Biolon™ Fact Sheet

Description

Biolon, OVD is an ophthalmic viscosurgical device, which contains a sterile, nonpyrogenic, optically clear, viscoelastic preparation of highly purified, high molecular weight sodium hyaluronate (NaHA).

Biolon viscoelastic contains 10 mg/ml of NaHA dissolved in a physiological sodium chloride phosphate buffer (pH 6.8 - 7.6). This high molecular weight polymer is made up of repeating disaccharide units of N-acetyl-glucosamine and sodium glucuronate linked by β-1,3 and β-1,4 glycosidic bonds.

Sodium hyaluronate is a physiological material that is widely distributed in the connective tissues of both animals and man. Chemically identical in all species, hyaluronate can be found in the vitreous and aqueous humor of the eye, the synovial fluid, the skin and the umbilical cord.¹

How Supplied

Biolon is a sterile, nonpyrogenic, optically clear viscoelastic preparation of highly purified Sodium Hyaluronate, supplied in sterile, disposable, 2.25 ml luer lock glass syringe.

Each syringe contains 1.0 ml of 1% sodium hyaluronate in phosphate-buffered salt solution. Each product package contains a blister-packed pre-filled syringe, a sterile, single-use 27G ophthalmic cannula (anterior chamber irrigator), patient chart labels and a package insert.

The Surgeon Evaluation Kit contains 9 Biolon syringe packages, Surgeon and Staff Evaluation Forms along with additional product information.

Place Your Order Today! To place your order for Biolon OVD or for additional information, please contact your surgical distributor, call 1.844.AMRING1 (267.4641) or visit biolonusa.com.
How to Order

To place your order for Biolon OVD or to request a free Surgeon Evaluation Kit, please contact your surgical distributor. For additional information, please call 1.844.AMRING1 or visit biolonusa.com.

Storage Instructions

Store in a cold (2°– 8°C; 36°– 46°F) dark place. May be kept at 25°C (77°F) for up to one month. Protect from freezing. Protect from light. Remove from refrigerator 20-30 minutes before use.

Shelf Life

Three years from date of manufacture.

Composition

Each milliliter of Biolon contains: sodium hyaluronate, 10 mg; sodium chloride, 8.5 mg; disodium hydrogen phosphate dodecahydrate, 0.56 mg; sodium dihydrogen phosphate dihydrate, 0.045 mg; water for injection q.s.

Indications

Bilon is indicated for use as a surgical aid to protect corneal endothelium during cataract extraction (extra-capsular) procedures, intraocular lens (IOL) implantation and anterior segment surgery. When introduced in the anterior segment of the eye during these surgical procedures, Biolon serves to maintain a deep anterior chamber.

In addition, Biolon helps to push back the vitreous face and prevent formation of a post-operative flat chamber.¹

Molecular weight

Approximately 3.0 million Daltons

Viscosity

High viscosity at shear rate 0.1/sec: 85,000 – 135,000 cps

pH

Between 6.8 and 7.6

Osmolality

258 – 381 mOsm/kg

Carton/Unit Dimensions:

6.7 in x 2.7 in x 1.25 in  (167 mm x 69 mm x 32 mm)

Contraindications

When used as recommended there are no known contraindications to the use of Biolon.
Precautions

- The Biolon syringe should be used only with the single-use cannula provided in the package.
- Cannulas are intended for single patient use only. If reuse becomes necessary on the same patient during the surgical procedures, rinse the cannula thoroughly with sterile distilled water to remove all traces of residual material.
- Verify that the cannula is properly locked to the Luer Lock Adaptor. Do not overtighten the Luer Lock Adaptor from the barrel.
- Use only if the solution is clear.
- Care should be taken to avoid trapping air bubbles behind Biolon.
- Do not overfill the eye chamber with Biolon, excessive amounts of OVD in the anterior segment of the eye may cause increased intraocular pressure.
- Pre-existing glaucoma or compromised outflow and 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 may increase post-operative intraocular pressure. Therefore,
  - Remove all remaining Biolon by irrigation and/or aspiration at the close of surgery.
  - Carefully monitor the intraocular pressure, especially during the immediate post-operative period. If a significant rise is observed, treat appropriately.
  - 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.

Biolon is a highly purified substance extracted from bacterial cells. However, physicians should be aware of immunological, allergic and other potential risks of the type that can occur from the injection of any biological substance since the presence of minute quantities of impurities (e.g., proteins) cannot be totally excluded.

Warnings

Mixing of quaternary ammonium salts such as benzalkonium chloride with sodium hyaluronate results in the formation of a precipitate. The eye should not be irrigated with any solution containing benzalkonium chloride if Biolon is to be used during surgery.
Dosage/Applications

Cataract Surgery and Intraocular Lens Implantation

Refrigerated Biolon should be allowed to attain room temperature (approximately 20–30 minutes) prior to use. The usual dose required is 0.2 to 0.5 ml of Biolon. Biolon OVD should be slowly and carefully introduced into the anterior segment of the eye using the provided cannula.

Injection of Biolon can be performed either before or after delivery of the lens. Biolon may also be used to coat surgical instruments and the intraocular lenses prior to insertion.

Additional Biolon can be injected during surgery to replace any Biolon lost during surgical manipulation (see Precautions Section).

Adverse Reactions

In clinical trials, 298 patients were treated with Biolon and 224 patients were treated with sodium hyaluronate, an approved comparative device on the U.S. market for more than five years at the time of the study. The incidences of adverse experiences that were reported in >1% of the patients are shown in table below.*

<table>
<thead>
<tr>
<th></th>
<th>Biolon</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased Intraocular Pressure Requiring Treatment*</td>
<td>22 (7.4)</td>
<td>17 (7.6)</td>
</tr>
<tr>
<td>Superficial &amp; Conjunctival Punctate Keratitis</td>
<td>12 (4.0)</td>
<td>5 (2.2)</td>
</tr>
<tr>
<td>Cystoid Macular Edema</td>
<td>8 (2.7)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Posterior Capsule Opacity</td>
<td>8 (2.7)</td>
<td>10 (4.5)</td>
</tr>
<tr>
<td>Seidel Phenomenon</td>
<td>4 (1.3)</td>
<td>4 (1.8)</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>3 (1.0)</td>
<td>3 (1.3)</td>
</tr>
<tr>
<td>Corneal Edema</td>
<td>3 (1.0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Corneal Erosion</td>
<td>3 (1.0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Sphincter Damage</td>
<td>3 (1.0)</td>
<td>1 (&lt;4)</td>
</tr>
<tr>
<td>Uveitis</td>
<td>3 (1.0)</td>
<td>3 (1.3)</td>
</tr>
</tbody>
</table>

*There is no statistically significant difference in the number of adverse events between the two treatment groups.
+Mean IOP Biolon = 36.7 mm Hg (30 mm Hg – 52 mm Hg)
+Mean IOP Control = 33.6 mm Hg (28 mm Hg – 48 mm Hg)

Adverse events which occurred in <1% and in at least 2 patients include: ocular hemorrhage, corneo-scleral leak, suture related adverse events, vitreous in anterior chamber, hyphema and hemat Tyndall, synechiae, capsule rupture, and cyclitic membrane.

1 Biolon package insert
2 Data on file
3 Versus syringe volume fill of 0.85mL

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