the saline crossover group, improvements in tCFS and eye dryness scores were **seen by Week 4 and maintained through Week 52**

Positive patient experience

- The majority of patients were satisfied with MIEBO treatment (mean VAS score [SD] at Week 52, 8.0 [2.3]) and found the study eye drops **comfortable** (8.4 [2.1]) and **easy to administer** (8.9 [1.9])
- **Most patients (~94%)** were considered compliant with dosing throughout the study*
- **Only ~5% of patients** (n = 10) used adjunctive artificial tears/mineral oil, as permitted after Week 4

To see more clinical data for MIEBO, including results from the pivotal phase 3 GOBI and MOJAVE studies, visit MIEBO-ECP.COM.

SD, standard deviation.
*Defined as administration of 80% to 120% of the expected doses.

IMPORTANT SAFETY INFORMATION (CONTINUED)

- The safety and efficacy in pediatric patients below the age of 18 have not been established
- The most common ocular adverse reaction was blurred vision (1% to 3% of patients reported blurred vision and conjunctival redness)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see additional Important Safety Information on previous page.
Click here for full Prescribing Information for MIEBO.

Study limitations include open-label design, lack of a control group, and exclusion of patients with severe dry eye (tCFS >11).

References: 1. MIEBO. Prescribing Information. Bausch & Lomb, Inc; 2023. **2.** Protzko EE, Segal BA, Korenfeld MS, Krösser S, Vittitow JL. Long-term safety and efficacy of perfluorohexyloctane ophthalmic solution for the treatment of patients with dry eye disease: the KALAHARI study. *Cornea*. Published online November 3, 2023. doi:10.1097/ICO.0000000000003418 **3.** Data on file. Bausch & Lomb, Inc; 2024.

BAUSCH + LOMB

MBO.0034.USA.24

Miebo™ (perfluorohexyloctane ophthalmic solution)