

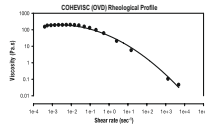
Cohevisc 1[®]

(Sodium Hyaluronate Sterile Ophthalmic Solution)

THIS LEAFLET CONTAINS IMPORTANT PRODUCT USE AND SAFETY INFORMATION, PLEASE READ CAREFULLY AND RETAIN FOR FURTHER FUTURE REFERENCE.

DESCRIPTION

Cohevisc 1 ophthalmic viscosurgical device is a sterile, non-pyrogenic, high molecular weight, non-inflammatory highly purified fraction of Sodium Hyaluronate dissolved in physiological sodium chloride, phosphate buffer. Each mL of **Cohevisc 1** contains 10mg of Sodium Hyaluronate in a sterile isotonic base. pH is adjusted with Sodium Hydroxide / Hydrochloric acid.



CHARACTERISTICS:

Sodium Hyaluronate is a high molecular weight poly saccharide, composed of sodium glucuronate and N-acetyl glucosamine which forms a repeating disaccharide unit by linking alternatively beta-1-3 and beta-1-4 glycosidic bonds. Sodium Hyaluronate Ophthalmic solution is a transparent & viscous used as an aid in Ophthalmic Surgery.

MODE OF ACTION (Mechanism of Action)

Sodium Hyaluronate functions as a tissue lubricant and is thought to play an important role in modulating the interactions between adjacent tissues. Mechanical protection for tissues (iris, retina) and cell layers (corneal endothelium, and epithelium) are provided by the high viscosity of the solution. Elasticity of the solution assists in absorbing mechanical stress and providing a protective buffer for tissues.

INTENDED USE

Cohevisc 1 is viscoelastic ophthalmic devices used as an aid for ophthalmic surgical procedures and anterior segment during cataract extraction and IOL implantation. **Cohevisc** helps to maintain deep anterior chamber during anterior segment surgery reduce trauma to the corneal endothelium and surrounding ocular tissue It helps to push back the vitreous face and prevent formation of a flat chamber during the surgery.

CONTRAINDICATIONS

At present there are no known contraindications for the use of **Cohevisc 1** ophthalmic visco surgical device.

WARNING

Do not use if the solution becomes dark brown or any floating particles are observed If pouch is damaged should not be reused. In-case of any serious accident in relation to the device, inform to the manufacturer and to the regulatory authority.

PRECAUTIONS:

Recommended to remove **Cohevisc 1** by irrigation and/or aspiration at the close of surgery. Do not overfill the anterior chamber. Post operative increase in intraocular pressure is reported with use of Sodium Hyaluronate. The rise in IOP should be monitored closely and appropriate drug therapy if significant intraocular pressure occurs. Do not reuse cannula. Avoid trapping air bubbles.

ADVERSE REACTION

Cohevisc 1 is well tolerated during ophthalmic surgical procedure in human eye. Like most of the viscoelastic rise in a transient rise in intraocular pressure is reported in some cases.

APPLICATION

Use a cannula slowly and carefully inject a sufficient quantity of **Cohevisc 1** into the anterior Chamber. **Cohevisc 1** may also be used to coat surgical instruments and intraocular lens prior to implantation. Additional **Cohevisc 1** can be injected during the surgery to replace any loss of viscoelastic during surgical manipulation.

HOW SUPPLIED:

COHEVISC 1 is a sterile, single use viscoelastic device supplied in a non-pyrogenic Glass Syringe containing 1ml with single use sterile angular cannula 27 G.

PREPARATION & ADMINISTRATION GUIDE

Cohevisc 1 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 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 **Cohevisc 1**.
6. At the closing of procedure, irrigate the bulk of the **Cohevisc 1** out of the anterior chamber with Balanced Salt Solution (BSS).

USABILITY & INFORMATION HAZARDS

Mishandling of the product for package leads to microbial contamination of the device and post-operative inflammation.

Improper removal of device from package leads to product damage and eye redness. use by unskilled personnel leads to product damage and eye redness.

Inadequate irrigation & aspiration of solution leads to reversible eye infection.

STORAGE

Store at 8°C to 25°C, Protect from light. Do not Freeze.

PACKING

COHEVISC 1 /1mL is packed in 2.25 ml glass syringe with onesterile disposable cannula.

For Intraocular use. Not for injection. Single use only.

STERILE **MD** Medical Device

- Do not re-use
- Do not re-sterilize
- Double Sterile Barrier System
- Keep away from sunlight
- Do not use if package is damaged
- Store Between 8°C to 25°C
- Consult instructions for use
- Caution
- Keep Dry
- Non-Pyrogenic
- Instructions for Use

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