Instructions for use
OphteisBio 1.6%, 1.8% and 3.0%

Content: OphteisBio 1.6%, 1.8% and 3.0% is a viscoelastic sodium hyaluronate solution.
Each product consists of 1.1 mL of viscoelastic solution in a single-use glass syringe for intraocular use. OphteisBio 1.6% and 1.8% is supplied together with one sterile 27 G cannula. OphteisBio 3.0% is supplied with one sterile 25 G cannula.

Description: OphteisBio 1.6%, 1.8% and 3.0% Viscosurgical Device is sterile, non-pyrogenic, clear, non-inflammatory, highly purified sodium hyaluronate dissolved in a buffered physiological saline solution. The highly-purified sodium hyaluronate is obtained from bacteria by fermentation.
1 mL of OphteisBio 1.6%/ 1.8%/ 3.0% contains 16.0 mg/ 18.0 mg/ 30.0 mg sodium hyaluronate, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate and water for injection.
OphteisBio 1.6%, 1.8% and 3.0% has a pH of 6.8 to 7.6 and osmolality of 300 to 350 mOsm/kg, similar to the aqueous humor.
The molecular weight of OphteisBio 1.6% and 1.8% is approximately 3.0 MDa. The molecular weight of OphteisBio 3.0% is approximately 0.75 MDa.
OphteisBio 1.6% has a zero shear viscosity of approximately 400.000 mPa s.
OphteisBio 1.8% has a zero shear viscosity of approximately 600.000 mPa s.
OphteisBio 3.0% has a zero shear viscosity of approximately 30.000 mPa s.
OphteisBio is easy to instil. Sodium hyaluronate is viscous at rest, but its pseudo-plastic properties allow for great ease of flow when pressure is applied to expel the solution through the cannula. After instillation the viscous properties are restored.

Indications: Intraocular surgery of the anterior segment, including cataract extraction and intraocular lens implantation.
The viscoelastic properties of OphteisBio 1.6%, 1.8% and 3.0% allow lubrication, support and protection of ocular tissues during ophthalmic surgery.
Maintains the depth of the anterior chamber during surgery, allows for efficient manipulation with reduced trauma to the corneal endothelium and other surrounding tissues.

Contraindications: Care should be taken in patients with hypersensitivity to any components in this solution.

Directions for Use: OphteisBio 1.6%, 1.8% and 3.0% is carefully injected into the anterior chamber using the supplied sterile single-use cannula. It is recommended for intraocular lens implantation to cover the implant and instruments with OphteisBio 1.6%, 1.8% and 3.0% immediately before surgery. This measure is to additionally protect the endothelium and the surrounding tissue. The OphteisBio 1.6%, 1.8% and 3.0% volume to be injected varies and depends on the type of surgery. As a substitute for viscoelastic lost by flow or irrigation, OphteisBio 1.6%, 1.8% and 3.0% can be injected several times. At the end of surgery, OphteisBio 1.6%, 1.8% and 3.0% must be removed completely using a suitable irrigation/aspiration device.

Warnings and Precautions: Residual viscoelastic not removed at the end of the surgical procedure is flushed out naturally via the trabecular system and Schlemm's canal. There is, however, a risk of blockage of the drainage channels, which can lead to an increase in intraocular pressure. To prevent the risk of IOP, irrigation/aspiration is used at the end of the surgical procedure to remove residual viscoelastic. In case of IOP increase, treat with the preferred therapy. Patients who have been diagnosed with wide-angle glaucoma, severe myopia, diabetic retinopathy or uveitis are at particular risk of increased intraocular therapy.

- Do not reuse syringe and cannula. Any repeat usage of the syringe and cannula carries a risk of contamination and infection of the patient.
- Do not re-sterilize the pre-filled syringe and cannula.
- Do not use if package is damaged or opened.
- Do not use after the expiry date printed on the pack.
- Dispose of the syringe and cannula in accordance with accepted medical practice and applicable national, local and institutional requirements.

There is no evidence concerning the safety of OphteisBio in human pregnancy and lactation. Administration during pregnancy and lactation is at the discretion of the ophthalmic surgeon.

Storage: Store between 2 °C – 25 °C. Protect from light and shocks.
Do not freeze.