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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑️</td>
<td>Caution, 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>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


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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 10 mg/mL of sodium hyaluronate dissolved in physiological sodium chloride solution. This heparin-molecule weight polymer is made up of repeating disaccharide units of N-acetyl-glucosamine and sodium glucuronate linked by 1-3 and 1-4 glycosidic bonds.

Characteristics

Sodium hyaluronate is a physiologically active substance that is widely distributed in the extracellular matrix of connective tissues in all 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 hyaluronates prepared 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 ophthalmosurgically ad use for anterior segment and vitreous procedures. It is specific in that:

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

Furthermore, 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 interfere with ophthalmoscopy 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 and retinal attachment surgery.

In surgical procedures in the anterior segment of the eye, instillation of the Healon OVD serves as a surgical aid to anterior segment surgery, allowing for efficient manipulation with less trauma to the corneal endothelium and other surrounding tissues.

In posterior segment surgery, intraocular pressure rises have been reported in some patients, especially in aphakic diabetics, after injection of large amounts of sodium hyaluronate.

Rapidly postoperative inflammatory reactions (iritis, hypopyon) as well as incidents of corneal edema and corneal decompensation have been reported. Their relationship to the Healon OVD has not been established.

Applications

Cataract surgery - IOL implantation.

A sufficient amount of the Healon OVD is slowly and carefully introduced (using a cannula or needle) into the anterior chamber. Injection of the Healon OVD can be performed either before or after delivery of the anterior chamber injection prior to lens delivery, however the latter have the added advantage of protecting the corneal endothelium from possible damage arising from the removal of the cataractous lens. The Healon OVD may also be used to coat surgical instruments and to insert intraocular lens (IOL) devices.

Additional Healon OVD can be injected during surgery to replace any Healon OVD lost during surgical manipulation (see Precautions section).

Glaucoma filtration surgery in conjunction with performing of the trabeculectomy, the Healon OVD is injected slowly and carefully through a corneal paracentesis to reconstitute the anterior chamber. Further injection of the Healon OVD can be continued allowing it to extrude into the suprachoroidal space and through and around the outer scleral orbit.

Corneal transplant surgery.

After removal of the corneal button, the anterior chamber is filled with the Healon OVD. The donor graft can be placed on top of the bed of Healon OVD and irrigated in place. Additional Healon OVD may be injected to replace any Healon OVD lost during surgical manipulation (see Precautions section).

Precautions

Naïve sutures around the sutured outer scleral flap.

To gently push back a detached retina or unroll a retinal flap, and to extrude into the subconjunctival filtration site and through and around the outer scleral orbit.

Sodium hyaluronate preparation in man.

References

7. AMO Upplands AB
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Healon GV® Sodium Hyaluronate

Product information

Description

The Healon GV® Ophthalmic Viscosurgical Device (OVD) is a sterile, nonpyrogenic, highly purified, noninflammatory, high molecular weight fraction of sodium hyaluronate. The Healon GV OVD contains 14 mg/mL of sodium hyaluronate 70000 dissolved in a physiological sodium chloride phosphate buffer (pH 7.0-7.3). This polymer consists of repeating disaccharide units of N-acetylglucosamine and sodium glucuronate linked by glycosidic bonds.

Sodium hyaluronate is a physiologically active 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 hyaluronates derived from various human and animal tissues are not chemically different from each other.

The Healon GV OVD is a fraction of sodium hyaluronate developed as an ophthalmosurgically ad use for anterior segment and vitreous procedures. It is specific in that:

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

Furthermore, 1% solution of the Healon GV 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 GV OVD also can be used to efficiently monovet a separate and control ocular issues.

Contraindications

There are no known contraindications to the use of the Healon GV OVD in the anterior segment.

Adverse reactions

Some patients, especially in aphakic diabetics, after injection of large amounts of sodium hyaluronate may lead to increased intraocular pressure, consequently, extra care should be taken in patients with these conditions.

Precautions

There are no known contraindications to the use of the Healon GV OVD in the anterior segment.

Postoperative intraocular pressure may be increased if the Healon GV OVD is left in the eye. Due to the greater viscosity of the Healon GV 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 pressures, including cases of significant elevation and subsequent complications, have been reported, the following precautions are strongly recommended:

- Special care should be taken to ensure complete removal as possible by continuing to irrigate/suprate after you see displacement of the initial bolus of fluid from the anterior chamber, continued irrigation/suprate should facilitate removal of viscoelastic which may remain in the anterior segment.

- Pre-existing glaucoma, other causes of compromised outflow, high preoperative 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.

- Treat with appropriate intraocular pressure lowering therapy, if required.

The Healon GV OVD is a highly purified fraction extracted from avian tissue which may cause postoperative IOP increase. The potential risk associated with the injection of biological material should be considered.

Express a small amount of the Healon GV OVD from the syringe prior to use and carefully examine it during use to avoid injecting minute particle rubbers which may be released when the syringes diaphragm is punctured.

Sodium hyaluronate solution may appear cloudy or form precipitates when it is introduced into the vitreous cavity. This phenomenon may be related to interactions with concomitantly used ophthalmic medications or detergents which remain in reused canu.

Reprocessed cannulas should not be used.

A sterile single-use 27 G cannula is enclosed in the 0.4 mL, 0.55 mL and 0.85 mL boxes.

Reprocessed Healon OVD should be allowed to attain room temperature (approximately 30 minutes) prior to use.

For intraocular use.

Store at 2 to 8°C (36 to 46°F).

Protect from freezing.

Protect from light.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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

References

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