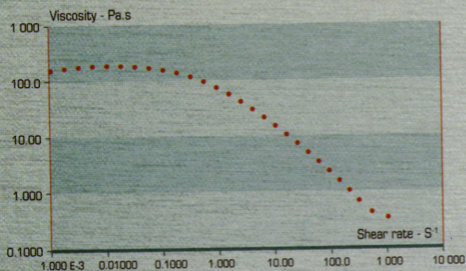


CRISTAVISC

With an average 170 000 millipascal second zero shear viscosity, CRISTAVISC c is ideally cohesive.



TECHNICAL SPECIFICATIONS

DESCRIPTION

Eur. Ph. Injectable quality hyaluronic acid for Intraocular use, from biofermentation origin	—
Each box contains	1 syringe - 1 x 27G7/8" canula - 1 leaflet - 8 traceability labels
Glass syringe, Pharmaceutical grade, Class I, latex free, prefilled	At 1 ml
NaHa concentration	15,5 mg/g
Molecular weight of the hyaluronic acid in the final sterile product	2,2 MDa (mean value)
Phosphate Buffer pH 7,2	q.s. 1g
With natural antioxidant	Mannitol
Isoosmolarity	280-360 mOsm
pH	6,8 - 7,6
Viscosity at 0,015-1 shear rate	170 Pa.s (170 000 cPoise) (mean value)
Apyrogen (free of endotoxins)	< 0,5 EU/g
Sterile (gel by autoclave - second packaging, blister by ETO)	SAL 10-6 (Sterility Assurance Level)
Proteins	< 20 ppm
Storage	2- 25°C during 36 months, room temperature
Medical Device	Class IIb
Biocompatible according to	ISO EN 10993 and ISO EN 15798
System of quality management in conformity to	ISO13485

INDICATIONS

- Anterior segment surgery.
- Protection of the corneal endothelium and maintenance of the intraocular space.