

Technical Data Sheet Synergy Plus viscoelastic 1.8% + taurine with cannula

Product code: SYNKP

Manufacturer viscoelastic: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia

Manufacturer cannula: Sterimedix

Assembler: Md Tech Srl - Via Fratelli Bandiera, Ncc - 80026 Casoria (Na), Campania Italia

Description: Synergy visc Plus is a viscoelastic solution based on Sodium Hyaluronate with pharmaceutical grade purity, registered as a medical device for intraocular injection use with taurine.

Intended Use: Synergy visc Plus is an indicator in eye surgery of the anterior segment including the cataract removal, intraocular lens insertion, corneal transplant, glaucoma and retinal detachment. Thanks to taurine action Synergy visc Plus plays a key role in reducing adverse effects and preventing beneficial effects through different pathways.

// General Features

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| Packaging | The package contains 1 27 G sterile cannula needle and 1 glass syringe sterile disposable, pre-filled with 1.1 ml of product. |
| Composition | Sodium Hyaluronate at different concentrations (18mg/mL – 16mg/mL -14mg /mL), Sodium Chloride, Disodium Hydrogen Phosphate Dodecahydrate, Sodium Dihydrogen Phosphate Dihydrate and Water for injections |

// Technical Features

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| | 1.8% |
| pH | 6.8 – 7.6 |
| Osmolality | 300 – 350 mOsm/Kg |
| Dynamic viscosity | 200000 – 300000 mPa.s |
| Molecular weight (Sodium Hyaluronate raw material) | 2.5 x10 ⁶ - 3x10 ⁶ Da |

// Other Specifications

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|---------------------------------------|---|
| Reference Standard | Directive 93/42 CEE |
| Class | II a |
| Product Type | Medical device in compliance with the current legislation |
| Compatibility With Solutions | Sodium hyaluronate is incompatible with ammonium compounds Quaternary such as Benzalkonium Chloride solutions. Therefore, Synergy pre-filled syringes should never come into contact with surgical instruments rinsed with these solutions or with ophthalmic products that contain quaternary ammonium compounds as preservatives. |
| Shelf Life and Sterilization Method | Product is valid for 2 years from the date of manufacture. Viscoelastic is steam sterilized in conformity to UNI EN ISO 17665, it must not be reused or resterilized. Cannula is sterilized with EtO in accordance with UNI EN ISO: 11135-1 / 2. The expiry date of kit is indicated on the packaging |
| Presence of Latex | No |
| Storage | Store at ambience condition, in dry place without humidity. Temperature must be in the range +2°C and +25°. |
| Information Reported on the Packaging | Batch number, expiry date, serial number, type of sterilization, manufacturer, CE mark. |

