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SODIUM HYALURONATE OPHTHALMIC SOLUTION

CE 0434

BIO-HYALUR™ & BIO-HYALUR™ Plus

10mg/ml 14mg/ml

Description:

Bio-Hyalur™/ Bio-Hyalur™ Plus is sterile, non pyrogenic, viscoelastic preparation of highly purified high molecular weight sodium hyaluronate dissolved in a physiological buffer. It is a clear solution supplied in a disposable glass syringe.

The average molecular weight of Sodium hyaluronate in Bio-Hyalur™/ Bio-Hyalur™ Plus is about 5 million dalton.

When Bio-Hyalur™/ Bio-Hyalur™ Plus is injected through a cannula, the viscosity reduces considerably so that solution is easy to inject. However, the high viscosity is regained in the chamber i.e. Bio-Hyalur™ Plus is highly pseudoplastic.

Bio-Hyalur™/ Bio-Hyalur™ Plus does not contain latex

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.

Sodium Hyaluronate is a physiological substance that is widely distributed in the extra cellular matrix of connective tissues in both animals and human. For example, it is present in the vitreous and aqueous humour of the eye, the synovial fluid, the skin, and the umbilical cord. Sodium Hyaluronates derived from various human or animal tissues and fermentation sources do not differ chemically.

Indications:

Bio-Hyalur™/ Bio-Hyalur™ Plus is mainly indicated for use in anterior segment ophthalmic surgical processes.

Bio-Hyalur™/ Bio-Hyalur™ Plus is indicated whenever protection and lubrication of delicate cells or tissues are needed, especially in ophthalmic procedures including:

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

It does not interfere with epithelization and normal wound healing. Any traces of Bio-Hyalur™/ Bio-Hyalur™ Plus left in the anterior segment of the eye after surgery dissipates mainly through Schlemm's canal.

Contra Indications:

Not known at present.

Adverse events :

Increased IOP is likely to occur if Bio-Hyalur™/ Bio-Hyalur™ Plus is not removed as completely as possible. IOP should be carefully monitored and appropriate therapy instituted, if significant increases occur.

Remove Bio-Hyalur™/ Bio-Hyalur™ Plus by irrigation and/or aspiration at the end of the surgery. Do not refill the anterior chamber.

Precautions :

The physician should be aware of potential allergic reaction that can occur with the injection of any biological material.

Warnings :

- For intra ocular use only.
- Bring to room temperature approximately 30 minutes prior to use.
- Do not use if the sterile package is ruptured or damaged.
- Use only if solution is clear.
- Discard the syringe if any floating particles are found.
- Do not reuse cannula and syringe.
- For single use only
- DO NOT RE-STERILE BY ANY METHOD

Presentation:

Supplied in a sterile disposable glass syringe delivering 0.55/0.85ml/1ml of Bio-Hyalur™/ Bio-Hyalur™ Plus solution.
A sterile single use 27G CE marked cannula is provided with each syringe.

Storage instructions:

Store between 2°C to 25°C. Protect from light.
Protect from freezing.
Bring to room temperature prior to use. Do not reuse. Do not use if floating particles are found.
Dose: As directed by the Physician.

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For further informations, please write to :

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Rx.

SODIUM HYALURONATE OPHTHALMIC SOLUTION

BIO-HYALUR™

CE 0434

10mg/ml

Composition :

Each ml contains Sodium Hyaluronate BP 10 mg
in a sterile isotonic vehicle q.s.

Store between 2°C to 25°C. Protect from light.
Protect from freezing.
Bring to room temperature prior to use.
Do not reuse. Do not use if floating particles are found.
Dose: As directed by the Physician.

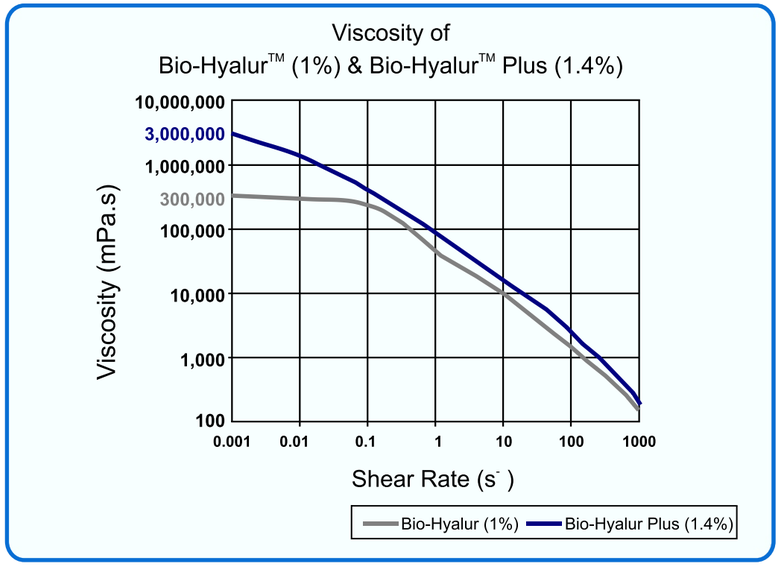
Description :

Category	DISPERSIVE
Molecule	NaHA
Origin	Bacterial Fermentation
Brand Name	BioHyalur
Concentration	10mg/ml (1%)
Molecular weight	5 Million Dalton
pH	6.5-7.5
Viscosity at rest	More than 300,000 mPas
Presentation	0.55ml/0.85ml/1ml In sterile glass syringe(B-D) with 27G CE marked sterile Cannula
Packaging	Finished product is available in medical grade Blister pack.

BIO-HYALUR™ & BIO-HYALUR™ Plus

The Trust Worthy Products

- **CE certified product**
- **Finished product is available in PFS in medical grade blister packing to ensure safety**
- **International standard sterile glass syringe from (B-D) Becton Dickinson (USA), which provides excellent luer-lock facility to ensure proper attachment of cannula and thus avoid leakage or spillage**
- **CE marked 27G cannula in a medical grade blister to ensure safety of product**



Rx.

SODIUM HYALURONATE OPHTHALMIC SOLUTION

BIO-HYALUR™ Plus

CE 0434

14mg/ml

Composition :

Each ml contains Sodium Hyaluronate BP 14 mg
in a sterile isotonic vehicle q.s.

Store between 2°C to 25°C. Protect from light.
Protect from freezing.
Bring to room temperature prior to use.
Do not reuse. Do not use if floating particles are found.
Dose: As directed by the Physician.

Description :

Category	COHESIVE
Molecule	NaHA
Origin	Bacterial Fermentation.
Brand Name	BioHyalur Plus
Concentration	14 mg/ml (1.4%)
Molecular weight	5 Million Dalton
pH	6.5-7.5
Viscosity at rest	More than 3,000,000 mPas
Presentation	0.55ml/0.85ml/1ml In sterile glass syringe(B-D) with 27G CE marked Sterile Cannula
Packaging	Finished product is available in medical grade Blister pack.