

MIEBO (perfluorohexyloctane ophthalmic solution)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Miebo (perfluorohexyloctane) ophthalmic solution is a semifluorinated alkane used to treat signs and symptoms of dry eye disease. Miebo is sterile, preservative-free, water-free, and steroid-free and packaged without excipients as active-ingredient only. Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. In patients whose tear evaporation is excessive due to an altered tear liquid layer, Miebo forms a monolayer at the air-liquid interface of the tear film and reduces evaporation. The exact mechanism of action is unknown (1-2).

Regulatory Status

FDA-approved indication: Miebo is a semifluorinated alkane indicated for treatment of the signs and symptoms of dry eye disease (DED) (1).

Each multidose bottle contains 3 mL of Miebo. The Miebo drop is small (11 μL), with each bottle containing approximately 270 drops, providing a 1 month supply (3).

The safety and effectiveness of Miebo in pediatric patients less than 18 years of age have not been established (1).

Summary

Miebo (perfluorohexyloctane) ophthalmic solution is used to treat dry eye disease (DED). It contains 100% of active ingredient, and free from water, preservative, and steroid. Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. In patients whose tear production is presumed to be suppressed due to ocular inflammation due to dry eye disease, Miebo forms a monolayer at the air-liquid interface of the tear film and reduce evaporation. The exact mechanism of action is unknown. Patient should be advised that contact lenses should be removed prior to and for at least 30 minutes after administration of Miebo. The safety and effectiveness of Miebo in pediatric patients less than 18 years of age have not been established (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of



Federal Employee Program.

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Miebo while maintaining optimal therapeutic outcomes.

References

- 1. Miebo [package insert]. Bridgewater, NJ: Bausch & Lomb Americas Inc.; May 2023.
- Dry Eyes Syndrome Preferred Practice Pattern. American Academy of Ophthalmology.
 September 2018.
- 3. The MIEBO experience. Accessed from: https://www.miebo-ecp.com/the-miebo-experience/.