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

CE 2460

HYDROXYPROPYL METHYLCELLULOSE OPHTHALMIC SOLUTIONS

OPHTHALMIC VISCOSURGICAL DEVICE

1. Products to which these instructions for use apply:

EYEVISC™ PFS (HYDROXYPROPYL METHYLCELLULOSE OPHTHALMIC SOLUTION USP 2%W/V)
EYEVISC™ PFS (HYDROXYPROPYL METHYLCELLULOSE OPHTHALMIC SOLUTION USP 2.4 %W/V)

2. Description:

EYEVISC™ range of products are a sterile, transparent, isotonic, non-pyrogenic, viscoelastic preparation of a non- inflammatory, highly purified grade Hydroxypropyl methylcellulose dissolved in a physiological buffer for intraocular application during the anterior segment surgeries. It contains no preservative.

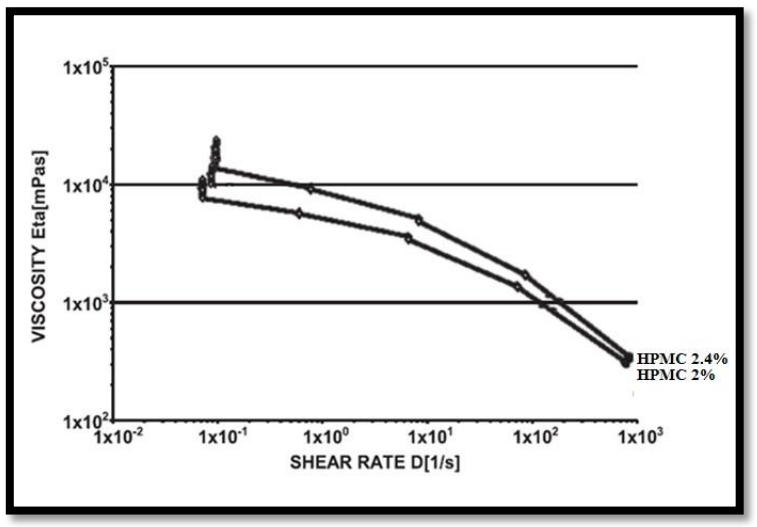
The molecular weight of Hydroxypropyl methylcellulose in EYEVISC™ range of products are greater than 80,000 Daltons. The Osmolality of EYEVISC™ range of products are 270-400 mOsm / kg and the pH is between 6.8 and 7.6 at 25°C ± 2°C.

Brand Name & Generic Name	Composition	Shear Viscosity at 25°C ± 2°C in mPas
EYEVISC™ PFS (HYDROXYPROPYL METHYLCELLULOSE OPHTHALMIC SOLUTION USP 2%W/V)	Each ml contains: Hydroxypropyl Methylcellulose USP.....2% w/v Sterile Isotonic Base.....q.s	Between 5250 to 8750
EYEVISC™ PFS (HYDROXYPROPYL METHYLCELLULOSE OPHTHALMIC SOLUTION USP 2.4%W/V)	Each ml contains: Hydroxypropyl Methylcellulose USP...2.4% w/v Sterile Isotonic Base .....q.s	Between 7500 to 12500

3. Graphical presentation:

Graphical presentation of the rheological profile of **EYEVISC™ range of products**.

VISCOSITY V/S SHEAR RATE GRAPH



4. How supplied:

EYEVISC™ range of products are supplied in a prefilled, disposable glass syringe with a Luer lock fitting delivering 2.0 ml of solution. The prefilled syringe is packed in a medical grade blister pack.
For mono carton : Each box contains one sterile syringe blister, five product traceability labels and one sterile single use 23G cannula (ETO sterilized) and one product information leaflet.
For pack of 10(EYEVISC™ PFS 2%) **:** Each box contains ten sterile syringe blister, fifty product traceability labels and 10 sterile single use 23G cannula(ETO sterilized) and one product information leaflet.
EYEVISC™ ranges of products are terminally sterilized using steam.

5. Clinical benefits:

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

6. Indications:

EYEVISC™ ranges of products are indicated for use as an ophthalmic surgical aid in anterior segment surgical procedures, including cataract extraction and intraocular lens implantation. **EYEVISC™ range of products are maintains** a deep chamber during anterior segment surgery and thereby allows for more efficient manipulation with less trauma to the corneal endothelium and other ocular tissues.

