



TRB CHEMEDICA

OPHTHALMIC LINE

NAME OF PRODUCT:

LASERVIS®

INTENDED USE:

Viscous masking and wetting solution in excimer laser surgery and other surgical procedures.

COMPOSITION:

Active ingredient:

Sodium hyaluronate 0.25%

Excipients:

Sodium chloride, potassium chloride, disodiumhydrogenphosphate, sodium citrate, magnesium chloride, calcium chloride, glucose, water for injection.

PRESENTATION:

One strip containing 5 sterile mono-use units. Each unit contains 2ml of 0.25% sodium hyaluronate for ophthalmic use. LASERVIS® is sterile by moist heat.

DOSAGE AND ADMINISTRATION:

Viscous Masking Solution:

Take a sterile mono-use container out of the sachet, twist off the cap and attach an appropriate sterile

canula. Squeeze the container and apply the product evenly onto the surface of the cornea or the stroma before, and alternating with, laser treatment. Sufficient solution should be applied to cover the entire surface of the cornea. The product may also be applied onto the surface of the eye before bandaging or applying other post-treatment protection.

Viscous Wetting Solution: Apply LASERVIS® as often as necessary so as to ensure that the cornea remains wet during the whole surgery.

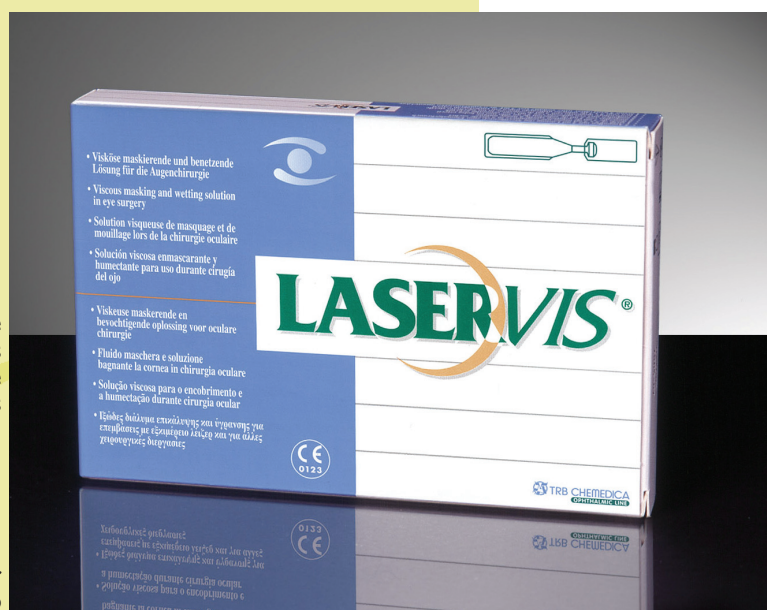
As LASERVIS® does not contain preservatives, any solution not used during the procedure should be discarded.

BACKGROUND AND RATIONALE:

Viscous Masking Solution: In the last few years, excimer-laser surgery has been increasingly used and today can be considered as a standard method in refractive surgery of myopia and for therapeutic purposes. Although the performance of laser machines has reached a very high level, there is still the need for an adequate masking solution which contributes to a smooth surface of the cornea or the stroma, improved refraction, less post-operative complications (such as haze) and better wound healing. Various attempts have been made in the search for a suitable masking solution in experimental trials^{1,2} with solutions of different viscosifying agents, but the results obtained were not satisfactory mainly due to the inadequate viscoelasticity of these solutions.

Viscous Wetting Solution: In current surgical procedures, hot microscope lights and the high volume of circulating air in the operating room rapidly desiccate the corneal surface when eyelids remain retracted. This leads to a loss of corneal transparency, a decrease in visualisation of surgical field, micropunctate keratitis and decreased epithelial cell viability, which results in prolonged post-operative recovery of patients.

In order to limit corneal desiccation, the surgeon or his/her assistant usually keeps the surface moist by periodically flushing the corneal surface with a saline solution.



