

Produces Consistent Results

TRUSTED AND PROVEN FORMULA FOR OVER 25 YEARS



ANIKAVISOC™

12 mg/mL SODIUM HYALURONATE
0.8 mL

OUTSTANDING CLARITY:: permits an unobstructed view of the surgical field

HIGH VISCOSITY:: provides excellent chamber stability and endothelial protection

HIGH COHESION:: makes viscoelastic removal quick and easy

HIGH EFFICIENCY:: allows for complete control throughout the procedure without needing a second viscoelastic



ANIKAVISC SPECIFICATIONS (AVIAN SOURCE, BUFFERED)

ANIKAVISC ophthalmic viscoelastic shall meet the following criteria:

Contents	Sodium Hyaluronate, Sodium Chloride, Sodium Phosphate Dibasic, Sodium Phosphate Monobasic, Hydrochloric Acid (to adjust pH if necessary), Sodium Hydroxide (to adjust pH if necessary), Water for Injection and no other ingredients
Appearance	Clear, viscous fluid
Identification	Conforms to standard spectrum
USP Sterility Test results	Sterile, USP
USP Bacterial Endotoxin Test	≤ 0.25 EU/mL
Volume	NLT 0.8 mL - NMT 0.94 mL
Chemical analysis test results for:	
pH	6.8 – 7.6
Dynamic viscosity @ 1 sec ⁻¹ , 25°C	34,300 – 46,500cps
Intrinsic viscosity	1,750 – 4,000 mL/g
NaHA Concentration	10 – 14 mg/mL
Molecular Weight	1,000,000 – 2,900,000 daltons
Osmolality	288 – 352 mOsm
Protein concentration	≤ 34 ppm
Galactosamine	None detected – limit of detection – 0.050% (w/w)
End group analysis.....	Increase in NAG
UV analysis	Conforms to standard spectrum

GENERAL REQUIREMENTS

Shelf Life	Twenty four (24) months
Storage Temperature	2-8° C; (36-46°F); Do Not Freeze



INDICATIONS Anikavisc is intended for use during surgery in the anterior and posterior segments of the human eye. Procedures include: Cataract extraction, Intraocular lens (IOL) implantation, Corneal transplantation surgery, Glaucoma filtering surgery and surgical procedures to reattach the retina. Anikavisc is designed to create and maintain anterior chamber depth and visibility, protect corneal endothelial cells and other intraocular tissues, minimize interaction between tissues during surgical manipulation, and act as a vitreous substitute during retinal reattachment surgery. Anikavisc also preserves tissue integrity and good visibility when used to fill the anterior and posterior segments of the eye following open sky procedures.

CONTRAINDICATIONS At the present time there are no contraindications to the use of Anikavisc when used as recommended.

PRECAUTIONS Those precautions normally considered during anterior segment and retinal attachment procedures are recommended. Transient increases in intraocular pressure may occur following surgery because of preexisting glaucoma or due to the surgery itself. For these reasons, the following precautions should be considered. An excess quantity of Anikavisc should not be used. Anikavisc should be thoroughly removed from the anterior chamber after surgery to prevent or minimize post-operative intraocular pressure increases (spikes). If the postoperative intraocular pressure increases above expected values, appropriate therapy should be initiated. Anikavisc is prepared from a biological source and the physician should be aware of the possible effects of using any biological material. A single use disposable cannula, such as the one provided in the package, should be used when administering Anikavisc. Reuse of cannula should be avoided. The repeated use of a cannula could release particulate matter as Anikavisc is injected. There have been isolated reports of diffuse particulates or haziness appearing after injection of products similar to Anikavisc into the eye. While such reports are infrequent and seldom associated with any effects on ocular tissues, the physician should be aware of the occurrence. If observed, the particulate matter should be removed by irrigation and/or aspiration.