NAME OF PRODUCT: VISIOL®

INTENDED USE: Viscoelastic solution for use as a surgical aid in surgery of the anterior and posterior segments of the eye including:
• Cataract extraction
• Intraocular lens (IOL) implantation
• Corneal transplantation surgery
• Glaucoma filtering surgery
• Surgical procedures to re-attach the retina.

COMPOSITION:
Active ingredient: Sodium hyaluronate 2.0%
Excipients: Sodium chloride, sodium monohydrogenphosphate, sodium dihydrogenphosphate, mannitol and water for injection. The solution is isotonic, adjusted to pH 7.3.

PRESENTATION: One sterile pre-filled syringe containing 20mg/1.0ml sodium hyaluronate in a sterile pouch and one sterile cannula size 25 G.

DOSAGE AND ADMINISTRATION:
Take VISIOL® out of the refrigerator 30 minutes prior to use. Take the pre-filled syringe out of the pouch, remove the cap from the Luer-Lok, attach the cannula (25 G) and secure it by turning slightly.

Cataract surgery and IOL implantation: VISIOL® can be used at any stage of the cataract surgery to create a deep anterior chamber, protect the tissues and facilitate the IOL implantation. Extrude the required amount of VISIOL® slowly and carefully into the anterior chamber through the cannula. VISIOL® may also be used to coat the surgical instruments and IOL before insertion. Additional VISIOL® can be injected during surgery, if needed.

Corneal transplant surgery: Remove the corneal button and fill the anterior chamber with VISIOL® until it is level with the surface of the cornea. Place the donor graft on top of VISIOL® and suture into place. Additional VISIOL® can be injected during surgery, if needed.

Glaucoma filtering surgery: When performing the trabeculectomy inject the required amount of VISIOL® slowly and carefully into the anterior chamber through a paracentesis. Additional VISIOL® can be injected during surgery, if needed.

Retinal attachment surgery: After release of subretinal fluid, inject the required amount of VISIOL® slowly and carefully into the vitreous cavity.

CHARACTERISTICS: Sodium hyaluronate, the active principle in VISIOL®, is a polysaccharide which consists of repeating sequences of glucuronic acid and N-acetylglicosamine. It is present in the extracellular matrix, in particular in the vitreous humour. The highly purified sodium hyaluronate, obtained by fermentation, in VISIOL® has an average molecular weight of 1.8 million.
Daltons. VISIOL® exhibits a pseudoplastic flow behaviour, i.e. the viscosity decreases when the shear rate is increased. The extrapolated zero-shear viscosity is approximately 60,000 mPas, as determined in accordance with the ISO norm No.15798:2001.

MODE OF ACTION:
1. VISIOL® helps create and maintain anterior chamber depth and visibility at all stages of the anterior segment surgery and minimises interaction between tissues during surgical manipulation. VISIOL® also serves as a tamponade and vitreous substitute in surgeries of the posterior segment, such as retinal re-attachment surgery.
2. VISIOL® protects intraocular tissues, such as the corneal endothelium, from damage due to the use of surgical instruments. VISIOL® may also be used to coat the surgical instruments and IOL before insertion.
3. VISIOL® also protects the corneal endothelium against damage caused by free radicals.
4. The mannitol present in VISIOL® helps maintain the rheological properties of the sodium hyaluronate during phacoemulsification in cataract surgery.
5. VISIOL® preserves tissue integrity and provides good visibility when used to fill the anterior and posterior segments of the eye following open sky procedures.

PRECAUTIONS AND SIDE EFFECTS:
The normal precautions associated with anterior segment and retinal attachment surgeries should be observed to avoid intra- and/or post-operative increase in intraocular pressure (IOP). VISIOL® should be removed by irrigation/aspiration at the end of the procedure. Clinical trials have shown that VISIOL® did not cause clinically significant elevation in IOP if some product remained in situ after the surgery.

BIOCOMPATIBILITY:
Results of acute, sub-acute and chronic toxicity studies together with the results of fertility, peri- and postnatal toxicity studies show that sodium hyaluronate is well tolerated.

INTERACTIONS:
Avoid using VISIOL® with instruments sterilised with quaternary ammonium salts solution.

STORAGE AND SHELF LIFE:
Store between 2-8°C in original sterile pack. Do not freeze. Shelf life of 3 years if stored in original unopened package at the correct temperature.

PACKAGING:
One pre-filled syringe of 20mg/1.0ml VISIOL® in a sterile pack. To be used by a physician only.

REFERENCES:
1. International Standard ISO 15798. 2001
   International Organization for Standardization
   Ophthalmic implants - Ophthalmic Viscosurgical Devices
2. TRB Chemedica SA
   data on file
   Protection of viscoelastic substances (sodium hyaluronate and 2% hydroxyethylcellulose) against experimental free radical damage to the corneal endothelium. Cornea 12(2):09-14.
   Sodium hyaluronate - based ophthalmic formulation for use in eye surgery
5. Lane SS, Naylor DW, Kullerstrand LJ, Knauth K, Lindstrom RL. 1991