Sodium hyaluronate is a linear polysaccharide composed of repeating disaccharides of sodium glucuronic acid and N-acetylglucosamine found throughout the tissues of the body with high concentrations in the vitreous humor, synovial fluid, and umbilical cord. It has a role in regulating the interactions between adhesion molecules, water, and ions. Sodium hyaluronate can also be a viscoelastic tissue filler, maintaining a separation between tissues. Sodium hyaluronate does not interfere with the normal wound healing process. Sodium hyaluronate is also present in the capsular material of certain bacteria. These bacteria may be cultured by a fermentation process to yield sodium hyaluronate. Sodium hyaluronate extracted and purified from different sources can have different molecular weights but has the same molecular structure. The sodium hyaluronate in Healon® OVD is a highly purified extract of a bacterial fermentation and is Tolobal® in the eye. It has an average molecular weight of approximately 300,000 Daltons in non-animal (1, 2, 3, 4- and non-protein). Healon® OVD is an ophthalmic viscoelastic containing 3% sodium hyaluronate indicated for use as a surgical aid in patients undergoing ophthalmic anterior segment procedures including: 
- Cataract surgery with an intraocular lens.
- Cataract surgery without an intraocular lens.
- Secondary intraocular lens implantation.

Healon® OVD is a sterile, non-pyrogenic solution of highly purified sodium hyaluronate with dispersive rheological properties. Healon® OVD is slowly released through the capsule into the anterior chamber. The use of Healon® OVD may be required to maintain a deep anterior chamber or to dilate the pupil. It is recommended that Healon® OVD be slowly injected into the anterior chamber with a sterile cannula and syringe. It is recommended to be used alone without an air bubble. It is recommended that Healon® OVD not be mixed with other drugs or solutions. Healon® OVD is non-ionic, non-protein and does not interfere with the normal wound healing process. Sodium hyaluronate is also present in the capsular material of certain bacteria. These bacteria may be cultured by a fermentation process to yield sodium hyaluronate. Sodium hyaluronate extracted and purified from different sources can have different molecular weights but has the same molecular structure. The sodium hyaluronate in Healon® OVD is a highly purified extract of a bacterial fermentation and is Tolobal® in the eye. It has an average molecular weight of approximately 300,000 Daltons in non-animal (1, 2, 3, 4- and non-protein).

INDICATIONS
Healon® OVD is an ophthalmic viscoelastic containing 3% sodium hyaluronate intended for use as a surgical aid in patients undergoing ophthalmic anterior segment procedures including:
- Cataract surgery with an intraocular lens.
- Cataract surgery without an intraocular lens.
- Secondary intraocular lens implantation.

Healon® OVD maintains a separating chamber during anterior segment surgery, aids in tissue manipulation during surgery, enhances visualization during the surgical procedure and protects the corneal endothelium and other ocular tissue. The viscosity of Healon® OVD helps maintain the normal position of the vitreous face and prevents formation of a flat chamber during a surgical procedure. It may be also be used to coat internal lenses and instruments prior to intraocular lens implantation.

CONTRAINDICATIONS
At present, there are no contraindications to the use of Healon® OVD when used as recommended.

The Healon® OVD Delivery system is not designed or intended to be attached to instruments other than the one provided with the product. Failure to follow the "Directions for Use" may result in damage to the cannula tip.

Mixing of guanethidine amine salts, such as benzalkonium chloride, with sodium hyaluronate results in a precipitate. The eye should not be irritated with any solution containing benzalkonium chloride if Healon® OVD is to be used during surgery.

DIRECTIONS FOR USE
Cataract surgery and intraocular lens (IOL) implantation: Inject Healon® OVD slowly through the cannula into the anterior chamber of the eye. The use of Healon® OVD is most effective when the injection is made through a phacoemulsification incision of the anterior chamber. The cannula tip should be placed in the mid-corneal stroma and slowly withdrawn as the fluid is injected. The Healon® OVD can be injected up to the vitreous base. The injection should be performed slowly and in a controlled manner. The cannula should be fastened securely to the syringe; however, over tightening may result in damage to the cannula tip. The end of the cannula should be lifted away from the eye, ensure that the cannula is securely attached to the fitting on the syringe. It may be used to coat internal lenses and instruments prior to intraocular lens implantation.

