INSTRUCTIONS FOR USE

SIDA-VISC™

Sodium Hyaluronate

Ophthalmic Solution

Description

The SIDA-VISC™ ophthalmic solution is a sterile, non-pyrogenic, viscoelastic preparation of a highly purified, non-inflammatory, high molecular weight fraction of sodium hyaluronate obtained by bacterial fermentation.

It contains sodium hyaluronate dissolved in physiological sodium chloride phosphate buffer in proportion ranging from 10 to 30 mg/mL (see box labeling for exact specification). This high- molecular-weight polymer is made up of repeating disaccharide units of N-acetyl-glucosamine and sodium glucuronate linked by β 1-3 and β 1-4 glycosidic bonds. SIDA-VISC™ has a high molecular weight greater than 3.3 x 106 daltons.

The osmolarity is 300 - 350 mOsm/kg and the viscosity is 40.000 cps for SIDA-VISC™ 1%; 80.000 cps for SIDA-VISC™ 1.4%; 100,000 cps for SIDA-VISC™ 1.6%; 120,000 cps for SIDA-VISC™ 1.8% and 160,000 cps for SIDA-VISC™ 3.0%. The pH is in between 6.8 - 7.6.

SIDA-VISC™ is a specific fraction of sodium hyaluronate developed as an ophthalmic surgical aid for use in anterior segment and vitreous procedures. It presents high molecular weight; it has high viscosity and is a cohesive viscoelastic. It is transparent, remains in anterior chamber for less than 6 days and protects the ocular structure.

Indications

SIDA-VISC™ is indicated for use as a space occupying tissue protective fluid and lubricant during various intraocular surgical procedures including intra-/ extracapsular cataract extraction, IOL implants and corneal transplantations. In surgical procedures in the anterior segment of the eye, instillation of the SIDA-VISC™ serves to maintain a deep anterior chamber during surgery, allowing for efficient manipulation with fewer traumas to the corneal endothelium and other surrounding tissues.

Contraindications

SIDA-VISC™ is contraindicated for any procedure where the risk of use of viscoelastic surgical fluid would outweigh any potential benefits during surgery.

Risks and side effects

The risks and side effects that may result from the use of SIDA-VISC™ are the same as those resulting from the use of any ophthalmic viscoelastic fluid.

Precautions

- Those precautions normally associated with the performed surgical procedure should be observed.
- Reprocessed cannulas should not be used.
- Use only if the solution is clear.

Adverse Reactions

Sodium Hyaluronate is a physiological substance present in many tissues of the body. It is extremely well tolerated in human eyes. However, there have been reports of transient postoperative ocular inflammation (oral and/or topical steroid treatments were administered) and transient postoperative increase of intraocular pressure is likely to occur if the SIDA-VISC™ is not removed as completely as possible.

In addition, the following adverse reactions have been reported following the use of Sodium Hyaluronate after intraocular surgery: post-operative inflammatory reactions such as hypopyon, iritis, corneal oedema, increased intraocular pressure, secondary glaucoma and corneal decompensation. Their relationship to sodium hyaluronate has not been established.

Preparation & Administration Guide

SIDA-VISC™ should be held at room temperature for approximately 30 minutes before use. Protect from freezing and exposure to light. For intraocular use.

1. Remove the syringe from its packaging in a sterile environment
2. Remove the cap from the tip of the syringe barrel
3. Open the 27G cannula and firmly screw it onto the lock fitting
4. Depress the plunger and discard the first 0.1 to 0.3 ml of fluid
5. Do not overfill the eye chamber with SIDA-VISC™.
6. At the closing of procedure, irrigate the bulk of the SIDA-VISC™ out of the anterior chamber with Balanced Salt Solution (BSS).

Storage Conditions

Store between 2 to 30 °C.

Box Contents

a. 1x sterile 1 mL prefilled glass syringe packed in blister, with each mL containing:
   – Sodium Hyaluronate B.P. (10 or 14 or 16 or 18 or 30 mg/mL),
   – Sodium Chloride USP (8.2 mg),
   – Disodium Hydrogen phosphate Dihydrate USP (1.9 mg)
   – Sodium Dihydrogen phosphate Dihydrate USP (0.3 mg)
   – W ater for injection USP

b. 1x sterile 27G angled Cannula

c. This Information for Use leaflet.

Applicable ref. Numbers

Sodium Hyaluronate	1.0%	1.4%	1.6%	1.8%	3.0%
Ref. No.	10000	10005	10006	10002	10007

Disclaimer

The manufacturer does not bear any responsibility for improper model selection by the surgeon, for improper handling, use, surgical technique applied or for any other iatrogenic error caused by the surgeon. This product is subject to change with or without prior notice. Improvement changes may be made in specification, shape and material. The manufacturer makes no expressed or implied warranties in connection with the sale of this product. The manufacturer is liable only for the design and production of this product and not for any incidental, consequential, indirect or exemplary damages of any kind, directly or indirectly arising from the purchase or use of it.

Graphical symbols

	**Caution! Consult accompanying document**		**CE mark and Notified Body No.**
	**Do not reuse**		**Reference number**
	**Read instructions before use**		**Lot/Batch Number**
	**Aseptically filled**		**Sterilization method: Radiation**
	**Do not resterilize**		**Keep away from sunlight**
	**Keep dry**		**Contribution to recycling system**
	**Manufacturer**		**Do not use if package is damaged**
	**Manufacture Date**		**Use by date**
	**Store between 2 to 30 °C**		

Manufacturer

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