

MEDICAL DEVICE
CLASS II A



PRESERVATIVE FREE HYPERTONIC SOLUTION FOR THE REDUCTION OF CORNEAL OEDEMA

TECHNICAL DESCRIPTION

COMPOSITION:

Sodium Chloride 5%, Sodium Hyaluronate 0,3%, P-Plus™, Potassium Chloride, Calcium Chloride Dihydrate, Magnesium Chloride Hexahydrate and purified Water.

GENERAL DESCRIPTION:

Corneal oedema refers to the swelling of the cornea following ocular surgery, trauma, infection, and inflammation. It can also be a consequence of various ocular diseases or following over-wear of certain types of contact lenses.

INDICATIONS:

NAVI®NaCl 5% PF is a hypertonic ophthalmic solution designed to reduce symptoms of corneal oedema. The solution contains a high concentration of Sodium Chloride, which creates a hypertonic tear film that draws excess fluid out of the cornea by osmotic effect, therefore providing temporary alleviation from the symptoms of oedema

BIBLIOGRAPHY

- [1] Clinical Results After Sodium Treatment in Post-operative Corneal Oedema Gaëlle Ho Wang Yin1,2,3*, Natanael Levy1
- [2] Ocular preservatives: associated risks and newer options Indu Pal Kaur, Shruti Lal, Cheena Rana, Shilpa Kakkar & Harinder Singh
- [3] Corneal oedema and its medical treatment Ciro Costagliola, Vito Romano, Eliana Forbice, Martina Angi, Arduino Pascotto, Tiziana Boccia, Francesco Semeraro
- [4] ophthalmic squeeze dispenser_osd_oct_2017 Degenhard Marx, PhD, and Matthias Birkhoff

The information reported here is meant to be used only by physicians

Le Principe de Stappier

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PHARMA

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NEW

NAVI®NaCl

5% PF

Hypertonic solution for the alleviation of
symptoms associated with corneal oedema



NOVAX®
PHARMA



- ✓ **Provides temporary alleviation of symptoms of oedema**
- ✓ **Improves eye lubrication**
- ✓ **Sustains normal corneal thickness**
- ✓ **Preservative free**

NAVI® NaCl

5% PF

CORNEAL OEDEMA⁽²⁾⁽³⁾

To perform its primary function of light refraction, the cornea must be relatively thin & dehydrated, with a smooth anterior surface.

In a normal cornea, optical transparency is directly related to the state of hydration of the tissue: If the cornea swells, it increases in thickness and its surface becomes irregular, impairing its optic properties.

Corneal oedema refers to the retention of excess fluid within one or multiple layers of the cornea. The over-hydration of the cornea can have different etiologies including mechanical, dystrophic, inflammatory and toxic causes.

Therefore the use of a hypertonic solution such as sodium chloride 5%:

- Reduces the oedema by drawing water out of the cornea,
- Improves vision and alleviates symptoms of discomfort.

OSD TECHNOLOGY

Ophthalmic Squeeze Dispenser⁽⁴⁾

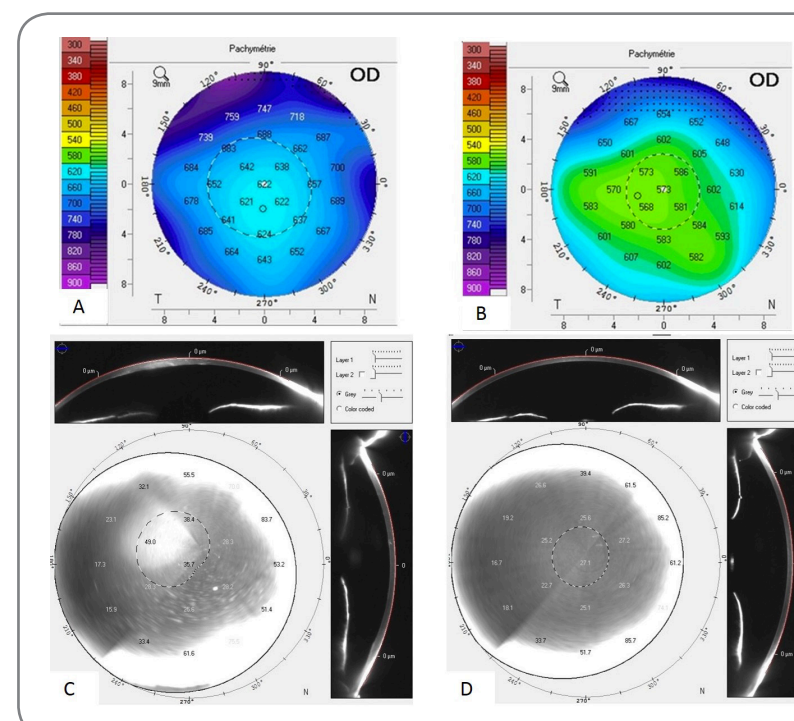
The OSD (Ophthalmic Squeeze Dispenser) technology allows the innovative delivery of a sterile preservative-free ophthalmic solution.



- Manufactured by APTAR
- Multidose Preservative-Free System
- Sterility is guaranteed by the innovative drop dispenser
- Patient friendly device
- Convenient and intuitive to use

EVALUATION OF THE EFFECTIVENESS OF 5% SODIUM CHLORIDE TREATMENT

CLINICAL RESULTS AFTER SODIUM TREATMENT IN POST-OPERATIVE CORNEAL OEDEMA



Example of pachymetric and densitometric maps in a patient treated by 5% hyperosmolar sodium chloride. A decrease in pachymetry and densitometry is observed from D1 to D7.

STUDY DESIGN

- Randomized study.
- 95 participants with post-operative corneal oedema.
- Treatment options:
 - a. Classical post-operative treatment = antibiotics, corticosteroids and artificial tears.
 - b. 5% sodium chloride + 0.15% sodium hyaluronate eye drops.
- 2 groups:
 - Group 1:** 45 patients treated with a + b.
 - Group 2:** 50 patients treated with a only.

RESULTS OF THE STUDY

The mean pachymetry was significantly reduced at day (D) 7 in group 1 (decrease of 17%, $p=0.04$), contrary to group 2 ($p=0.96$).

CONCLUSION

5% sodium chloride hypertonic eye drops treatment significantly reduces post operative corneal oedema as shown by the downward trend in pachymetry.

Reference to Bibliography[1]
Clinical Results After Sodium Treatment in Post-operative Corneal Oedema Gaelle Ho Wang Yin & Natanael Levy.
The Journal of Eye Diseases and Disorders 2018 3:1. The present article does not refer to Novax Pharma product.

P-PLUS™

- P-PLUS™ has filmogenous, bioadhesive and lubricant properties.
- P-PLUS™ enhances the effectiveness of sodium hyaluronate.
- P-PLUS™ improves tear break-up time (TBUT)

HA 0,30%

- Sodium Hyaluronate is a highly hydrophilic physiological polymer.
- Sodium Hyaluronate has biophysical properties similar to those of natural tears.
- Sodium Hyaluronate has an optimal molecular weight.

CONCLUSION

A SOLUTION WITH 5% NaCl CAN IMPROVE SYMPTOMS OF CORNEAL OEDEMA BY:

- Improving eye lubrication
- Reducing corneal thickness