CE 2460

FOR THE USE OF A REGISTERED MEDICAL PRACTITIONER OR A HOSPITAL OR A LABORATORY ONLY

SODIUM HYALURONATE OPHTHALMIC SOLUTIONS

OPHTHALMIC VISCOSURGICAL DEVICE

1. Products to which these instructions for use apply:

BIO-HYALUR™ (Sodium Hyaluronate Ophthalmic Solution 1.0 % W/V)
BIO-HYALUR™ PLUS (Sodium Hyaluronate Ophthalmic Solution 1.4 % W/V)
BIO-HYALUR™ EV (Sodium Hyaluronate Ophthalmic Solution 1.8 % W/V)
BIO-HYALUR™ HV (Sodium Hyaluronate Ophthalmic Solution 2.4 % W/V)
BIO-HYALUR™ SV (Sodium Hyaluronate Ophthalmic Solution 3 % W/V)

2. Description:

BIO-HYALUR™ range of products are a sterile, nonpyrogenic, viscoelastic preparation of highly purified, non-inflammatory and high molecular weight sodium hyaluronate dissolved in a physiological buffer having Osmolality of product 270 – 400 mOsm / kg and pH 6.8 to 7.6. It is a clear and colorless solution supplied in a disposable glass syringe.

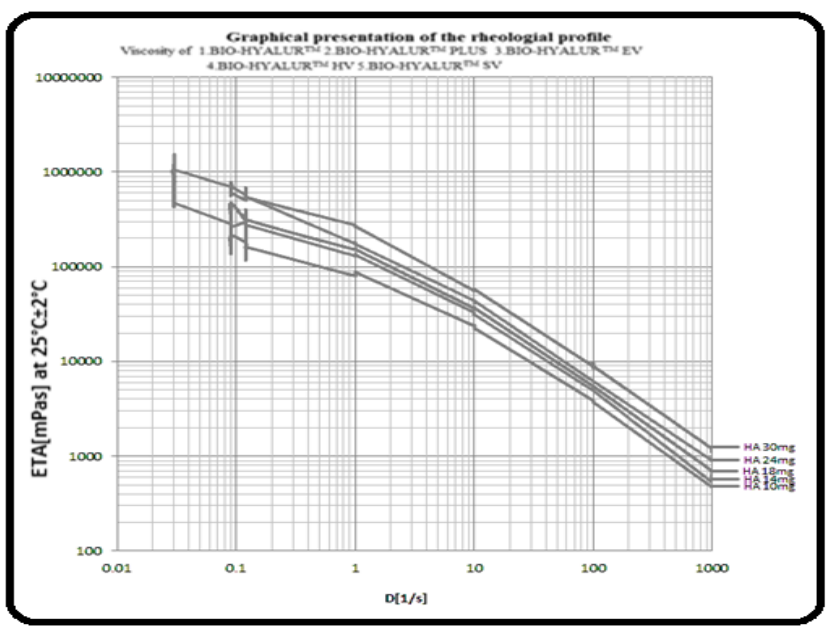
Sodium hyaluronate is a physiological substance that is widely distributed in the extracellular matrix of connective tissues in both animals and man. For example, it is present in the vitreous and aqueous humor of the eye, the synovial fluid, the skin and the umbilical cord. Sodium hyaluronates prepared from various human and animal tissues and bacterial fermentation source are not chemically different from each other. Sodium hyaluronate is a naturally occurring, high molecular weight polysaccharide, composed of sodium glucuronate and N-acetyl glucosamine which forms a repeating unit by linking alternatively beta 1-3 and beta 1-4 glycosidic bonds. The average molecular weight of Sodium hyaluronate in **BIO-HYALUR™** range of products is about 2.8 to 3.2 Million Daltons and is derived from bacterial fermentation source.

BIO-HYALUR™ ranges of products are highly viscous products and does not contain latex.

