



FOR THE TREATMENT OF SEVERE DRY EYE:

- Stabilizes the tear film
- Has a long-lasting effect
- Improves quality of vision
- Helps to maintain a healthy ocular surface
- Contains a unique, safe and biocompatible preservative system



TECHNICAL DESCRIPTION

Lubricating ophthalmic solution with Sodium Hyaluronate and Vitamin B12

Sodium Hyaluronate 0,3%, P-Plus™, Vitamin B12, Sodium Chloride, Potassium Chloride, Calcium Chloride, Magnesium Chloride, SCO® in an isotonic buffered solution.

VISIONLUX® PLUS is a refreshing, revitalizing and lubricating ophthalmic solution, containing **Sodium Hyaluronate 0,3%**, obtained by fermentation and not of animal origin. The activity of the **Sodium Hyaluronate** is optimised and prolonged by the synergic action of P-PlusTM.

P-Plus™ is a hydrosoluble polymer with filmogenous and lubricant properties. The association of **Sodium Hyaluronate and P-Plus™** not only increases the viscosity of the solution but also improves its mucoadhesivity properties.

The presence of **Electrolytes** (Cl⁺, Na⁺, K⁺, Ca⁺⁺ and Mg⁺⁺), essential for the cellular biochemical processes, helps to keep the ocular surface in good physiological conditions. Vitamin B12 (Cyanocobalamine) has antioxidant properties, thus protecting the ocular surface from the damage induced by reactive oxygen species (ROS). It is therefore an essential factor in the maintenance of a healthy ocular surface.

VISIONLUX® PLUS is preserved with a special preservative system called SCO® (Stabilized Complex Oxychloro) that keeps the solution sterile in the bottle. When exposed to light, SCO® dissipates into components naturally found in human tears such as sodium chloride, oxygen and water, making it very well tolerated.

VISIONLUX® PLUS provides long and lasting relief to the sensations of severe dry, stressed and tired eyes of pathological or non-pathological origin.

VISIONLUX® PLUS protects cells from damaging oxidative free radicals and replaces locally low levels of the nutrients in the tears.

VISIONLUX® PLUS is compatible with all types of contact lenses.

INSTRUCTIONS FOR USE

- . Wash, rinse and dry your hands thoroughly
- Make sure the seal is intact.
- To open the bottle, unscrew the top completely and break the safety seal.
 Instill 1 or 2 drops in each eye, as required, or according to the specialist's advice.
- · Close the bottle tightly after use.

- To prevent possible contamination, do not let the tip of the dropper come into contact with any surface or the eye.
- Do not use in case of specific hypersensitivity towards any of the constituents.
- In some cases, slight sensitivity may cause a brief stinging or irritation upon instillation that disappears after blinking.
- . Do not swallow the solution
- . Keep out of the sight and reach of children.
- After the bottle has been opened, the solution must be used within 90 days.
- . Do not use after the expiry date.
- · If symptoms persist, consult your eye specialist.
- Do not use if the bottle is damaged. • Do not expose to direct sunlight.

• Store between 5 and 35°C and protect from a direct source of light.







NOVAX®PHARMA

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1. In vitro evaluation of the cytoxicity, Novax Pharma Data - 2. Delayed hypersensitivity test on guinea pig maximization test, Novax Pharma Data - 3. Ocular irritation test, Novax Pharma Data - 4. Compatibility with contact lenses, Novax Pharma Data - 5. Evaluation of the microbiological stability, Novax Pharma Data - 6. In vitro evaluation of the mucoadhesivity on reconstructed human cornea-like epithelium, Novax Pharma Data - 7. Lubricant eye drops. The electrolyte factor, Jeffrey P. Gilbard MD& Dennis Pardo OD July 15 2005 - 8. Vitamins and polymers in the treatment of ocular surface disease, Dr. Frank J.Holly February 2004 - 9. Tear Substitutes, Mark B. Abelson, George Ousler, Russel Anderson October 2016 - 10. Hyaluronan: A review of its properties, ophtalmic uses and research, Marjorie Rah OD PhD. 11. Kaur et al., Cutan Ocul Toxicol. 2009;28(3):93-103. 12. Jain et al., J Clin Exp Ophthalmol 2017, 8:5

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SODIUM HYALURONATE 0,30%

- Sodium Hyaluronate is a highly hydrophilic physiological polymer.
- Sodium Hyaluronate provides VISIONLUX® PLUS with biophysical properties similar to those of natural tears.
- Sodium Hyaluronate has an optimum molecular weight.

