198 mm

49,5 mm

200 mm

TEKNOMEK

Medikal Malzemeleri San. ve Tic. Ltd. Şti.

EN

SODIUM HYALURONATE (HYOTEK) INSTRUCTIONS FOR USE

Read the instructions for use cautiously!

1.PRODUCT INFORMATION

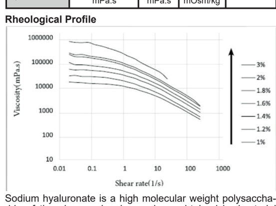
Product Name: Sodium Hyaluronate
Product Model: See the catalog or web-site for the models
BUDI-DI: 868054899025NK
Product Concentration Percentages: 1%, 1.2%, 1.4%, 1.6%, 1.8%,2.0%, 3.0%
Size: 0.55, 0.85, 1, 1.5 or 2 milliliters (in a glass syringe)
Shelf Life: Shelf life is three years. Stated on the product.
Class:IIb

Chemical Properties	Sodium Hyaluronate Concentration	Molecular Weight	pH
Hyotek%1	%1	2.3-3.2 MDa	6.8-7.6
Hyotek%1.2	%1.2	2.3-3.2 MDa	6.8-7.6
Hyotek%1.4	%1.4	2.3-3.2 MDa	6.8-7.6
Hyotek%1.6	%1.6	2.3-3.2 MDa	6.8-7.6
Hyotek%1.8	%1.8	2.3-3.2 MDa	6.8-7.6
Hyotek%2	%2	2.3-3.2 MDa	6.8-7.6
Hyotek%3	%3	2.3-3.2 MDa	6.8-7.6

Chemical Properties	Density	Concentration	Endotoxicity
Hyotek%1	0,988-1.001 g/cm³	10mg/ml	<0.2EU/ml
Hyotek%1.2	0,990-1.000 g/cm³	12mg/ml	<0.2EU/ml
Hyotek%1.4	0,994-1.002 g/cm³	14mg/ml	<0.2EU/ml
Hyotek%1.6	0,998-1.005 g/cm³	16mg/ml	<0.2EU/ml
Hyotek%1.8	0,998-1.008 g/cm³	18mg/ml	<0.2EU/ml
Hyotek%2	1.000-1.009 g/cm³	20mg/ml	<0.2EU/ml
Hyotek%3	1.001-1.020 g/cm³	30mg/ml	<0.2EU/ml

Chemical Properties	Viscosity	Tolerance	Osmolality	Refractive Index
Hyotek%1	10,000-30,000 mPa.s	NA	200-400 mOsm/kg	1.337-1.338
Hyotek%1.2	30,000-60,000 mPa.s	NA	200-400 mOsm/kg	1.337-1.338
Hyotek%1.4	60,000-100,000 mPa.s	NA	200-400 mOsm/kg	1.337-1.338
Hyotek%1.6	100,000-150,000 mPa.s	NA	200-400 mOsm/kg	1.337-1.338
Hyotek%1.8	150,000-300,000 mPa.s	NA	200-400 mOsm/kg	1.337-1.338
Hyotek%2	300,000-400,000 mPa.s	NA	200-400 mOsm/kg	1.337-1.338
Hyotek%3	400,000-900,000 mPa.s	+70,000 mPa.s	200-400 mOsm/kg	1.337-1.338

Rheological Profile



Sodium hyaluronate is a high molecular weight polysaccharide of the glycosaminoglycan class, obtained by bacterial fermentation method. Contains sodium hyaluronate powder, sodium hydrogen phosphate salts, sodium chloride and distilled water. The product is a clear, colorless, odorless and sterile viscoelastic solution for intraocular application. Does not contain any preservatives.

2.PACKAGING and STERILIZATION

Sodium Hyaluronate is offered in 0.55ml, 0.85ml, 1ml, 1.5ml or 2ml sterile single use glass syringes. The product is offered with a 23-27 G thin blunt-ended sterile single use cannula. The product is in ready-to-use form. The amount is specified on the product packaging. The product is sterilized with steam sterilization, its package with ethylene oxide.

3.INTENDED PURPOSE

The main purpose of using Sodium Hyaluronate in surgeries is to sustain a stable anterior chamber depth, to protect the corneal endothelial cells.

The product protects the corneal endothelium by stabilizing cavity during intraocular manipulation It is used in surgeries such as cataract, glaucoma, corneal transplantation and lens implantation to protect the anterior chamber depth.