Brand Name & Generic Name	Composition	Shear Viscosity at 25°C ± 2°C in mPas
BIO-HYALUR™ (1.0 ml / 1.6 ml) Sodium Hyaluronate Ophthalmic Solution 1.0 % W/V	Each ml contains: Sodium Hyaluronate EP .....10mg. Phosphate Buffer Saline .....q.s.	Between 300000 to 450000
BIO-HYALUR™ PLUS (1.0 ml / 1.6 ml) Sodium Hyaluronate Ophthalmic Solution 1.4% W/V	Each ml contains: Sodium Hyaluronate EP .....14mg. Phosphate Buffer Saline .....q.s	Between 400000 to 600000
BIO-HYALUR™ EV (1.0 ml / 1.6 ml) Sodium Hyaluronate Ophthalmic Solution 1.8% W/	Each ml contains. Sodium Hyaluronate EP....18mg. Phosphate Buffer Saline....q.s.	Between 6,00,000 to 7,50,000
BIO-HYALUR™ HV (1.0 ml /1.6 ml) Sodium Hyaluronate Ophthalmic Solution 2.4% W/V	Each ml contains: Sodium Hyaluronate EP .....24mg Phosphate Buffer Saline .....q.s.	Between 850000 to 1100000
BIO-HYALUR™ SV (1.0 ml /1.6 ml) Sodium Hyaluronate Ophthalmic Solution 3% W/V	Each ml contains. Sodium Hyaluronate EP ....30 mg Phosphate Buffer Saline…..q.s.	Between 10,00,000 to 13,50,000

3. Graphical presentation:

Graphical presentation of the rheological profile of **BIO-HYALUR™** range of products.



4. How supplied:

BIO-HYALUR™ range of products are supplied in a single use glass prefilled syringe with a Luer-lock fitting, packed in a medical grade blister pack. Each box contains one sterile syringe blister, five product traceability labels , one sterile single use 27G cannula (ETO sterilized) and one product information leaflet(IFU). **BIO-HYALUR™** range of products are terminally sterilized using steam.

5. Clinical benefits:

BIO-HYALUR™ range of products, through its physical properties, provides protection to the patient's corneal endothelium and other ocular tissues during ophthalmic surgery.

6. Indications:

BIO-HYALUR™ range of products are indicated for the protection and lubrication of delicate cells tissues when required, especially in ophthalmic procedures including:

1. Anterior segment surgery,
2. IOL implantation and Cataract surgery,
3. Glaucoma surgery
4. Corneal transplantation

It does not interfere with epithelization and normal wound healing. Any traces of **BIO-HYALUR™** range of products are left in the anterior segment of the eye after surgery, dissipates mainly through Schlemm's canal.

7. Mode of action:

In surgical procedures of the anterior segment of the eye, instillation of the **BIO-HYALUR™** range of products serves to maintain a deep anterior chamber during surgery, allowing for efficient manipulation with less trauma to the corneal endothelium and other surrounding tissues.
Furthermore, its viscoelasticity helps to push back the vitreous face and prevent formation of a postoperative flat chamber.

8. Directions for use:

Under strict aseptic conditions open the blister at the marked end and take out the prefilled syringe. Hold the luer lock. Twist the cap carefully with the other hand in anti-clock direction and remove it. Hold the syringe and insert the cannula, turn the cannula in clockwise direction to lock it as tightly as possible so that the cannula may not come off while injecting the product. Gently push plunger rod to expel air bubbles from syringe tip and cannula.

9. Contraindications:

At present there are no known contraindications to the use of the **BIO-HYALUR™** range of products when used as recommended.

10. Incompatibilities:

Sodium Hyaluronate is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. **BIO-HYALUR™** range of products should never come in contact with these substances or with medical surgical instrumentation which has been treated with this type of substance.

11. Adverse events:

Increased Intraocular Pressure (IOP) is likely to occur if **BIO-HYALUR™** range of products are not removed as completely as possible, IOP should be carefully monitored and appropriate therapy instituted, if significant increases occur.
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 with the use of sodium hyaluronate solution has not been established.

