



Omk1[®]-LF

Citicoline and Hyaluronic Acid in Liposomal Ophthalmic Solution

TECHNICAL DATA SHEET

1. PRODUCT NAME

OMK1[®]-LF

2. CATEGORY

MEDICAL DEVICE **CE** Class IIa.

3. DESCRIPTION AND CHARACTERISTICS

Sterile ophthalmic solution preservative free in a bottle of 10 ml.

4. COMPOSITION

Citicoline monosodium salt*, Hyaluronic acid monosodium salt, Hydrogenated phospholipids, Sodium phosphate dibasic dihydrate, Sodium phosphate monobasic dihydrate, Sodium chloride, Highly purified water.

*Citicoline – Kyowa Hakko Bio, Japan



5. NATURE AND CONTENTS OF CONTAINER

Cardboard box containing 1 bottle of 10 ml.

6. PROPERTIES

OMK1[®]-LF is an ophthalmic solution containing 2% Citicoline and 0,075% of high molecular weight Hyaluronic acid in a liposomal formulation that acts as a carrier for Citicoline. The solution is slightly opalescent, white in color.

OMK1[®]-LF, thanks to the presence of Citicoline, gives a useful and beneficial structural support in restoring the integrity of cell membranes damaged by degenerative eye pathologies, as Glaucoma.

7. INTENDED USE

OMK1[®]-LF, thanks to the presence of Citicoline and to its structural action on retinal ganglion cells, is indicated as coadjuvant to antihypertensive therapy in Glaucomatous patients.

Moreover, the wetting and protective properties of the product ensure ocular relief in case of irritation, burning and foreign body sensation caused by environmental factors, eye surgery or conjunctivitis.

8. METHOD OF USE

It is recommended to instill 1 drop 3 times daily, as needed.

9. WARNINGS

Shake before use.

Do not use if the bottle is damaged. Do not use in case of incompatibility to any preparation component.

Do not use after the expiry date printed on the pack. Avoid contact of the tube-tip with the eye.

A temporary blurring of vision may occur after its administration. It is suggested to wait a few seconds before starting any activity which requires visual clarity. Wait 10-15 minutes after its use before instilling ophthalmic medicinal product for topical use. The product shall be used within 30 days after first opening.

Keep the product out of the reach and sight of children. The product is only for external ophthalmic use.

Do not store above 25°C. Do not disperse the bottle after the use.

10. SHELF LIFE

24 months from the date of production.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

12. MANUFACTURER

Omikron Italia s.r.l. – Rome - Italy.

13. PRODUCER

Bulk: NIOLIP S.r.l. - Pomezia (RM) - Italy

Finished Product: C.O.C. Farmaceutici S.r.l. – Rovereto (MO) Italy

OMK1[®]-LF is an Omikron Italia s.r.l. International Patent.

European Patent n° EP2538918

United States Patent n° US8822429

Japanese Patent n° JP5801324

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