solatum™

Sodium Hyaluronate

solatumfarma

Viscoelastic Device (VED) for Ophthalmic Surgery Pre-filled Syringe

Indication

Solatum™ gel is intended to aid anterior or posterior segment ophthalmic surgery:

- Cataract extraction with/without implantation of intraocular lens
- Corneal transplant surgery
- Glaucoma filtering surgery
- Secondary lens implantation.

Contraindications

Not suitable for the following patient groups:

- With known hypersensitivity to the individual components of the product.

Description

Hyaluronic acid is a substance naturally present in the body including in fluids in the eye and has viscoelastic properties. Sodium Hyaluronate Viscoelastic device (VED) for ophthalmic surgery when injected into the eye can help lubricate and protect the ocular structures during surgical eye procedures. The active substance is a highly purified sodium salt of hyaluronic acid. Sodium Hyaluronate Viscoelastic device for ophthalmic surgery is terminally sterilised by moist heat. The product is for single use only. Its final packaging includes a 27G blunt cannula (Rycroft Cannula) which is terminally sterilised by ethylene oxide.

Contents

Each Solatum™ VED gel prefilled syringe contains sodium hyaluronate in a phosphate buffered saline for a single surgical procedure. The following volumes and concentration of HA are available: 1ml and 2ml of 15mg/ml and 1ml of 23mg/ml and 30mg/ml.

Warnings

- Do not use if sterile packaging has been damaged, or if there is damage to the pre-filled syringe.
- Avoid contact with drugs containing benzalkonium chloride due to interaction.
- Never overfill the eye chamber (except in glaucoma surgery).
- Do not use for intravenous injection.
- Do not use if solution is cloudy.
- Avoid trapping any air bubbles.
- Avoid contact with instruments sterilized with quarternary ammonium salts solution or disinfectant containing quaternary ammonium salts.
- Do not use after the expiry date printed on the package.

Precautions

- The pre-filled syringe is intended for single procedure use only. The contents of the syringe must be used immediately after the packaging is opened. Discard any unused gel. Reuse may cause infection.
- Strict aseptic administration technique must be followed to minimise danger of cross infection.
- Only for injection into the eye cavity.
- Overfilling the eye anterior or posterior segment with gel may lead to increased intraocular pressure, glaucoma, or other ocular damage.
- Postoperative intraocular pressure may also be elevated as result of pre-existing glaucoma, compromised outflow and by operative procedure and events following, including enzymatic zonulysis, absence of an iridectomy, trauma to filtration structures, and by blood and lenticular remnants in the anterior chamber.
- In posterior segment procedures in the aphakic diabetic patient, special care should be exercised to avoid using large amounts of Solatum™ VED gel.
- Remove all remaining gel by irrigation and/or aspiration at the close of surgery (except in glaucoma surgery).

- Carefully monitor the intraocular pressure especially during the immediate postoperative period. If significant rises are observed, treat with appropriate therapy.
- Rarely, viscoelastic Solatum™ VED gel has been observed to become slightly opaque or to form a slight precipitate upon instillation into the eye. Should this be observed, the cloudy or precipitated material should be removed by irrigation and/or aspiration.
- Product should be stored in its original packaging at a temperature between 2°C – 25°C. Do not freeze.

Directions for Use

First expel the air out of the ophthalmic Luer-lock syringe and cannula, then inject Solatum™ VED gel appropriately into the anterior chamber of the eye. The amount injected must be adjusted according to the type of surgical procedure.

The cannula should fit to the syringe Luer-lock tip; however, overtightening may cause the hub to weaken and possibly detach from the syringe. Extrusion of a test droplet is recommended prior to entering the eye and excessive force on the plunger should be avoided.

Applications

- **Cataract surgery and Intra Ocular Lens (OCL) implantation**

The required amount of Solatum™ VED gel is slowly infused through the cannula into the anterior chamber. The protective effect of Solatum™ VED gel as an aid is optimised when the injection is performed prior to cataract extraction and insertion of the IOL and is effective for both intra and extra capsular cataract procedures. Solatum™ VED gel may be applied to IOL prior to insertion. Additional gel can be injected as required to facilitate the surgical procedure.

- **Corneal transplant surgery**

The corneal button is removed and the anterior chamber filled with Solatum™ VED gel to a level with the surface of the cornea. The donor graft is then placed on top of the gel and sutured into place. Additional Solatum™ VED gel can be used as required as an aid during the operation.

- **Glaucoma filtration surgery**

Solatum™ VED gel is injected through a corneal paracentesis to restore and maintain anterior chamber volume during the performance of the trabulectomy. Additional gel can be used as required to aid the surgical procedure.

Storage Conditions

Store between 2°C and 25°C in a well ventilated and clean area with relative humidity below 80%. Do not freeze. Protect from light. Poor storage conditions will affect the products performance or could lead to product contamination.

Disposal

Dispose after use in a sharps bin or appropriate container.

Adverse Event

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should be reported to Solatumfarma on 01922 895 262.

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