Adverse events
Increased intraocular pressure has been reported after use of the Healon GV OVD.
- Increased intraocular pressure is likely to occur if the Healon GV OVD is not removed as completely as possible. Clinical judgement concerning the use of this product should be considered in cases where thorough removal may not be possible. The Precautions noted above should be taken to manage any increased postoperative intraocular pressure and to reduce the likelihood of occurrence of related postoperative complications such as optic neuropathy, pupillary atonia and dilation, and iris atrophy.

Rarely postoperative inflammatory reactions (iritis, hypopyon, endophthalmitis) following the use of sodium hyaluronate, as well as incidents of corneal edema and corneal decompensation, have been reported. Their relationship to sodium hyaluronate has not been established.

How supplied
The Healon GV OVD is a sterile, non-pyrogenic, viscoelastic preparation supplied in disposable 0.85 mL and 0.55 mL glass syringes. Each mL of the Healon GV OVD contains:
- 14 mg sodium hyaluronate 7000
- 8.5 mg sodium chloride
- 0.28 mg disodium hydrogen phosphate dihydrate
- 0.04 mg sodium dihydrogen phosphate dihydrate
- q.s. water for injection USP

The Healon GV OVD syringes are terminally sterilized and aseptically packaged.
A sterile single-use, 27 gauge cannula is included with each syringe.

Preparation and storage
Refrigerated Healon GV OVD should be held at room temperature for approximately 30 minutes before use. Protect from freezing and exposure to light.
For intraocular use.
Store between 2 to 8°C (36 to 46°F).

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>☒</td>
<td>Caution, see instructions for use</td>
</tr>
<tr>
<td>☑</td>
<td>See instructions for use</td>
</tr>
<tr>
<td>☑</td>
<td>Do not reuse</td>
</tr>
<tr>
<td>☑</td>
<td>Protect from light</td>
</tr>
<tr>
<td>☑</td>
<td>Do not use if the packaging has been opened or damaged</td>
</tr>
<tr>
<td>☑</td>
<td>Protect from freezing</td>
</tr>
<tr>
<td>☑</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>☑</td>
<td>Sterilized using steam</td>
</tr>
<tr>
<td>☑</td>
<td>Sterilized by ethylene oxide</td>
</tr>
<tr>
<td>☑</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>☑</td>
<td>Batch code</td>
</tr>
<tr>
<td>☑</td>
<td>Use by (YYYYMMDD - year month-day)</td>
</tr>
<tr>
<td>☑</td>
<td>Latex Free</td>
</tr>
<tr>
<td>☑</td>
<td>Catalogue number</td>
</tr>
</tbody>
</table>

References

©2014 Abbott Medical Optics Inc.
Healon® Sodium Hyaluronate

Product information

Description

The Healon® Ophthalmic Viscosurgical Device (OVD) is a sterile, nonpyrogenic, highly purified, noninflammatory, high molecular weight fraction of sodium hyaluronate. The Healon OVD contains 14 mg/mL of sodium hyaluronate. 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, the synovial fluid, the skin and the umbilical cord. Sodium hyaluronate preparations from various human and animal tissues are not chemically different from each other. The Healon OVD is a specific fraction of sodium hyaluronate developed as an ophthalmosurgical aid for use in anterior segment and vitreous procedures. It is specific in that:

1. It has a high molecular weight.
2. It is nonpyrogenic.
3. It does not cause inflammatory or foreign body reactions.
4. It has a high viscosity.

Furthermore, the 1% solution of the Healon OVD is transparent, is reported to remain in the anterior chamber for less than 6 days and protects corneal endothelial cells and other ocular structures. The Healon OVD does not interact with epithelialization and normal wound healing.

Uses

The Healon OVD is indicated for use as a surgical aid in cataract extraction (intra- and extracapsular), IOL implantation, corneal transplant, glaucoma filtration surgery, and conjunctival filtration. In surgical procedures in the posterior segment of the eye, the Healon OVD is slowly introduced into the vitreous cavity. By directing the Healon OVD to efficiently maneuver, separate, and control ocular tissues. It facilitates manipulation inside the eye with reduced trauma to the corneal endothelium and surrounding structures.

Contraindications

There are no known contraindications to the use of the Healon OVD when used as recommended. They are used with care as they are intended for use in surgical procedures and may be used for a variety of ocular procedures.

Precautions

Postoperative intraocular pressure may be increased if the Healon OVD is left in the eye. Due to the greater viscosity of the Healon OVD, this increase in postoperative IOP may be higher than that caused by leaving the same amount of other sodium hyaluronate viscoelastic products, with lower zero shear viscosity, in the anterior segment. Since rises in postoperative intraocular pressure, including cases of significant elevation and subsequent complications, have been reported, it is recommended that precautionary measures be taken.

Special care should be taken to ensure complete removal as possible by continuing to irrigate/aspire after you see displacement of the initial bolus of the Healon OVD from the anterior chamber. Continued irrigation/aspiration should facilitate removal of viscoscous which may remain in the anterior segment.

Pre-existing glaucoma, other causes of compromised IOP, high postoperative intraocular pressure and complications in surgical procedures also may lead to increased intraocular pressure, consequently extra care should be taken in patients with these conditions.

Carefully monitor intraocular pressure, particularly during the early postoperative period.

Postoperative intraocular pressure may increase due to intraocular gas bubble formation and may cause increased intraocular pressure, consequently extra care should be taken in patients with these conditions.

Product of Sweden

Abbott Medical Optics Inc.
1700 E. Arques Avenue
Sunnyvale, CA 94089 USA
1-877-AMO-4-LIFE

References


AMO Upplands Vång
Roppragatan
SE-751 36 Uppsala, Sweden

Product of Sweden

Abbott Medical Optics Inc.
1700 E. Arques Avenue
Sunnyvale, CA 94089
1-877-AMO-4-LIFE

Revision date 09/01/14

Healon and Healon GV are trademarks owned by or licensed to Abbott Laboratories, its subsidiaries or affiliates. All rights reserved.

©2014 Abbott Medical Optics Inc.