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 stenosis 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-syngentic, 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
- 3.0 mg sodium dihydrogen phosphate dihydrate
- 0.28 mg disodium hydrogen phosphate dihydrate
- q.s. water for injection USP

The Healon GV OVD syringes are terminally sterilized and aseptically packaged.

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
Manufacturer
Batch code
Use by (YYYYMMDD - year month-day)
Latex Free
Catalogue number

References

Sodium Hyaluronate

Instructions

Sterile opening technique
- Tear off the paper covering.
- 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

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The Healon® Ophthalmic Viscosurgical Device (OVD) is a sterile, non-ergonomic extracapsular cataract extraction technique preparation of a highly purified, noninflammatory, high molecular weight fraction of sodium hyaluronate. The Healon OVD contains 10 mg/mL of sodium hyaluronate (5,000,000), which is present in the vitreous and aqueous humor of the eye, the synovial fluid, the skin, and the umbilical cord. 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 hyaluronates derived 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 reported to be non-antigenic.
3. It does not cause inflammation 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 interfere with epithelialization and normal wound healing.

Uses

The Healon OVD is indicated for use as a surgical aid in extracapsular (extra- and intracapsular), IOL implantation, corneal transplant, glaucoma surgery, and anterior chamber. Since the exact role of these factors is difficult to predict in each individual case, the following precautions are recommended:

- Don’t overfill the eye chambers with the Healon OVD (except in glaucoma surgery). Postoperative intraocular pressure may also be elevated as a result of preoperative intraocular pressure and complications in surgical procedures that may contain minute amounts of protein. The potential risks associated with the injection of any biological material.
- Pre-existing glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure, and complications in surgical procedures that may contain minute amounts of protein. The potential risks associated with the injection of any biological material.

Contraindications

There are no known contraindications to the use of the Healon OVD when used as recommended.

Precautions

Those normally associated with the surgical procedure being performed. Overfilling the anterior or posterior segment of the eye with the Healon OVD may cause increased intraocular pressure, glaucoma, or other ocular damage.

Postoperative intraocular pressure may also be elevated as a result of preoperative intraocular pressure and complications in surgical procedures that may contain minute amounts of protein. The potential risks associated with the injection of any biological material.

- Don’t overfill the eye chambers with the Healon OVD (except in glaucoma surgery). Postoperative intraocular pressure may also be elevated as a result of preoperative intraocular pressure and complications in surgical procedures that may contain minute amounts of protein. The potential risks associated with the injection of any biological material.
- Pre-existing glaucoma, other causes of compromised outflow, higher preoperative intraocular pressure, and complications in surgical procedures that may contain minute amounts of protein. The potential risks associated with the injection of any biological material.

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

How supplied

The Healon OVD is a sterile, non-ergonomic, viscoelastic preparation supplied in disposable glass syringes, delivering 0.5 mL, 0.55 mL, or 0.4 mL sodium hyaluronate (10 mg/mL) suspended in physiologic sodium chloride phosphate buffer (pH 7.0-7.5). Each mL of Healon OVD contains 10 mg of sodium hyaluronate, 8.5 mg sodium chloride, 0.28 mg of disodium hydrogen phosphate dyes, and a q.w. water for injection U.S.P. The Healon OVD syringes are terminally sterilized and aseptically packaged.

A sterile single-use 27 gauge needle is enclosed in the 0.5 mL, 0.55 mL, and 0.4 mL syringes. Radiopaque 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 light.

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

- Use if the packaging has been opened or damaged.
- Do not use if the packaging has been opened or damaged.
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