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Sodium Hyaluronate Ophthalmic Solution

HYALVUE™-14

11.9 mg/0.85 ml

PRODUCT INFORMATION

DESCRIPTION

HYALVUE-14 is a sterile, non-pyrogenic, transparent viscoelastic preparation of highly purified, non-inflammatory, high molecular weight fraction of Sodium Hyaluronate. **HYALVUE-14** contains 11.9mg/0.85ml of Sodium Hyaluronate BP dissolved in a physiological Sodium phosphate buffer (pH 7.0 - 7.5). This polymer consists of repeating disaccharide units of β-acetyl-glucosamine and Sodium glucuronate linked by β (1-3) and β (1-4) glycosidic bonds.

CHARACTERISTICS

Sodium Hyaluronate is a physiological substance that is widely distributed in the extra cellular matrix of connective tissues. 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 derived from various human or animal tissues do not differ chemically.

INDICATIONS

HYALVUE-14 is indicated for use in anterior segment ophthalmic surgical procedures. **HYALVUE-14** creates and maintains deep anterior chamber, facilitating easy manipulation inside the eye. It also coats the corneal endothelium and protects it as well as other surrounding tissues, reducing trauma during surgical intervention. A viscous cohesive **HYALVUE-14** is optimally suited for ophthalmic surgeries that require cohesive viscoelastic properties.

CONTRAINDICATIONS

As of now, there are no known contraindications to the use of **HYALVUE-14**, when used as recommended.

PRECAUTIONS

Precautions which are normally followed during ophthalmic surgical procedures should be taken. Postoperative intra ocular pressure may be increased if **HYALVUE-14** is left in the eye. Since there are chances of postoperative increase in the intra-ocular pressure, the following precautions are strongly recommended:

- Special care should be taken to ensure complete removal as possible by continuing to irrigate/aspirate when displacement of the initial bolus of viscoelastic from the eye is seen; continual irrigiation/aspiration facilitates removal of viscoelastic, which remains in the anterior segment.
- Pre-existing glaucoma, other causes of compromised outflow, higher preoperative intra ocular pressure and complications in surgical procedures may also lead to increased intra-ocular pressure, and consequently, extra care should be taken in patients with these conditions.
- The intra-ocular pressure needs to be carefully monitored particularly during the early postoperative period.
- Appropriate intra ocular pressure lowering therapy should be initiated , if required.

Sodium Hyaluronate solution may appear cloudy or form precipitates when it is injected. Based on *in vitro* laboratory studies, this phenomenon may be related to interactions with concomitantly used ophthalmic medications or detergents, which remain in the used cannulas. Therefore avoid reuse of cannulas.

ADVERSE EVENTS

Increase in the intra-ocular pressure is likely to occur if **HYALVUE-14** is not removed as completely as possible. Clinical judgement concerning the use of this product should be considered in case where its thorough removal may not be possible. The precautions mentioned above should be taken to manage any increased postoperative intra-ocular pressure and to reduce the likelihood of occurrence of any related postoperative complications such as optic neuropathy, papillary atonia and dilation, and iris atrophy. Rarely, postoperative inflammatory reactions such as 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 use of **HYALVUE-14** has not been established.

PRESENTATION

HYALVUE-14 is a sterile, non-pyrogenic, viscoelastic preparation supplied in the volumes of 0.85 ml per syringe in disposable glass PFS. A sterile 27G Angular Cannula. supplied along with this pack.

Each 0.85 ml Sodium Hyalorante
Opthalmic Solution contains: (Prefilled Syringe)

Sodium Hyaluronate	BP	11.9 mg
Sodium Chloride	IP	7.20 mg
Di-sodium Hydrogen Phosphate dihydrate	USP	0.238 mg
Monosodium Phosphate monohydrate IP		0.034 mg
Water for Injection	IP	q.s.

Contains no preservatives.

HYALVUE-14 is terminally sterilized and is a aseptically packaged product.

STORAGE

Store below 30^0C.
Do not freeze.
If refrigerated, then HYALVUE-14 should be held at room temperature for approximately 30 minutes before use.

For intra-ocular use only.

Keep out of reach and sight of children.

STERILE

Do not reuse

Do not use if pack is damaged.

References:

1. *Balazs EA. Ultra pure hyaluronic acid and the use thereof US patent 4141973 (1979).*
2. *Richer W, Ryde E, Zetterstrom EO, Nonimmunogenicity of purified sodium hyaluronate preparation in man. Int Arch Allergy Immunol 1979; 59: 45-8.*
3. *Pape LG, Balazs EA. The use of sodium hyaluronate in human anterior segment surgery. Ophthalmology 1980; 87: 699-705.*
4. *Satoshi M, Shuzo I. Effect on intraocular pressure and clearance from the anterior chamber. J Ocular Pharmacology 1989; 5: 221-30.*

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LAVUE

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