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.
- Caution, see instructions for use
- See instructions for use
- Do not reuse
- Protect from light
- Do not use if the packaging has been opened or damaged
- Protect from freezing
- Temperature limitation
- Sterilized using steam
- Sterilized by ethylene oxide
- Manufactured
- Batch code
- Use by (YYYYMMDD - year month-day)
- Latex Free
- Catalogue number

Sodium Hyaluronate

Instructions
Sterile opening technique
Tear off the paper covering.
Bend the plastic backwards at the central indentation so as to fully expose the white plastic rod.
Dislodge syringe and place onto sterile field.

Assembly
Press the vial completely into the holder so that the needle perforates the membrane.

Important
Perforate the membrane before screwing on the plastic rod.

Remove the plastic rod.

Screw the plastic rod into the blue plunger.

Connect the cannula and check for proper function.

Store at 2 to 8°C (36 to 46°F). For single use only.
The Healon OVD is a sterile, nonpyrogenic, viscoelastic preparation of a 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 phosphate buffer (pH 7.0-7.3). This pH may change slightly during storage, but should not exceed ±0.1 of the indicated pH.

The Healon OVD is extremely well tolerated after injection into human eyes. It is reported to be nonantigenic and nonimmunogenic. It does not cause inflammatory or foreign body reactions. It does not interfere with epithelialization and normal wound healing.

Care should be taken to avoid trapping air bubbles behind the Healon OVD. Excessive injection pressure should be avoided.

Sporadic reports have been received indicating that the Healon OVD may cause inflammatory or foreign body reactions following injection into the eye. The clinical significance of these reports, if any, is not known since the majority received to date do not indicate any harmful effects on ocular tissues. The physician should be aware of this phenomenon and, should it be observed, remove the cloudy or precipitated material by irrigation and aspiration.

In vitro studies suggest that this phenomenon may be related to interactions with certain condutromically administered ophthalmic medications. Use only if solution is clear.

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 IOL. Injection prior to lens delivery will, however, have the additional 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 the IOL prior to insertion.

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

Glassman filtration surgery
In conjunction with performing 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 subconjunctival filtration site and through and around the sutured outer scleral flap.

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 held in place. Additional Healon OVD may be injected to replace the Healon OVD lost as a result of surgical manipulation (see Precautions section).

Glaucoma filtration surgery
If the trabeculectomy has failed, a punch can be placed on the top of the bed of Healon OVD and held in place. Additional Healon OVD may be injected to replace the Healon OVD lost as a result of surgical manipulation (see Precautions section).

Retinal attachment surgery
The Healon OVD is slowly introduced into the vitreous cavity. By directing the injection, the Healon OVD can be used to separate membranes (e.g. epiretinal membranes) away from the retina for safe excision and release of traction. The Healon OVD also serves to maneuver tissues into the desired position, e.g. to gently push back a detached retina or relax a retinal tear, and aids in holding the retina against the sclera for reattachment.

How supplied
The Healon OVD is a sterile, nonpyrogenic, viscoelastic preparation supplied in disposable glass syringes, delivering 0.85 mL, 0.55 mL or 0.4 mL sodium hyaluronate (10 mg/mL) dissolved in physiological sodium chloride phosphate buffer (pH 7.0-7.3). Each mL of Healon OVD contains 10 mg of sodium hyaluronate, 8.5 mg sodium chloride, 0.28 mg of disodium hydrogen phosphate dihydrate, 0.04 mg of sodium dihydrogen phosphate and 0.05 mg of sodium hydroxide.

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 intracocular 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

©2014 Abbott Medical Optics Inc.