Definition of symbols on cannula, syringe-, blister label and carton.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEALON® OVD</td>
<td>Sterile opening technique</td>
</tr>
<tr>
<td></td>
<td>Press the vein completely into the holder so that the needle perforates the membrane.</td>
</tr>
<tr>
<td></td>
<td>Important Perforate the membrane before screwing on the plastic rod.</td>
</tr>
<tr>
<td></td>
<td>Remove the plastic rod.</td>
</tr>
<tr>
<td></td>
<td>Screw the plastic rod into the blue plunger.</td>
</tr>
<tr>
<td></td>
<td>Connect the cannula and check for proper function.</td>
</tr>
</tbody>
</table>

Table 6. Adverse Events. Number of patients in whom a medical event occurred at least once. All randomized qualified patients.

<table>
<thead>
<tr>
<th>Body system</th>
<th>Healon® OVD N=187</th>
<th>Healon N=172</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preferred term</td>
<td>N</td>
<td>%</td>
<td>N</td>
</tr>
<tr>
<td>CONJUNCTIVAL HEMORRHAGE</td>
<td>2</td>
<td>1.1</td>
<td>1</td>
</tr>
<tr>
<td>CORNEAL OPACITY</td>
<td>0</td>
<td>0.0</td>
<td>1</td>
</tr>
<tr>
<td>EYE INFECTION</td>
<td>0</td>
<td>0.0</td>
<td>1</td>
</tr>
<tr>
<td>EYE PAIN</td>
<td>0</td>
<td>0.0</td>
<td>1</td>
</tr>
<tr>
<td>INCREASED INTRAOCULAR PRESSURE</td>
<td>4</td>
<td>2.1</td>
<td>4</td>
</tr>
</tbody>
</table>

The difference in percent change in endothelial cell counts between the Healon® OVD and the Healon OVD has been investigated in another clinical study. The endothelial cell count evaluation included 81 patients in the Healon® OVD group and 78 in the Healon OVD group. The mean age in the Healon® OVD group was 67.9 years and in the Healon OVD group 68.9 years.

No difference was observed between the treatment groups with regard to the change from pre-operative values to the values determined at 3 months after surgery. The percentage cell loss in the Healon® OVD group was 9.4 and in the Healon OVD group 11.2%.

Table 7. Endothelial cell counts, changes and percentage change in endothelial cell counts from pre-surgery at 3 months.

<table>
<thead>
<tr>
<th>Visit</th>
<th>Healon® OVD</th>
<th>Healon OVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endothelial cell counts</td>
<td>81</td>
<td>78</td>
</tr>
<tr>
<td>Change from pre-surgery</td>
<td>-243 ± 283</td>
<td>-276 ± 295</td>
</tr>
<tr>
<td>Percentage change from pre-surgery</td>
<td>-9.45 ± 10.67</td>
<td>-11.20 ± 11.50</td>
</tr>
</tbody>
</table>

How Supplied

The Healon® OVD is a sterile, non-pyrogenic, viscoelastic preparation supplied in disposable 0.6 mL glass syringe. Each mL of the Healon® OVD contains:

- 23 mg sodium hyaluronate 5000
- 85 mg sodium chloride
- 0.28 mg disodium hydrogen phosphate dihydrate
- 0.04 mg sodium dihydrogen phosphate dihydrate
- q.s. water for injection

The Healon® OVD syringes are terminally steam sterilized and aseptically packed.

A sterile single-use, 25 gauge cannula is included with each syringe.

Preparation and Storage

Refrigerated Healon® OVD should be held at room temperature for approximately 30 minutes before use.

Store between 2° to 8°C (36° to 46°F).

Protect from freezing and exposure to light.

Reference

4. Pharmacia & Upjohn Anterior chamber depth maintenance capacity of sodium hyaluronate 5000, 23 mg/mL, during phacoemulsification in pig cadaver eyes. Data on file.
5. Holst A, Osterling L. An open, randomized, parallel group, phase III study of Healon5® OVD compared to Healon® OVD during cataract surgery with a 7 day follow up period. Pharmacia & Upjohn Report c0025536
6. Lundberg K, Osterling L. A double-blind, randomized, parallel group study evaluating the safety of a new viscoelastic agent UPG-96 (Healon5® OVD), compared to Healon® OVD in the phacoemulsification with intraocular lens implantation. Pharmacia & Upjohn Report c0002131

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Sodium Hyaluronate

**Product information**

**Description**

The Healon5™ Ophthalmic Viscosurgical Device (OVD) is a sterile, non-ionic, non-thermal, non-protein viscoelastic preparation of a highly purified, nonimmunogenic, high molecular weight fraction (average molecular weight 4 million) of sodium hyaluronate. The Healon5 OVD contains 23 mg/mL of sodium hyaluronate 5000, dissolved in repeating disaccharide units of N-acetylglucosamine and sodium glucuronate linked by glucosidic bonds.

Sodium hyaluronate is a physiological substance that is widely distributed in the extracellular matrix of connective tissues in both animals and man. For example, it is present in the vitreous and aqueous humor of the eye, synovial fluid, the skin, and the umbilical cord. Sodium hyaluronates derived from various human or animal tissues do not differ chemically.

The fraction of sodium hyaluronate in the Healon5 OVD is reported to be nonantigenic1,3 and does not cause inflammatory2 or foreign body reactions. The fraction of sodium hyaluronate in the Healon5 OVD is not designed to have any pharmacological effect. The allosteric sodium hyaluronate solution may appear cloudy or form precipitates when it is injected. In-vitro studies have shown incompatibility, resulting in opalescence, between sodium hyaluronate and solutions containing cationic components, e.g., dextran and benzalkonium chloride.

Represents corneas should not be used. Do not use if the blister package has been damaged. Do not resterilize.

**Contraindications**

- The Healon5 OVD is for single use.
- The specified complications were similar for both groups. All of the complications are commonly seen after cataract surgery. Blurred vision, strabismus, foreign body sensation, itching, burning sensation, corneal edema, represented most of the complications recorded in both groups.

**Adverse Events**

- Increased intraocular pressure has been reported after use of sodium hyaluronate solutions.
- Increased intraocular pressure is likely to occur if the Healon5 OVD is not removed as completely as possible. Clinical judgment using the use of this product should be considered in cases where thorough removal may not be possible.

**Clinical Trials**

A clinical trial of the Healon5 OVD was initiated on August 23rd, 1999. A total of 379 patients were included. 187 patients with a mean age of 74.1 years were randomized into the Healon5 OVD group and 172 patients with a mean age of 73.2 years into the Healon OVD group.

A one day postoperative visit was performed in both groups. No antiglaucoma medication was permitted until the 1st hour postoperative. At the end of the study, 73 patients in the Healon5 OVD group and 10% of the Healon OVD group experienced IOP spikes ≥30 mmHg at 5 hours postoperatively.

**Table 2. Number of Patients in IOP Categories per Visit. All randomized qualified patients.**

<table>
<thead>
<tr>
<th>Visit</th>
<th>Healon5 OVD</th>
<th>Healon OVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 hours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3. IOP (mmHg) during the study. All randomized qualified patients.**

<table>
<thead>
<tr>
<th>Group</th>
<th>Healon5 OVD</th>
<th>Healon OVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Std</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For patient 144 complications related to surgery at visit 5 had not been recorded.