PRECAUTIONS
- Injection of viscoselastic creates pressure in the syringe. To prevent expulsion of the cannula into the eye, ensure that the tip is securely attached to the fitting on the syringe. Use of the cannula guard is recommended to prevent accidental needlestick injuries.
- Do not react the cannula. The cannula should be fastened securely to the syringe. Product and cannula are for single use only. Re-use may cause eye inflammation.
- The potential for early and short-term postoperative intraocular pressure (IOP) spikes exists with dispersive OVD, which potentially require more time and care to remove from the eye. There is the potential for early and short-term postoperative IOP spikes with dispersive OVD removed from the anterior chamber. The eye may be irritated by impinging and aspirating with sterile irrigation solution. Due to the adherent nature of a dispersive viscoelastic more time and care may be required to remove the viscoelastic completely from the eye.

CONTRAINDICATIONS
- Product should not be used in the presence of compromised trabecular meshwork. Compromised trabecular meshwork can cause increased intraocular pressure after the procedure (4).
- Do not use in the presence of compromised trabecular meshwork.
- Healon® OVD should be used with caution in patients with pre-existing glaucoma, the surgery itself, or retained viscoelastic (particularly in patients with a compromised trabecular meshwork). The eye may be irritated by impinging and aspirating with sterile irrigation solution.

Observe the usual precautions taken during anterior segment surgery.

- Pre-existing glaucoma, the surgery itself, or retained viscoelastic (particularly in patients with a compromised trabecular meshwork) can cause increased intraocular pressure after the procedure (4).
- Observe the usual precautions taken during anterior segment surgery.

The following precautions should be considered:
- The intracameral pressure of postsurgical patients should be carefully monitored, particularly in the early postoperative period.
- Do not use excessive amounts of Healon® OVD.
- Remove Healon® OVD completely from the anterior chamber at the end of the procedure.
- Remove Healon® OVD if instilled into the irrigation system.
- Use of Healon® OVD may require irrigation and aspiration to remove remaining fluid.
- Healon® OVD slowly through the cannula into the anterior chamber of the eye. The use of Healon® OVD is most effective when the injection is made through a phacoemulsification incision of the anterior chamber. The cannula tip should be placed in the mid-corneal stroma and slowly withdrawn as the fluid is injected. The Healon® OVD can be injected up to the vitreous base. The injection should be performed slowly and in a controlled manner. The cannula should be fastened securely to the syringe; however, over tightening may result in damage to the cannula tip. The end of the cannula should be lifted away from the eye, ensure that the cannula is securely attached to the fitting on the syringe. It may be used to coat internal lenses and instruments prior to intraocular lens implantation.

The use of Healon® OVD may cause eye inflammation.

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The use of Healon® OVD may cause eye inflammation.
The distribution of postoperative medical findings/observations was similar between the two study groups and within the range of what would typically be reported. In the early postoperative period, inflammatory cells in the anterior chamber were the most reported form of inflammation for both viscoelastic groups. Reports of inflammatory cells diminished over time to minimal levels by the one-month visit in both viscoelastic groups. Early postoperative incidence rates of corneal epithelial and stromal edema were low with similar results in both groups, diminishing over time. For other general slit-lamp findings, the majority of subjects in both groups were reported as “none” at all postoperative visits.

Clinical Trial Adverse Events
Safety Population

Thirty-nine subjects experienced adverse events in the study. None of the adverse events were considered unanticipated. Ninety-two percent of the adverse events were IOP >30 mmHg, incidence of IOP >30 mmHg occurring at a rate of 10.5% in the Healon® EndoCoat® OVD group, and 7.5% in the Viscoat® OVD group. The three adverse events not related to IOP >30 mmHg include: one subject in the Healon® EndoCoat® OVD group who developed cystoid macular edema (CME) requiring treatment and two subjects in the Viscoat® OVD group; one who underwent a lens explant in the study eye due to a stromal haptic and another who had an intracorneal foreign body removed from the study eye. None of these three events was considered by the investigators to be related to the viscoelastic used.