P-PLUS[™]

- P-PLUSTM has filmogenous, bioadhesive and lubricant properties.
- P-PLUS[™] enhances the effectiveness of sodium hyaluronate.
- P-PLUSTM is a substitute for mucin in artificial tears.
- P-PLUSTM improves tear break-up time (TBUT), and symptoms in severe dry-eye patients.

ELECTROLYTES

 The presence of electrolytes (Ca⁺⁺, Mg⁺⁺, K⁺, Cl⁻, Na⁺) helps keep the surface of the eye in good physiological condition.



VITAMIN B12

- Vitamin B12 is an essential factor in maintaining a healthy ocular surface.
- Vitamin B12 has anti-oxidant properties, which protect the ocular surface from damage induced by reactive oxygen species (ROS).
- Vitamin B12 is often lacking in severe dry-eye patients suffering from neuropathic ocular pain.

SCO® THE ADVANCED PRESERVATIVE TECHNOLOGY (STABILIZED COMPLEX OXYCHLORO)

SCO® is an oxidative-type preservative and a mixture of chlorine dioxide, chlorite and chlorate. When exposed to light, SCO® dissociates into components naturally found in the human tears such as sodium chloride, oxygen and water, making it very well tolerated.

What are the benefits of SCO®

- SCO® only remains in its original form when inside the eye drop bottle.
- As soon as it leaves the bottle as part of a drop it reacts with light and rapidly dissipates into components naturally found in human tears such as sodium chloride, oxygen and water without causing any cellular damage to the ocular surface.
- SCO® has been shown to be much safer on the ocular surface than those eye drops preserved with other chemical preservatives.
- SCO® is SAFE, EFFECTIVE, GENTLE and COMFORTABLE.





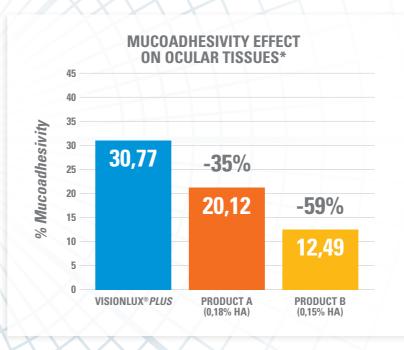




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SEVERE DRY EYE

IN VITRO EVALUATION OF MUCOADHESIVITY ON RECONSTRUCTED HUMAN CORNEA-LIKE EPITHELIUM AND VISCOSITY DETERMINATION



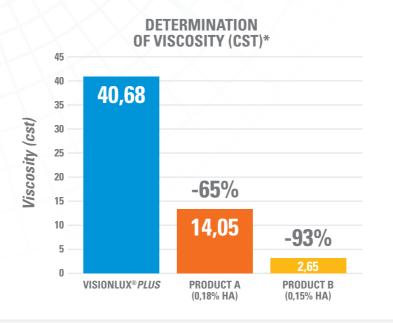
AIM

Evaluation of in vitro mucoadhesivity effect of the products on ocular tissues.

RESULTS

VISIONLUX® PLUS is 35% and 59% more mucoadhesive compared to other existing products found on the market.

*The tests are available for consultation in the Novax bibliographic files



AIM

Viscosity comparison between the products.

RESULTS

VISIONLUX® PLUS is 65% and 93% more viscous compared to other existing products found on the market.

*The tests are available for consultation in the Novax bibliographic files

CONCLUSIONS

- VISIONLUX® PLUS has superior properties compared to other existing products on the market.
- Association of Sodium Hyaluronate and P-Plus™, not only increases the viscosity of the solution but also improves its mucoadhesivity properties.

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