7. Mode of action:

When used in ophthalmic surgeries, **EYEVISC™ range of products** acts as a space occupying and tissue protective substance. It does not have any pharmacological effect and acts through its physical properties. It possesses a high dynamic viscoelasticity and coating ability and provides protection to the corneal endothelium and other ocular tissues. **EYEVISC™ range of products may** also be used to coat an intraocular lens as well as tips of surgical instruments prior to implantation surgery. Additionally, **EYEVISC™ range of products** may be injected during anterior segment surgery to fully maintain the chamber, or to replace fluid lost during the surgical procedure. It is easily removed at the end of the surgery and does not interfere with normal wound healing process.

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:

EYEVISC™ ranges of products are contraindicated in patients with known history of hypersensitivity to its ingredients. It may cause an allergic reaction in hypersensitive patients.

10. Adverse reactions:

A transient rise in intraocular pressure postoperatively has been reported in some cases.
In clinical data of similar products some rare adverse reactions such as postoperative inflammatory reactions (iritis, hypopyon), as well as incidents of corneal edema and corneal decompensation, have been reported.

11. Warning and Precautions:

- A high level of surgical skill is required for proper use. Careful preoperative evaluation and clinical judgment should be made by the surgeon to decide the benefit/risk ratio of use. The volume to be applied depends on the type of the intervention.
- Use the product immediately after opening.
- The cannula and syringe are for single intraocular use only. Check the integrity of the packaging before use to ensure the product has remained sterile. Precautions are limited to those normally associated with the ophthalmic surgical procedure being performed. The Intraocular pressure should be checked following operations and if significant increase is observed, appropriate therapy should be administered.
- **Eyevisc™ 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 **Eyevisc™ 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, Eyevisc™ range of products near the corneal endothelium can be removed with irrigation flow directed towards endothelium.
- Do not use if the package is opened or damaged.
- Discard solution if found turbid or if particles are noticed.
- Discard unused contents of **EYEVISC™ range of product** after each use.
- Do not re-use cannula and/or syringe.
- Do not re-sterilize by any method.
- Do not use the product after its expiry date.
- To be used by an authorized medical practitioner only.
- Keep away from sunlight.
- Do not freeze
- 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.

12. Storage conditions:

Store between 2°C to 35°C.

13. Expiration date:

The expiration date is 36 months from the date of manufacturing.
EYEVISC™ range of product must be used prior to the expiry date printed on the package.

14. 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.

15. 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.

16. Explanation of international symbols:

SYMBOL	EXPLANATION
	Consult instructions for use or consult electronic instructions for use
	Use-by date (YYYY / MM)
	Batch Number
	Date of manufacture
	Manufacturer
	Medical Device
	Caution
	Temperature limit.
	Keep away from sunlight.
	Do not use if package is damaged and consult instructions for use
	Do not re-sterilize.
	Do not re-use.
	Double sterile barrier system
	Country for manufacturer
	Sterilized using steam.
	European Representative
	CE2460 certified product (For **EYEVISC™ range of products**)
	CE0123 certified product (For Cannula)

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FOR EYEVISC™ RANGE OF PRODUCTS

Bio-Tech Vision Care Pvt. Ltd.
Plot No. 4, PHARMEZ, Sarkhej-Bavla N.H. 8A,
Village: Matoda, Taluka: Sanand,
Dist.: Ahmedabad - 382213,
Gujarat, India.
Customer Care No. - +91 79 66823000
www.biotechhealthcare.com
sales@biotechhealthcare.com
Mfg. Lic. No.: G/28/1622

FOR CANNULA:

Sterimedix Ltd
Thornhill Road,
North Moons Moat, Redditch,
Worcestershire B98 9ND,
UNITED KINGDOM.

CE 2460 EC REP

Biotech Europe Meditech Inc Limited,
AF2, IDA Business & Technology Park,
Roscommon, Ireland.

EC REP CE 0123

Bausch & Lomb GmbH,
Brunsbutteler Damm, 165-173,
13581, Berlin, Germany