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AKCOAT
Sodium Hyaluronate and Sodium Chondroitin Sulfate Intraocular Solution

Supplied in a sterile Pre-filled Syringe with grip and a sterile single use cannula.

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DM/IFU/OVD/05 Ver.01

INSTRUCTION FOR USE

- Avoid freezing.
- Do not use the product beyond the stated expiry date.

RETURN OF DAMAGED PRODUCT

- Products that have been opened, used, modified, reprocessed, or improperly stored must not be returned.
- Any damaged, defective, or nonconforming product should be clearly identified and segregated from usable stock.
- The manufacturer or authorized distributor should be notified immediately regarding any quality concerns or product defects.
- The product should be returned only in accordance with the manufacturer's instructions and applicable regulatory requirements.
- Any adverse event associated with the use of the product should be reported to the manufacturer and the relevant regulatory authority.

DISPOSAL OF DISCARDED PRODUCT AND PACKAGING

Dispose of the used device, unused contents, and packaging materials in accordance with applicable biomedical waste regulations. Appropriate disposal measures should be taken to prevent contamination and to protect the environment, healthcare personnel, children, and animals.

INSTRUCTION FOR USE

DESCRIPTION

The ophthalmic viscoelastic device (OVD) is a sterile, transparent, pyrogen-free, viscoelastic solution containing sodium hyaluronate and sodium chondroitin sulfate dissolved in an isotonic buffered medium.

The sodium hyaluronate used in the formulation is produced through a controlled bacterial fermentation process and purified to meet the required quality specifications. The product is formulated to maintain physiological pH and osmolarity and exhibits viscoelastic properties that facilitate ophthalmic surgical procedures.

Properties	Details
Molecular weight	≥1.5x106 dalton
PH	6.8 – 7.4
Shear Viscosity at 25°C (in cps)	60000 -125000

INTENDED USE

This device is intended for intraocular use during anterior segment ophthalmic procedures, including cataract extraction and intraocular lens implantation.

The product is intended to:

- Maintain the depth of the anterior chamber.
- Protect delicate intraocular tissues.
- Improve visualization during surgery.
- Facilitate the manipulation and placement of surgical instruments and intraocular lenses.
- Reduce trauma to the corneal endothelium and surrounding tissues.

CONTRAINDICATIONS

No specific contraindications have been established when the device is used according to the prescribed instructions. However, the device should not be used in patients with known hypersensitivity to any component of the formulation.

The product is supplied as a sterile ophthalmic viscoelastic solution in a prefilled syringe.

Each package contains the following components:

- One sterile prefilled syringe containing the OVDsolution.
- One sterile 25 G or 27 G cannula.
- Protective packaging in the form of a blister pack or heat-sealed pouch.

The available fill volume may vary according to the product configuration.

STERLLIZATLON

The solution is manufactured and aseptically filled into sterile syringes under controlled environmental conditions. The accompanying cannula is sterilized using validated ethylene oxide (EO) sterilization procedures.

INSTRUCTIONS FOR USE

- Verify the integrity of the packaging before use.
- Confirm that the product has not exceeded its expiry date.
- Carefully remove the syringe from the sterile package using an aseptic technique.
- Secure the supplied cannula to the luer-lock fitting of the syringe.
- Gently depress the plunger until a small amount of solution appears at the cannula tip.
- Introduce the cannula into the surgical site in accordance with the surgical procedure.
- Dispense the solution gradually while avoiding excessive force.
- Remove any residual OVD from the eye upon completion of the procedure.
- This product is intended for use only by qualified ophthalmic surgeons.
- The device is intended for single use only.
- Do not use the product if the package is damaged.
- Do not use the solution if discoloration, cloudiness, or particulate matter is observed.
- Dispose of the product according to applicable local regulations.
- Reuse of the device may
    - o The device may compromise its sterility, safety, and performance.
    - o Damage the syringe, cannula, or packaging components.
    - o increase the risk of contamination, infection, inflammation, and other postoperative complications.
    - o Any unused portion of the product should be discarded after the procedure.
    - o The manufacturer is not responsible for adverse events resulting from improper use, reuse, reprocessing, or resterilization of the device.
- Do not re-sterilize the device. Resterilization of the OVD will have a
    - o Detrimental effect on its rheological and chemical properties there by
    - o rendering it inappropriate for the intended use.
- Risk of implantation: Ensure complete removal of OVD after surgery.
    - o The use of machine assisted Irrigation/Aspiration is recommended for removal.
    - o Post operatively, verify the absence of OVD in the eye during follow up.
- Ensure safe and proper disposal of used/discarded product and packaging
    - o As per established procedure for handling biomedical waste.
- Read Instructions before Use

STORAGE

- Store in a cool and dry place.
- Protect the product from direct sunlight.

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