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2. **E.W. Kornmehl et al. (1991):**
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3. **S.A. Arshinoff, E. Khoury. (1997)**
HsH versus a balanced salt solution as a corneal wetting agent during routine cataract extraction and lens implantation. *J Cataract Refract Surg*; 23:1221-5
4. **T. Nishida et al. (1991):**
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10. **A. Caporossi et al. (2001):**
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11. **J.L. Alio, J.I. Belda, A.M. Shalaby (2001):**
Correction of irregular astigmatism with excimer laser assisted by sodium hyaluronate. *Ophthalmology*; 108(7):1246-60.
12. **E. Dal Fiume et al. (1993):**
Valutazione della tollerabilità di una soluzione salina sterile viscosizzata in pazienti sottoposti ad intervento di chirurgia oculare. *Ravenna, Clinical Report*, data on file.
13. **I.F. Wessels, R. DeBarge, D. A. Wessels (1998)**
Salvaged viscoelastic reduces irrigation frequency during cataract surgery. *Ophthalmic Surg Lasers*; (8):688-91.
14. **Biocompatibility:**
Data on file.

CHARACTERISTICS AND MODE OF ACTION

Viscous Masking Solution: LASERVIS® contains sodium hyaluronate (SH), a natural polymer which is also present in the structures of the eye. The physical characteristics of SH confer important rheological properties to the product. LASERVIS® has been formulated to have a photo-ablation rate similar to that of corneal tissue. LASERVIS® forms a stable and uniform coating on the delicate surfaces of the eye, filling depressions on the cornea and effectively masking tissues to be protected against ablation by the laser pulses. It has also been shown that SH improves the wound healing process by stimulating corneal epithelial migration *in vitro*⁴ and by promoting the proliferation of cultured epithelial cells⁵.

This contributes to a smoother surface of the cornea or the stroma after the procedure and to a reduction of scar formation, regression and haze.

Results of studies in which SH was used as a masking fluid following PTK and PRK showed that fewer patients suffered loss of Visual Acuity (VA)^{6,7} and post-operative hyperopic shifts. Furthermore irregular astigmatism (IA) was avoided⁸ and ablation depth precision improved⁹.

Caporossi¹⁰ showed that the eyes smoothed with LASERVIS® after standard PRK surgery had faster re-epithelialisation, faster visual recovery and fewer subjective symptoms of ocular dryness compared with the standard PRK procedure. Alio¹¹ demonstrated that LASERVIS® was effective in the correction of IA by improving the superficial corneal surface quality, image distortion, VA, safety and efficacy indices.

Viscous Wetting Solution: Due to the unique non-Newtonian behaviour of SH, LASERVIS® uniformly coats the entire surface of the eye and significantly increases tear film break-up time compared to a balanced saline solution. In addition, SH exhibits water entrapping and mucoadhesive properties, which delay the evaporation of the product from the eye surface. As a result, LASERVIS® ensures that the cornea remains wet and transparent during surgical procedures and minimises visual obstruction of the surgical field, thus improving the surgeon's concentration.

SH, used as a corneal viscous wetting solution in patients who underwent cataract surgeries¹³, showed that the average frequency of irrigation as well as volume of solution used were significantly reduced compared to those using saline. Dal Fiume¹² further demonstrated that LASERVIS® favorably reduces the onset of post-surgery haze in different types of surgeries and facilitates the suturing procedures.

BIOCOMPATIBILITY:

Results of acute, sub-acute and chronic toxicity studies together with the results of foetal toxicity, fertility, peri- and post-natal toxicity studies show that sodium hyaluronate is well tolerated¹⁴. The tolerability of LASERVIS® was assessed on corneal cell culture and eye culture. The results showed that LASERVIS® was well tolerated by corneal cells and that the degree of tolerability was similar to that observed for cells exposed to saline solution. The eye culture studies confirmed that LASERVIS® and saline solution were equally well tolerated.¹⁴

INTERACTIONS:

LASERVIS® may modify the effects of drugs administered concomitantly on the eye.

STORAGE AND SHELF LIFE:

Store at room temperature, below 25°C, in original box, away from heat sources and light. Shelf life is 3 years if stored undamaged in its original package.



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