Safety Population
Operative Parameters - Removal of Viscoelastic agent

<table>
<thead>
<tr>
<th>Viscoelastic Remova</th>
<th>Healon® EndoCoat® OVD N = 200</th>
<th>Viscoat® OVD N = 200</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosclastic removal time (seconds)</td>
<td>Mean 149.1</td>
<td>133.7</td>
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<tr>
<td>5D</td>
<td>37.80</td>
<td>35.21</td>
</tr>
<tr>
<td>Median</td>
<td>175.0</td>
<td>121.0</td>
</tr>
<tr>
<td>Min</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Max</td>
<td>105</td>
<td>454</td>
</tr>
<tr>
<td>Ease of viscoelastic removal (no. of cases)</td>
<td>Easy</td>
<td>7</td>
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<tr>
<td>Average</td>
<td>178</td>
<td>142</td>
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<tr>
<td>Difficult</td>
<td>86</td>
<td>35</td>
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<tr>
<td>Very Difficult</td>
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</table>

HOW SUPPLIED

Healon® EndoCoat® OVD is a sterile, non-pyrogenic preparation supplied in a disposable single-use glass syringe, delivering 0.85 ml of a solution of sodium hyaluronate in a physiological buffered salt solution. A sterile, single-use 25-gauge, disposable, bent, blunt-tip thin-wall cannula and cannula guard are provided within the package. The cannula sheath should be used to firmly attach the cannula to the syringe. Contents of unopened and undamaged blister package are sterile. Do not use if package is opened or damaged.

Contents

Each ml of Healon® EndoCoat® OVD contains:

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Contents per ml</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium hyaluronate</td>
<td>30.00 mg</td>
</tr>
<tr>
<td>sodium chloride</td>
<td>5.56 mg</td>
</tr>
<tr>
<td>potassium chloride</td>
<td>0.55 mg</td>
</tr>
<tr>
<td>calcium chloride</td>
<td>0.36 mg</td>
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<tr>
<td>magnesium chloride</td>
<td>0.32 mg</td>
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<tr>
<td>sodium acetate</td>
<td>2.92 mg</td>
</tr>
<tr>
<td>sodium citrate</td>
<td>1.22 mg</td>
</tr>
<tr>
<td>sodium phosphate dibasic</td>
<td>0.08 mg</td>
</tr>
<tr>
<td>sodium phosphate monobasic</td>
<td>0.07 mg</td>
</tr>
<tr>
<td>water for injection</td>
<td>as required</td>
</tr>
</tbody>
</table>

REFERENCES

1. Richter W. Non-immunogenicity of purified hyaluronic acid preparations tested by passive cutaneous anaphylaxis. Int Arch Allergy 1974; 47:211.
5. Caution: Federal (USA) law restricts this device to sale, distribution, or use by or on the order of a physician.

SYMBOLS USED ON STERILE PACKAGING

Healon® EndoCoat Ophthalmic Viscosurgical Device

SYMBOLS

<table>
<thead>
<tr>
<th>Symbol</th>
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<tbody>
<tr>
<td>□</td>
<td>Consult Instructions For Use</td>
</tr>
<tr>
<td>◊</td>
<td>Do Not Use if Package is Damaged</td>
</tr>
<tr>
<td>○</td>
<td>Do Not Dispose</td>
</tr>
<tr>
<td>☐</td>
<td>Sterile using Aseptic Processing Techniques</td>
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<tr>
<td>♦</td>
<td>Packaging and Cannula Sterilized using Ethylene Oxide</td>
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<tr>
<td>P</td>
<td>Catalogue Number</td>
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<tr>
<td>Lot Number</td>
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<tr>
<td>USE BY (YYYY-MM-DD: year-month-day)</td>
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<tr>
<td>◀</td>
<td>Protect From Light</td>
</tr>
<tr>
<td>☑</td>
<td>Protect From Freezing</td>
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<tr>
<td>♤</td>
<td>Temperature Limitation</td>
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<tr>
<td>Manufacturer</td>
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</table>

Authorised Representative in the European Community

Date of Manufacture (YYYY-MM-DD: year-month-day)

AMO Ireland
Black B
Liffey Valley Office Campus
Quayview, Co. Dublin, Ireland

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<table>
<thead>
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<th>Product of USA</th>
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<tbody>
<tr>
<td>1</td>
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</tr>
<tr>
<td>3</td>
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