













Read this package insert completely before use and comply with the instructions for use.

PreviscAid[®] Ophthalmic Viscoelastic

MOHW-MD-No. 004560

GRAPHICAL SYMBOLS

	Do not re-use		Catalogue number
	Consult instructions for use		Batch code
	Use-by date		Sterilized using aseptic processing techniques
	Manufacturer		Sterilized using ethylene oxide
	Do not re-sterilize		Store at 2-8°C
	Do not use if package is damaged		Keep away from sunlight

Description

PreviscAid[®] Ophthalmic Viscoelastic (PreviscAid[®]) is a sterile, non-pyrogenic, ophthalmic viscosurgical device prepared of the non-inflammatory, medium molecular weight sodium chondroitin sulfate and sodium hyaluronate. PreviscAid[®] Ophthalmic Viscoelastic is composed of sodium chondroitin sulfate and sodium hyaluronate which are biological polymers found in the extracellular matrix of animals and humans. The cornea is the ocular tissue having the greatest concentration of sodium chondroitin sulfate, while sodium hyaluronate is typically exists in extracellular matrix of connective tissues, especially vitreous, joint synovium, skin, etc. It is also the main component of the vitreous body and aqueous humour and mainly used as tissue lubricants. It plays a critical role in tissue interaction due to its lubricating and viscoelastic properties. PreviscAid[®] Ophthalmic Viscoelastic is formulated to a viscosity of 40 ± 20 Pa.s. The osmolality of PreviscAid[®] is 325 ± 40 mOsm; the pH is 6.8-7.5. This product is a clear and transparent viscous liquid filled in glass syringe with a disposable sterile cannula (25G). This product is only indicated for single use. The sterilization method and cannula gauge can be identified on the package of cannula. The information of quantity and capacity are indicated on the product packaging.

Indications

PreviscAid[®] is indicated for use as surgical aids in ophthalmic anterior and posterior segment surgeries including intra-/extra- cataract extraction with or without implantation of an intraocular lens (IOL), intraocular lens implantation, keratoplasty / corneal transplantation surgery, glaucoma filtering surgery, and surgical procedures to reattach the retina. PreviscAid[®] has also been used successfully as a vitreum replacement after vitrectomy and retinal detachment surgery. Due to its lubricating, transparent and viscoelastic properties, PreviscAid[®] aids in maintaining a deep chamber and visibility during anterior segment surgeries, while allowing for more efficient manipulation and implantation with less trauma to the corneal endothelium and other surrounding ocular tissues. PreviscAid[®] may also be used to coat an intraocular lens as well as the tips of surgical instruments prior to implantation surgery. The corneal endothelial cells and surrounding tissues are protected from possible damage arising from surgical instrumentation during ophthalmic surgeries. PreviscAid[®] also preserves the tissue integrity and good visibility when used to fill the anterior or posterior segments of the eye following open sky procedures.

Precaution

It may cause an allergic reaction. And do not use if package is damaged.

Contraindications

At present there are no known contraindications to the use of PreviscAid[®] when used as recommended.

Instructions

1. PreviscAid[®] is for intraocular use only.
2. PreviscAid[®] and cannula are intended only for single use.
3. Remove packaging using sterile opening technique.
4. Remove the tip cap from syringe tip.
5. Depress the plunger rod with one hand to discharge air bubbles.
6. Thread the cannula onto the syringe (using only the cannula provided), and confirm that it is firmly seated.
7. Remove the plastic sheath from the cannula by pulling it away in a straight motion (being sure not to twist or unscrew the cannula while removing the sheath).

8. Purge the remaining air from the system by holding the syringe barrel and gently depressing the plunger rod with one hand until PreviscAid[®] appears at the cannula tip.
9. Refrigerated PreviscAid[®] should be allowed to attain room temperature prior to use (approximately 20-40 minutes, depending on the quantity).
10. PreviscAid[®] is only used by physicians.

Adverse Reaction

Sodium hyaluronate is a natural component in the tissues of the body and is extremely well tolerated in human eyes. Transient postoperative inflammatory reactions have been reported and oral or topical steroid preparation were administered. Animal study has confirmed the fact that sodium hyaluronate are non-inflammatory, hence any phlogistic response is considered to be consequences of the surgical procedures. The best index of the degree of inflammatory response is the postoperative clarity of the vitreous cavity. A transient postoperative increase in intraocular pressure has been observed following the use of sodium hyaluronate in anterior segment surgery. On rare occasions, postoperative reactions including inflammation, corneal edema and corneal decompensation have been reported. The relationship to the use of this product has not been established.

Clinical Application

For cataract surgery and IOL implantation, PreviscAid[®] is carefully injected into the anterior chamber to replace the aqueous humor before any instrument is introduced into the eye. It can protect corneal endothelium from surgical instrument damage. PreviscAid[®] can be used before or after removal of the lens. It can also be coated in IOL and surgical instrument. Injection of PreviscAid[®] during surgery can maintain the shape of the anterior chamber. Additional PreviscAid[®] can be injected as required during surgery to replace any loss to facilitate surgical manipulation.

After surgery, PreviscAid[®] can be removed by normal saline.

Storage Condition

1. Store at 2-8°C : 36-46 °F.
2. DO NOT FREEZE.

Shelf Life: 24 months

Product Specification

Specification	PA-01	PA-02	PA-03
Content	0.5 mL	0.75 mL	1.0 mL
Needle	Enclosed needle 25G × 1/2" × 1		

Sodium hyaluronate	30.0000 mg/mL
Sodium chondroitin sulfate	40.0000 mg/mL
Sodium chloride	2.7800 mg/mL
Sodium hydrogen phosphate	2.7800 mg/mL
Sodium dihydrogen phosphate	0.0973 mg/mL
Water	924.3427 mg/mL
Total	1000.0000 mg/mL

Warning

- Do not concomitantly use disinfectants containing quaternary ammonium salts because hyaluronate can be precipitated in their presence.
- Anaphylactic and allergic reactions have been reported with this product.
- STERILE CONTENTS. The syringe is intended for single use only. Discard any unused PreviscAid[®].

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