PRODUCT INFORMATION

FORMULA
Each ml of Biolon® contains:

Sodium hyaluronate	10 mg
Sodium chloride	8.5 mg
Disodium hydrogen phosphate dodecahydrate	0.56 mg
Sodium dihydrogen phosphate dihydrate	0.05 mg
Water for injections	q.s.

DESCRIPTION
Sodium hyaluronate is a physiological material found in both animal and human tissues. It is a polysaccharide consisting of a repeating disaccharide of N-acetylglucosamine and sodium glucuronate, linked by alternating β-1,3 and β1,4 glycosidic bonds. Chemically identical in all species, hyaluronate can be found in the vitreous and aqueous humor of the eye, in synovial fluid, in skin and in the umbilical cord. Biolon® is a sterile 1% solution of highly purified, high molecular weight viscoelastic sodium hyaluronate in phosphate-buffered saline. When introduced into the anterior segment of the eye during surgical procedures, Biolon® maintains a deep anterior chamber throughout surgery, facilitates surgery and reduces trauma to the corneal endothelium and surrounding tissues. Its viscoelasticity also helps to repel the vitreous face and discourage formation of a post-operative flat chamber. In posterior segment surgery, Biolon® serves as a surgical aid in separating, moving, and holding tissues. Biolon® creates a clear field of vision for inspection of the retina and for photocoagulation during and after surgery. It does not interfere with epithelization and normal wound healing. Any traces of Biolon® left in the anterior segment of the eye after surgery dissipate through Schlemm's canal within a week.

INDICATION
Eye surgery, including intraocular lens insertion, intracapsular and extracapsular lens extraction, glaucoma surgery, corneal graft surgery for accidental trauma, retinal detachment and vitreal replacement procedures.

CONTRAINDICATIONS
When used as recommended, there are no known contraindications.

PRECAUTIONS
Precautions are limited to those normally associated with the surgical procedures being performed. Instilling excessive amounts of Biolon® into the anterior or posterior segments of the eye may increase intraocular pressure. Increased postoperative intraocular pressure may also be caused by a pre-existing glaucoma condition or by compromised outflow and by operative procedures and sequelae thereto, including enzymatic zonulysis, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber. Because these factors vary from case to case and are difficult to predict, the following precautions are recommended: Do not overfill the eye with Biolon®. Avoid using large amounts of Biolon® for posterior segment procedures in aphakic diabetic patients. At the end of the surgery, all remaining Biolon® should be removed by irrigation or aspiration. Carefully monitor the intraocular pressure, especially during the immediate postoperative period. If a significant increase in pressure is observed, treat appropriately. Avoid the trapping of air bubbles behind Biolon®. Biolon® is a very highly purified substance extracted from bacterial cells. Since the presence of minute quantities of impurities (proteins, etc.) cannot be totally excluded, the physician should be aware of immunological, allergic and other potential risks associated with the injection of biological substances. On rare occasions, viscoelastic products containing sodium Hyaluronate have been observed to become slightly opaque or to

form a slight precipitate upon instillation into the eye. The clinical significance, if any, of this phenomenon is not known. The physician should, however, be aware of this possibility, and, should it be observed, the cloudy or precipitated material should be removed by irrigation and/or aspiration. Avoid re-use of the cannula. If re-use is necessary, rinse the cannula thoroughly to remove all traces of residual materials.

DOSAGE
Dosage varies with type of surgery. Usually a dose of 0.2 to 0.6 ml is injected into the anterior segment of the eye. Greater amounts are used in the posterior segment.

EXAMPLES OF SURGICAL APPLICATIONS
Cataract Surgery: Before lens extraction, Biolon® is introduced into the anterior chamber to protect the corneal endothelium and to maintain a deep anterior chamber. Additional amounts may also be introduced before implantation of an intraocular lens, and to coat the artificial lens and the surgical instruments.

Glaucoma Surgery: Biolon® is instilled before the trabeculectomy in order to reconstitute the anterior chamber. At the close of surgery, further instillation of Biolon® may be required to achieve good sub-conjunctival filtration and to prevent tissue adherences.

Corneal Transplant Surgery: In trepanation of the cornea, the anterior chamber is filled with Biolon®. The donor graft should be placed on the surface of the solution and sutured into position. Additional amounts Biolon® may be injected to maintain a deep anterior chamber. Biolon® may also be used in the anterior chamber of the donor eye to protect the corneal endothelial cells of the graft prior to trepanation, and to protect the exposed endothelial layer of the donor button during preparation of the recipient eye.

Retinal and Vitreous Surgery: Biolon® should be introduced slowly into the vitreous cavity. By carefully directing the injection, Biolon® can be used to separate membranes from the retina for safe excision and release of traction. Biolon® also helps in moving tissues into desired positions. For example, it is helpful in gently pushing back a detached retina, in unrolling a retinal flap, or in holding the retina against the sclera during reattachment.

INCOMPATIBILITIES
Mixing of quaternary ammonium salts such as benzalkonium chloride with sodium hyaluronate solutions results in formation of a precipitate. Biolon® should not be administered through a cannula previously used with medical solutions containing benzalkonium chloride.

ADVERSE REACTIONS
Biolon® is well-tolerated in the human eye. Transient rises of post-operative intraocular pressure have been reported in some cases. A causal relationship has not been established between
Biolon® use and postoperative inflammatory reactions (iritis), corneal edema and corneal decompensation.

INTERACTIONS: None currently known.

PRESENTATIONS Biolon® is supplied in sterile disposable syringes containing 1.0 ml solution.

SHELF LIFE: 3 years.

STORAGE INSTRUCTIONS
Store at 2˚C-8˚C. May be kept at 25˚C for up to six months. Do not freeze. Protect from light.

MANUFACTERED BY
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