3.1.Clinical Benefit

- Sodium hyaluronate in cohesive form provides protection for eye tissues during ophthalmic surgery.
- Pseudoplasticity characteristic provides easy flow during injection and helps regain high viscosity values after injection.
- Enables surgeons to easily perform surgical maneuvers during operations.

4.INDICATIONS

Sodium hyaluronate is indicated in all cases where eye tissues need to be protected. Used in any anterior segment surgery, intraocular lens implantation, cataract surgery, glaucoma surgery and corneal transplantation.

4.1.Patient Information

The targeted patient group includes all age groups, all nationalities, and the whole population in need of ophthalmologic surgery without indicating any weight restrictions. The International Patient Identification Card is issued to the patient with instructions to keep the implant as a permanent record and to show it to any future ophthalmologist.

4.2.Patient Preparation

The product is used in eye surgery. The patient is prepared for the surgical procedure in line with the doctor's instructions. The product does not require any special preparation any training.

5.CONTRAINDICATIONS

The solution should not be used in patients who are allergic to any component of sodium hyaluronate. The viscoelastic solution must be completely removed following the surgery, otherwise it may cause high intraocular pressure. The surgeon should use careful pre- and peri-operative evaluation and solid clinical judgment to decide the benefit/risk ratio before administering a sodium hyaluronate injection to a patient with one or more of the following conditions. The evaluation of each individual case is at surgeon's discretion.

- In patients who are sensitive to any substance in the solution,
- In patients with very high intraocular pressure,
- Use for children pregnant or lactating women is under the initiative of the ophthalmic surgeon.

6.SIDE EFFECTS

Temporary high intraocular pressure abnormalities may occur following the surgery. The patient should be warned that he/she should consult his/her doctor if intraocular pressure increases. Since sodium hyaluronate is discordant with quaternary ammonium compounds such as solutions containing benzalkonium chloride, contact with surgical instruments washed with solutions containing these substances or with ophthalmic products containing quaternary ammonium as a preservative should be avoided. Risk analysis conducted by the manufacturer's risk management team specified that the remaining risk is as low as reasonably possible.

7.USAGE

It should be completely clean in the eye after the procedure is completed. The amount to be injected varies in each specific case and should be designated by the surgeon during the operation. Do not mix with any other substance before use.

- Take out the products from the box.
- Open the product packaging just before use.
- Open the sterile packaged products taken out of the box to a sterile area by following the sterile opening rules and the opening direction shown on the package. **(Picture A)**

peel here

Picture A: Symbol of Blister Pack Open Direction

Instructions to remove the syringe luer cap correctly:

1. Take the syringe from the box out of its package.
2. Hold the syringe luer as shown.
3. Carefully twist the luer cap.
4. Remove the luer cap.

2 4

Instructions to place the cannula correctly:

5. Take the cannula from the box out of its package.
6. Hold the syringe.
7. Place the cannula on the syringe.
8. Twist and secure.
9. After the air is purged out of the cannula tip, the solution is ready to be injected. Sodium hyaluronate viscoelastic is completely cleaned/removed from the eye by irrigation and/or aspiration method at the end of the surgery.

8 9

8.WARNINGS and PRECAUTIONS

⚠	It is for single-use.
⚠	Do not shake the product.
⚠	Do not re-sterilize. Reuse and/or resterilization may adversely affect device performance, which could seriously harm patient health and safety.
⚠	Do not use the product whose sterile package has been opened or damaged.
⚠	Apply with a sterile single use syringe and a sterile single use cannula.
⚠	Do not use expired products.
⚠	The product is restricted for use by surgeons trained in ophthalmic surgery.
⚠	Stop the application in case of an adverse reaction. In case of any adverse reaction,notify the manufacturer.
⚠	Conduct the application according to the instructions written in the instructions for use. Otherwise the manufacturer is not responsible.
⚠	Use for children pregnant or lactating women is under the initiative of the ophthalmic surgeon.
⚠	It should not be used in conjunction with other devices and/or general purpose equipment.
⚠	Suitable for intra-ocular use only.
⚠	Used for a short time in operations and must be completely cleaned following the operation.
⚠	Ensure that the product is completely cleaned following the application.
⚠	The remaining viscoelastic after surgical operation is naturally excreted through the trabecular system and Schlemm's canal. Intraocular pressure may increase in any case where the drainage channels may be blocked. In such a case, the surgeon should implement the appropriate treatment.
⚠	Even though there are no cases reported up to the present, it may interact with concomitant medications and cause condensation. In case such a case is observed, physicians should consider this potential.
⚠	Failure to follow all assembly instructions or applying an alternative cannula may cause cannula separation and serious injury possibility.
⚠	Sodium hyaluronate is incompatible with quaternary ammonium compounds like solutions containing benzalkonium chloride. For this reason, contact of Sodium hyaluronate with surgical instruments washed with solutions containing the substances in question or with ophthalmic products containing quaternary ammonium as a preservative should be avoided.

