Viscoelastic gel for use in ocular surgery

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 1 ml syringe containing of 20 mg of sodium hyaluronate in a sterile pack 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 sterile pack, unscrew the Luer lok cap from the syringe, 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 AND MODE OF ACTION:
Sodium hyaluronate, the active principle in VISIOL®, is a polysaccharide which consists of repeating sequences of glucuronic acid and N-acetylglucosamine. 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.15798:2001.¹
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® acts as a free radical scavenging, limits the breakdown of sodium hyaluronate and therefore 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 postoperative 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 foetal toxicity, fertility, perinatal and post-natal 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 20 mg/1.0 ml VISIOL® in a sterile pack and one sterile cannula size 25 G.

To be used by a physician only.

REFERENCES: