

MEDICAL DEVICE  
CLASS II B



LUXYAL<sup>®</sup>  
PLUS  
EYE DROPS

MULTIDOSE LUBRICATING  
SOLUTION WITH A BIODEGRADABLE  
PRESERVATIVE SCOR<sup>®</sup>

A NEW TEAR SUBSTITUTE FOR  
THE TREATMENT OF SYMPTOMS  
OF MILD TO MODERATE DRY EYE

LUXYAL<sup>®</sup>  
PLUS  
EYE DROPS

## TECHNICAL DESCRIPTION<sup>(1)</sup>

### COMPOSITION

**Sodium Hyaluronate 0,3%, PEG 400**, Potassium Chloride, Calcium Chloride, Magnesium Chloride, Sodium Chloride, **SCOR**<sup>®</sup>, in an isotonic buffered solution.

### DESCRIPTION

**LUXYAL<sup>®</sup> PLUS** is a refreshing 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 **PEG 400**.

**PEG 400** is a hydro soluble polymer with filmogenous and lubricant properties. The association of **Sodium Hyaluronate and PEG 400** not only increases the viscosity of the solution but also improves its mucoadhesivity properties.

The presence of **Electrolytes** (Cl<sup>-</sup>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup> and Mg<sup>++</sup>), essential for the cellular biochemical processes, helps to keep the ocular surface in good physiological conditions.

**LUXYAL<sup>®</sup> PLUS** contains **SCOR**<sup>®</sup> (Stabilised Complex Oxichloro) a special preservative system that keeps the solution sterile in the bottle and once in contact with the eyes, dissipates into components already found in human tears (Na<sup>+</sup>, Cl<sup>-</sup>, O<sub>2</sub>, and H<sub>2</sub>O) so **it is not irritating or toxic** for the ocular mucosa and helps to maintain healthy the epithelial cells.

### INDICATIONS

**LUXYAL<sup>®</sup> PLUS** provides long and lasting relief in the cases of dry eye sensation, tired eye conditions, associated with itching burning, foreign body ingress and irritation of the eye, caused by pathological or non-pathological conditions associated with external factors such as prolonged exposure to video screens and monitors, air conditioning, air pollution, smoke etc<sup>(3)</sup>.

**LUXYAL<sup>®</sup> PLUS** is compatible for the use with all types of contact lenses<sup>(4)</sup>.

### INSTRUCTIONS FOR USE

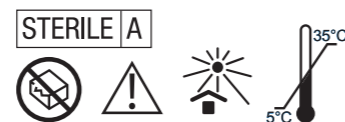
- Wash, rinse and dry your hands thoroughly.
- Make sure the seal is intact.
- To open the bottle, unscrew the top completely and break the safety seal.
- Instill 1 or 2 drops in each eye, as required, or according to the specialist's advice.
- Close the bottle tightly after use.

### WARNINGS

- 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<sup>(6)</sup>.
- In some cases, slight sensitivity may cause a brief stinging or irritation on the instillation that disappears after blinking<sup>(5,7)</sup>.
- 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 expose to direct sunlight.**

### STORAGE

- Store between 5° and 35°C.



Manufacturer:  
**NOVAX<sup>®</sup> PHARMA**  
Le Coronado  
20 avenue de Fontvieille  
MC98000 MONACO

CE  
0051  
Rev. 18/07/2019

**NOVAX<sup>®</sup>**  
PHARMA

The information reported here is meant to be used only by physicians  
BR LUP REV 01 16/09/2022  
Le Principe de Stappier



## STATE OF THE ART TEAR PRODUCT

A new tear substitute to relieve  
symptoms of mild to moderate dry eye

**NOVAX<sup>®</sup>**  
PHARMA

### BIBLIOGRAPHIC REFERENCES

(1) Tear substitutes, M.B. Abelson, G. Ousler, R. Anderson, Albert&Jakobiec's Principles&Practices of Ophthalmology, Chapter 27, 2016. (2) Effectiveness of hyaluronan on corneal epithelial barrier function in dry eye, N. Yokoi, A. Komuro, K. Nishida, S. Kinoshita, 1997, British Journal of Ophthalmology. (3) Ocular Surface Diseases, 2016 World Ophthalmic Congress in Mexico. (4) Contact Lens Compatibility test Luxyal Plus, Novax Pharma data. (5) Cytotoxicity test Luxyal Plus, Novax Pharma data. (6) Hypersensitivity test Luxyal Plus, Novax Pharma data. (7) Ocular irritation Luxyal Plus, Novax Pharma data. (8) Mucoadhesivity test, Novax Pharma data. (9) Brochure SCOR, Novax Pharma internal data.



FOR THE RELIEF OF SYMPTOMS ASSOCIATED WITH DRY EYE

MEDICAL DEVICE CLASS II B



- ✓ **HIGH LUBRICATING POWER**  
*Stabilises the lachrymal film*
- ✓ **HIGH VISCOSITY POWER**  
*Long-lasting effect, improved vision quality*
- ✓ **HIGH MUCOADHESIVITY ACTION<sup>(8)</sup>**  
*Bioadhesive to the corneal epithelium*
- ✓ **A SAFE BIODEGRADABLE PRESERVATIVE**  
*Absence of epithelial toxicity*
- ✓ **COMPATIBLE WITH ALL TYPES OF CONTACT LENSES<sup>(4)</sup>**

**SODIUM HYALURONATE 0,30%<sup>(2)</sup>**

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

**ELECTROLYTES**

- The presence of electrolytes (Ca<sup>++</sup>, Mg<sup>++</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Na<sup>+</sup>) helps keep the surface of the eye in good physiological condition.

**PEG 400**

- PEG 400 has filmogenous, bioadhesive and lubricant properties.
- PEG 400 enhances the effectiveness of sodium hyaluronate.
- PEG 400 is a substitute for mucin in artificial tears.
- PEG 400 improves tear break-up time (TBUT), and symptoms in severe dry-eye patients.

LUXYAL<sup>®</sup> PLUS is a lubricating ophthalmic solution, containing Sodium Hyaluronate extracted from a fermentation process (not from animal origin), associated to PEG 400, a filmogenous polymer that provides an optimal and prolonged comfort.

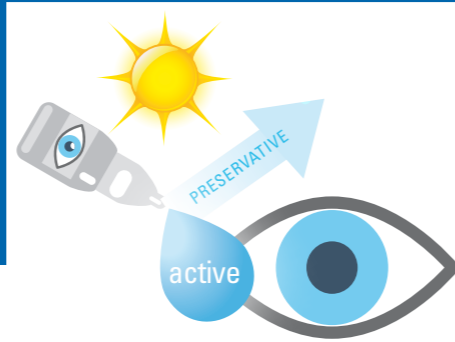
This association increases the efficacy of the Sodium Hyaluronate and optimises the viscoelastic properties of LUXYAL<sup>®</sup> PLUS eye drops.

**SCO<sup>®</sup> THE ADVANCED PRESERVATIVE TECHNOLOGY (STABILIZED COMPLEX OXYCHLORO)<sup>(9)</sup>**

SCO<sup>®</sup> is an oxidative-type preservative and a mixture of chlorine dioxide, chlorite and chlorate. When exposed to light, SCO<sup>®</sup> 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<sup>®</sup> :

- SCO<sup>®</sup> 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<sup>®</sup> has been shown to be much safer on the ocular surface than those eye drops preserved with other chemical preservatives.
- SCO<sup>®</sup> is SAFE, EFFECTIVE, GENTLE and COMFORTABLE.

