

MEDICAL DEVICE
CLASS II B



LUBRICATING SOLUTION
WITH A BIODEGRADABLE
PRESERVATIVE

SCO™




NOVAX®
PHARMA

Antioxidant and lubricant ophthalmic solution with
sodium hyaluronate, vitamin A, vitamin E and Carboxymethyl β -glucan

Protects and soothes

Dry eyes
Contact lens wearing
Oxidative stress due to light exposure and/or an increase in free radicals on the ocular surface
Ocular irritation caused by pathologies such as keratitis, adverse effects following corneal surgery, traumatic ulcers, corneal inflammation

Sodium Hyaluronate 0,15%

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

Vitamin A

- Stabilizes the fatty phase of the tear film
- Helps to maintain natural hydration
- Reduces the symptoms of ocular dryness



SCO™ THE ADVANCED PRESERVATIVE TECHNOLOGY (Stabilised 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.

es the ocular surface

1 or 2 drops in each eye

3 to 6 times a day, or according to medical prescription



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Vitamin E

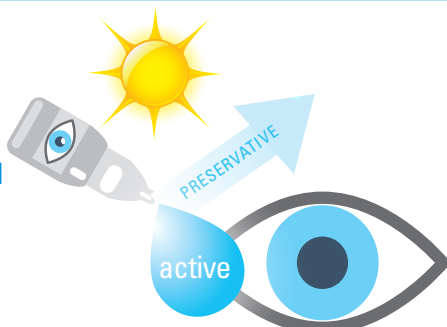
- Antioxidant
- Reduces the concentration of free radicals in the lachrymal fluid
- Enhances the protection of corneal and conjunctival epithelial cells
- Decreases the risk of inflammation

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Carboxymethyl β -glucan

- Is a viscoelastic agent
- Has a lubricating effect

SCO™
PROVIDES
NOTHING BUT
WATER, OXYGEN
& NATURAL
ELECTROLYTES
TO THE EYES.



Bibliography

1. Carboxymethyl beta-glucan binds to corneal epithelial cells and increases cell adhesion to laminin and resistance to oxidative stress. Porcu M, Guarna F, Formentini L, Faraco G, Fossati S, Mencucci R, Rapizzi E, Menchini U, Moroni F, Chiarugi A. (Jan. 2007). 2. Vitamins and Polymers in the Treatment of Ocular Surface Disease. Dr. Frank J. Holly (February 2004) 3. Tear Substitutes Mark B. Abelson, George Ousler and Russell Anderson (2016). 3. Carboxymethyl beta-glucan binds to corneal epithelial cells and increases cell adhesion to laminin and resistance to oxidative stress - Porcu M, Guarna F, Formentini L, Faraco G, Fossati S, Mencucci R, Rapizzi E, Menchini U, Moroni F, Chiarugi A. - 2007 Jan;26(1): 73-9. 4. Efficacy of antimicrobial preservation on Navitae Plus - Novax Pharma internal data. 5. Citotoxicity - agar diffusion test on Navitae Plus - Novax Pharma internal data. 6. Compatibility between Navitae Plus and soft contact lenses - Novax Pharma internal data. 7. Delayed Hypersensitivity test on Navitae Plus - Novax Pharma internal data. 8. Ocular irritation on Navitae Plus - Novax Pharma internal data.



TECHNICAL DESCRIPTION

NAVITAE®PLUS contains polysaccharidic lubricants such as Sodium Hyaluronate and Carboxymethyl Beta-glucan, and a protective lubricant lipophilic system composed of Vitamin A and pegylated Vitamin E.

The topical ocular use of Vitamin A improves contact lens wearing by reducing the frictional, mechanical damage that they can cause on epithelial cells of the cornea and conjunctiva.

Vitamin A stabilizes the fatty phase of the lachrymal film by increasing its capacity to maintain natural hydration, therefore reducing the symptoms of ocular dryness. This activity is also exerted by the polysaccharides present in the product.

Vitamin E is an antioxidant that helps to reduce the concentration of free radicals in the lachrymal fluid, and therefore enhances the protection of corneal and conjunctival epithelial cells, decreasing the risk of inflammation.

NAVITAE®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 the human tears such as sodium chloride, oxygen and water, making it very well tolerated.

INDICATIONS:

NAVITAE®PLUS is a lubricant ophthalmic solution with an antioxidant and moisturizing effect used for the relief of dry eyes and ocular discomfort caused by:

- Ocular irritation caused by pathologies such as keratitis, adverse effects following corneal surgery, traumatic ulcers, corneal inflammation.
- Oxidative stress due to light exposure and/or an increase in free radicals on the ocular surface.
- Contact lens wearing.

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

INSTRUCTIONS FOR USE:

Instill 1 or 2 drops into each eye, 3 to 6 times a day, or according to the specialist's advice.

COMPOSITION:

Sodium Hyaluronate 0,15%, Carboxymethyl Beta-Glucan, Vitamin A Palmitate, Vitamin E TPGS, SCO™ in an isotonic solution buffered pH 7,0.

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.
- In some cases, slight sensitivity may cause a brief stinging or irritation upon instillation that disappears after blinking.
- If the ocular irritation persists and you experience pain, redness or change in vision following the instillation, consult your specialist.
- Do not swallow the solution.
- Keep out of the sight and reach of children.
- Do not use the solution after the expiry date.
- After the bottle has been opened, the solution must be used within 90 days.
- Do not use if the bottle is damaged.
- Do not expose to direct sunlight.

STORAGE:

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



Manufacturer:
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Rev. 06/07/2018

NOVAX®
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