12. Warnings and Precautions:

- For intraocular use only.
- Bring to room temperature approximately 30 minutes prior to use.
- Do not use if the package is opened or damaged.
- Postoperative intraocular pressure may also be elevated as a result of preexisting glaucoma, compromised outflow and by operative procedures and sequelae thereto, including enzymatic zonulysis, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber. Since the exact role of these factors is difficult to predict in any individual case, the following precautions are recommended:
  - Don't overfill the eye chambers with the **BIO-HYALUR™** range of products.
  - **BIO-HYALUR™** range of products should be removed completely at the end of the surgery after IOL implantation with the help of Irrigation aspiration Hand-piece. Removal of **BIO-HYALUR™** range of products are achieved from anterior chamber as well as from behind the IOL with high flow and high vacuum setting with due care of protecting post capsule. If needed, **BIO-HYALUR™** range of products near the corneal endothelium can be removed with irrigation flow directed towards endothelium.
  - Carefully monitor the intraocular pressure, especially during the immediate postoperative period. If significant rises are observed, treat with appropriate therapy.
- Care should be taken to avoid trapping air bubbles behind the **BIO-HYALUR™** range of products.
- Use only if solution is clear. Discard the syringe if any floating particles are found.
- Do not re-use cannula and/or syringe.
- Keep away from sunlight.
- Do not freeze.
- For single use only.
- Do not re-sterilize by any method.
- Do not use the product after expiry date.
- To be used by an authorized medical practitioner only.
- All the accessories (cannula/syringe) provided to use the product, product itself and its primary packaging are considered as biological waste after usage of the product. It should not be reused in any case and further disposed as per the applicable guideline of the country. If reused, it may lead to any biological reactions including but not limited to inflammation, infection, injury or any unknown clinical condition.

13. Storage conditions:

Store between 2°C to 25°C.

14. Expiration date:

The expiration date is 36 months from the date of manufacturing.
BIO-HYALUR™ range of products must be used prior to the expiry date printed on the package.

15. Reporting of serious incidents:

Users should report serious incident with medical device information to the manufacturer and/or to the national competent authority depending on national practice.

Once corrective (or other) action is identified from manufacturer, hospital administrators, medical practitioners and other health-care professionals, and USER representatives responsible for the maintenance and the safety of MEDICAL DEVICEs, can take the necessary steps. Such steps should, where practicable, be taken in co-operation with the MANUFACTURER.

For the purposes of Medical Devices Vigilance System in member states are represented by appointed National Competent Authorities, their vigilance contact points being listed on the European Commission web site: http://ec.europa.eu/growth/sectors/medical-devices/contacts/index_en.htm.

16. Electronic IFU

The electronic IFU can be obtained via the following link: http://eifu.biotechhealthcare.com

Any national version has been translated from the core English text. In case of discrepancy, English text shall be considered final. For the latest version of the IFU, please refer the English version of electronic IFU. The content of this document is subject to change without prior notice.

17. Explanation of international symbols:

SYMBOL	EXPLANATION
	Consult instructions for use or consult electronic instructions for use
	Use-by date (YYYY / MM)
LOT	Batch Number
	Date of manufacture
	Manufacturer
MD	Medical Device
	Caution
25°C 2°C	Temperature limit
	Keep away from sunlight
	Do not use if package is damaged and consult instructions for use
2 STERILIZE	Do not re-sterilize
2	Do not re-use
	Double sterile barrier system
IND	Country for manufacturer
STERILE	Sterilized using steam
LATEX FREE	Does not contain latex
EC REP	European Representative
CE 2460	CE2460 certified product (For BIO-HYALUR™ range of products PFS)
CE 0123	CE0123 certified product (For Cannula)

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FOR BIO-HYALUR™ RANGE OF PRODUCTS PFS:

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Mfg. Lic. No.: G/28/1622

EC REP

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CE 2460

FOR CANNULA:

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EC REP

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CE 0123

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