Viscoelastic gel for use in ocular surgery

NAME OF PRODUCT:
VISIOL®

INDICATIONS:
Viscoelastic solution indicated for use as a surgical aid in the surgery of the anterior segment of the eye such as cataract surgery, intraocular lens (IOL) implantation, corneal transplantation surgery and glaucoma filtering surgery.

COMPOSITION:
Sodium hyaluronate 2%, disodium phosphate, sodium dihydrogen phosphate, mannitol and water for injections. The solution is isotonic (270-330 mOsmol/kg) with pH ranging from 6.8 - 7.5.

DOSAGE AND ADMINISTRATION:
The content and outer surface of the VISIOL® pre-filled syringe are sterile as long as the sterile pack remains unbroken. Take the pre-filled syringe out of the sterile pack, unscrew the Luer-Lock cap, attach a suitable needle (for example ophthalmologic needle 25 G) and secure by turning slightly. Remove any air bubble, if present, before injection.

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

CHARACTERISTICS AND MODE OF ACTION:
Sodium hyaluronate (SH), 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 synovial fluid and the umbilical cord. The highly purified SH, obtained by fermentation in VISIOL® has an average molecular weight of 1.7-1.8 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 tested in compliance with ISO 15798.[1]

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.
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. SH protects the corneal endothelium against damage caused by free radicals.[2] In addition, mannitol contained in VISIOL® acts as a free radical scavenger, slows down the degradation of sodium hyaluronate long chains by reactive oxidative species and therefore helps maintain the rheological properties of SH during phacoemulsification in cataract surgery.[3, 4]
4. VISIOL® preserves tissue integrity and provides good visibility during eye surgery.

PRECAUTIONS AND SIDE EFFECTS:

The normal precautions associated with eye surgery should be observed to avoid intra- and/or post-operative increase in intraocular pressure (IOP).[5, 6] The product must be administered with care and under close monitoring, particularly in patients with pre-existing glaucoma and in cases of glaucoma surgery. If intra-ocular pressure rises above normal after surgery, appropriate treatment should be provided. The product should be removed by irrigation and/or aspiration at the end of the procedure. Clinical trials have shown that VISIOL® did not cause clinically significant increase in IOP if some product remained in situ after the surgery.[7] For detailed information please refer to the instructions for use.

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 SH is well tolerated.

INTERACTIONS:

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

STORAGE AND SHELF-LIFE:

Store between 2-25°C in original sterile pack. Do not freeze. Shelf life of 3 years if stored in original unopened packaging at the correct temperature.

PACKAGING:

One pre-filled syringe of 20 mg/1.0 ml VISIOL® in a sterile pack.

To be used by a physician only.

REFERENCES:

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4. Belda JI, Artola A, Garcia-Manzanares MD, Ferrer C, Haroun HE, Hassanein A, Baeyens V, Munoz G, Aliò JL. J Cataract Refract Surg 2005; 31:1213–8.
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6. Holzer MP, Tetz MR, Auffarth GU, Welt R, Volcker HE. J Cataract Refract Surg 2001; 27(2):213-8.
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