9.WASTE DISPOSAL

Used products must be disposed of properly to avoid possible risks of infection. Disposal of the products after use should be performed by authorized persons in line with hospital procedures. Manufacturer is not responsible for waste disposal procedures.

10.STORAGE AND TRANSFER CONDITIONS

Store at temperatures between 10°C (50°F or 283.15°K) and 25°C (77°F or 298.15°K). Store in a dry place. Protect against light and impact. If it is wanted to be transferred, it can be transported in the boxes belonging to the product.

11.WARRANTY AND LIMITATION OF LIABILITY

Teknomek Medikal is not responsible for any injuries or damages that may arise from non-compliance with the recommendations and suggestions in the instructions for use and that are not suitable for the patient in the specified criteria. The risk of contamination which may arise from re-sterilizing the product by ignoring its single use quality is not the responsibility of the manufacturer. Teknomek Medikal is not responsible for the injuries or damages that the patient may suffer if it is not used by the doctor in line with the instructions for use.

12.SAFETY and CLINICAL PERFORMANCE

The product does not contain tissue, cell or derivatives of human or animal There are no accessories and software for the device. There are no medicinal substances or biological materials included in the device as an integral part of the device. No CMR substances or materials that contain or consist of endocrine disruptors as an integral part of the device or that may cause sensitization or an allergic reaction to the patient or user are included in the device. Please contact the manufacturer for detailed safety and performance information.

13.RETURN AND EXCHANGE POLICY

Please contact the manufacturer or your local distributor for the return or exchange of the product.

14.SYMBOLS

The symbols given on the product box and in the instructions for use are listed below.

Symbol	Meaning
	Manufacturer
LOT	Batch Code
10°C – 25°C	Temperature Limit
20% – 70%	Humidity Limitation
	Do not re-use.
STERILIZE	Do not resterilize.
	Use-by Date
	Caution
	Keep away from sunlight
STERILE EO	The package is sterilized using packaged ethylene oxide
STERILE	The product is sterilized using steam. Single sterile barrier system.
	Keep dry
	Consult instructions for use
	Do not use if package is damaged and consult instructions for use.
MD	Medical Device
UDI	Unique Device Identifier
LATEX	Does not contain natural rubber latex

15.ABBREVIATIONS

IFU	Instructions for Use
EN	English
%	Percentage
˚K	Kelvin
˚C	Centigrade
˚F	Fahrenheit
CMR	Carcinogenic, mutagenic, reprotoxic substances
mPa	Mili pascal
Pa	Pascal
mPas	Milli pascal second
G	Gauge
ml	Milliliter
kg	Kilogram
mg	Miligram
g	Gram
g/ml	Gram/Milliliter
mg/ml	Milligram/Milliliter
EU/ml	Endotoxin per milliliter
mOsm/kg	Miliosmol / Kilogram
BUDI-DI	Basic Unique Device Identification - Device Identifier
MDa	Megadalton

Üretici: TEKNOMEK Medikal Malzemeleri Sanayi ve Ticaret Ltd. Şti Karamehmet Mah. Avrupa Serbest Bölgesi 9. Sk. No:14 Ergene / Tekirdağ / Türkiye
Tel: +90 212 369 1263, Fax: +90 212 210 3432
Website: www.teknomek.net e-mail: info@teknomek.net

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Translated by:
Atlantik Tercüme Hizmetleri Tic. Ltd. Şti
Address: Kervangeçmez Cad. Hark Sok. Çağdaş Apt. No:2/5 34381 Mecidiyeköy, İstanbul, Türkiye
Tel: +90 212 217 92 06
e-mail: info@atlantiktercume.com