



Omk1[®]

(Citicoline and Hyaluronic Acid in ophthalmic solution)

TECHNICAL DATA SHEET

1. PRODUCT NAME

OMK1[®]

2. CATEGORY

MEDICAL DEVICE Class IIa

3. DESCRIPTION ^{CE} AND CHARACTERISTICS

Sterile ophthalmic solution in a bottle of 10 ml for topical use.

4. COMPOSITION

Citicoline monosodium salt*, Hyaluronic acid, Sodium phosphate monobasic monohydrate, Sodium phosphate dibasic dodecahydrate, Sodium chloride, Benzalkonium chloride, Water for Injection.

*Citicoline – Kyowa Hakko Bio, Japan

5. NATURE AND CONTENTS OF CONTAINER

Cardboard box containing 1 bottle of 10 ml.

6. PROPERTIES

OMK1[®] is an ophthalmic solution containing 2% of Citicoline and 0,2% of high molecular weight Hyaluronic acid.

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

Furthermore, thanks to Hyaluronic acid and to its mucoadhesive and viscoelastic properties, OMK1[®] is able to establish a favorable microenvironment for ocular surface repairing processes in cases of corneal and conjunctival epithelia damage, improving tear film stability and thus maintaining the ocular surface lubricated, hydrated and protected.

7. INTENDED USE

OMK1[®], 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.

9. WARNINGS

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 use before instilling ophthalmic medicinal product for topical use. The product must be used within 30 days after first opening. Keep OMK1[®] out of the reach and sight of children. The product is only for external ophthalmic use.

Do not dispose the bottle in the environment after use.

The product contains benzalkonium chloride (0.01%).

Benzalkonium chloride, even if at low concentration, may cause eye irritation, especially in people suffering with chronic dry eye or corneal disease. If you experience abnormal sensations, burning or pain after using this eye drops, contact your doctor.

In case of prolonged use, patients with chronic dry eye or corneal disease shall be kept under observation.

Benzalkonium chloride can be absorbed by soft contact lenses and can change its color. It is recommended to remove the contact lenses before using the product and to wait 15 minutes before putting them back.

10. SHELF LIFE

36 months from the date of production.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

12. MANUFACTURER

Omikron Italia s.r.l. – Roma - Italy

13. PRODUCER

Farmigea S.p.A. – Pisa - Italy

Tubilux Pharma S.p.A. - Pomezia (RM) - Italy

OMK1[®] is an International patent Omikron Italia s.r.l.

European Patent n° EP2538918

United States Patent n° US8822429

Japanese Patent n° JP5801324