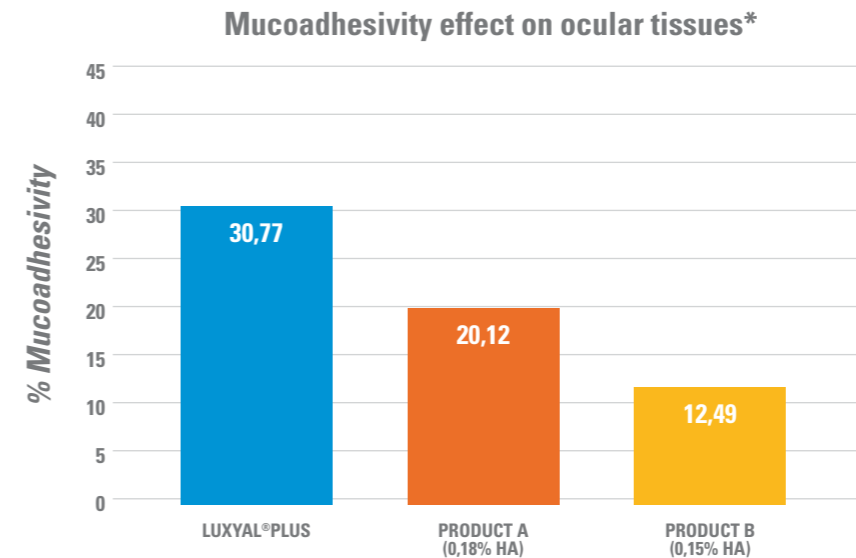


SCO<sup>®</sup> provides nothing BUT water, oxygen & natural electrolytes to the eyes.

THE BEST PERFORMING TEAR IN TERMS OF VISCOSITY AND MUCOADHESIVITY



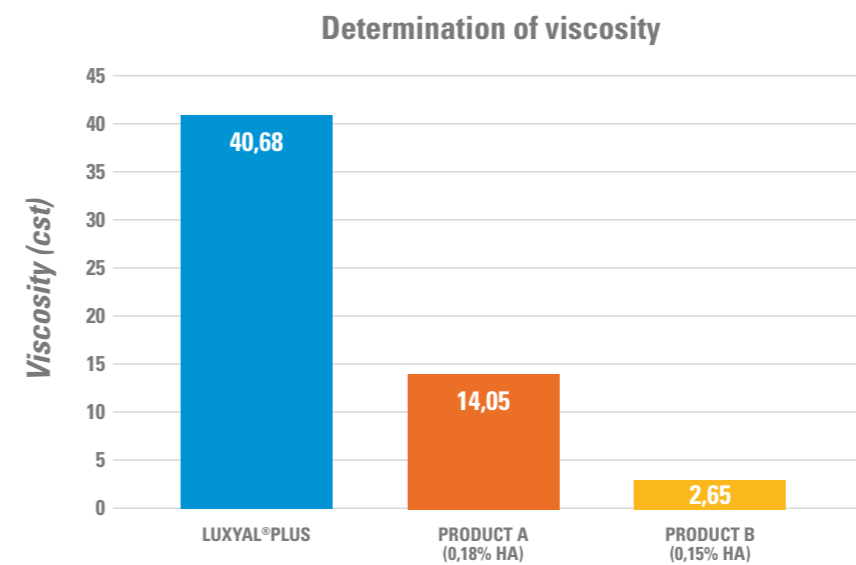
**In vitro evaluation of mucoadhesivity on reconstructed human cornea-like epithelium and viscosity determination**



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

**AIM: The aim of the test is to evaluate the in vitro mucoadhesivity of the tested products.**

The results showed that the mucoadhesivity of the sample LUXYAL<sup>®</sup> PLUS is 30.77% higher than the mucoadhesivity of Product A (20.12%) and of Product B (12.49%).



LUXYAL<sup>®</sup> PLUS has a significantly higher viscosity compared to Product A (0,18 % HA) and Product B (0,15 % HA).

**CONCLUSIONS**

**LUXYAL<sup>®</sup> PLUS has superior properties compared to other existing products on the market. The association of Sodium Hyaluronate and PEG 400 not only increases the viscosity of the solution but also improves its mucoadhesivity properties.**