

PRODUCT PROFILE

MIEBO Perfluorohexyloctane ophthalmic solution

Manufacturer

Bausch & Lomb Americas Inc.

Indication

- Miebo is indicated for the treatment of the signs and symptoms of dry eye disease (DED).¹

Dosing and Administration

- Instill 1 drop of Miebo 4 times daily into the affected eye(s).¹
- Contact lenses should be removed prior to and for at least 30 minutes after the administration of Miebo.¹

Storage and Handling

- Miebo is supplied as a sterile, clear, and colorless liquid in multiple-dose 5-mL polypropylene bottles with drop-per tips and screw caps, all packaged in a carton.¹
- Store Miebo at 15 to 25 °C (59-77 °F). After opening, Miebo can be used until the expiration date on the bottle.¹

Safety/Warnings

- Miebo should not be administered when patients are wearing contact lenses. Advise patients that contact lenses should be removed prior to and for at least 30 minutes after administration of Miebo.¹
- The most common ocular adverse event was blurred vision. Blurred vision and conjunctival redness were reported in 1% to 3% of individuals.¹
- The safety and efficacy in pediatric patients younger than 18 years have not been established.¹

Disease State Background

- DED is a common condition in which tear film abnormalities lead to a cycle of tear hyperosmolarity and accompanying ocular surface inflammation and damage.²
- Symptoms of DED include discomfort (eg, dryness, itching, burning), visual fatigue, and blurred vision.²
- There are an estimated 16 million US adults diagnosed with DED, and the prevalence of DED increases with patient age.³
- Several factors contribute to the disease by disrupting the homeostasis of the ocular tear film.² This homeostasis may be disrupted by reduced lacrimal secretion, excessive tear evaporation, or a combination of both.² Meibomian gland dysfunction (MGD) contributes to excessive tear evaporation in an estimated 86% of patients with DED.^{4,5}

Place in Therapy

- The goal of therapy for DED is to restore tear film homeostasis to resolve ocular signs and symptoms.⁶
- The exact mechanism of action for Miebo in DED is not known, but the medication may reduce tear evaporation by forming a monolayer at the air-liquid interface of the tear film.¹
- Prescription treatments for DED include off-label topical and oral antibiotics, cyclosporine- or lifitegrast-containing prescription eye drops, corticosteroid eye drops, and varenicline nasal spray.⁶ The prescription eye drops manage signs and symptoms of DED, but they may not address the root cause of the disease.⁶
- Other treatments for DED include OTC topical lubricating eye drops, essential fatty acid supplementation, eyelid hygiene, and in-office treatments (eg, punctal plugs).⁶

Managed Care Considerations

- DED is associated with substantial visual, social, and economic impact.² Patients with DED may experience decreased quality of life including impairment of vision quality, activities of daily living, and mental health.⁴
- Patients with DED often exhibit low adherence to cyclosporine or lifitegrast eye drops, which leads to high discontinuation rates; this highlights a significant unmet need in standard treatment.⁷

Market Insights

- Miebo is the first FDA approved prescription eye drop that directly targets excessive evaporation, a key DED mechanism.¹
- The safety and efficacy of Miebo was studied in 2 randomized, double-masked, saline-controlled clinical trials—GOBI (NCT04139798) and MOJAVE (NCT04567329).^{1,7,8} In both trials, treatment with Miebo was associated with clinically meaningful improvements in signs and symptoms at week 8.^{8,9} The rate of ocular adverse events was low and similar between treatment arms in both trials.^{8,9}
- Long-term treatment of Miebo was evaluated in the phase 3 open-label KALAHARI extension trial (NCT04140227).¹⁰ Over 15 months, clinically meaningful improvements persisted, and Miebo was well-tolerated.¹⁰
- With its recent FDA approval, Miebo may address unmet needs in the DED treatment landscape.

REFERENCES

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