


Brand Name	S_{IDA}-VISC 1.6%
Product Group	Ophthalmic Viscoelastic Solutions
Ref. No.	10006 (1 mL); 10016 (1.5 mL)
Properties	16mg/mL sodium hyaluronate ophthalmic solution. Clear, colorless, odorless, sterile, isotonic solution. For intraocular use only. Not for injection.
How Supplied	Prefilled glass syringe of 1 mL or 1.5 mL volume
Intended Use	S _{IDA} -VISC 1.6% is indicated for use as a space occupying tissue protective fluid and lubricant during various intraocular surgical procedures including intra-/ extracapsular cataract extraction, IOL implants and corneal transplantations. In surgical procedures in the anterior segment of the eye, instillation of the S _{IDA} -VISC serves to maintain a deep anterior chamber during surgery, allowing for efficient manipulation with fewer traumas to the corneal endothelium and other surrounding tissues.
Features	Molecular weight : 1.100.000 - 2.600.000 Dalton Viscosity : 80.000 - 140.000 mPa·s (dispersive) pH : 6.8 - 7.6 Osmolality : 270 - 400 mOsm/kg
Origin	Biofermentation
Sterilization	Steam (solution); Ethylene oxide (accompanying cannula)
Shelf life	3 years
Storage Conditions	2°C - 25°C
Certification	CE ₂₈₀₃
Classification	Class IIb, according to Annex IX of Council Directive 93/42/EEC
Conformity	MEDDEV 2.4/1 Rev. 9 - June 2010 Rule 8
Applicable Standards	ISO 9001, ISO 13485, ISO 14971, ISO 11607, ISO 10993, ISO 17665, ISO 11737, ISO 14644, ISO 15798, ISO 15223
Depiction	
Primary Packing	Pre-filled syringe packed in blister; Viscoelastic Cannula 27G packed in blister
Secondary Packing	Individual paper box containing blisters and set of labels for administrative use.
Instructions for Use	Available in electronic form (eIFU) via dedicated microsite.