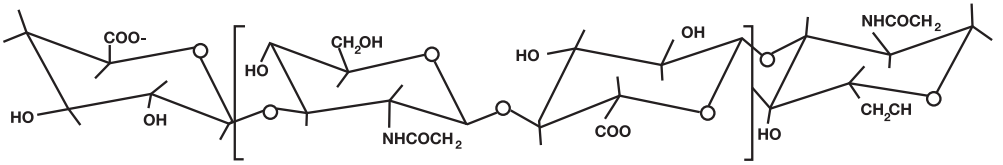
REF 6910

NeoVisc®

(Single Dose)
Sterile Sodium Hyaluronate Solution 1.0%
Synovial Fluid Replacement/Replenishment

Description: Sodium hyaluronate in NeoVisc® is a naturally occurring linear polysaccharide composed of repeating disaccharide unit of D-glucuronic acid and N-acetyl-D-glucosamine linked by ß1-3 and ß1-4 glycosidic bond.



N-Acetylglucosamine **D-Glucuronic Acid**

Hyaluronate maintains the structure of proteoglycan molecules. Proteoglycans bind hyaluronate chains to form large aggregates in the range of 10^8 Daltons. The linking proteins of aggregates stabilize the macromolecular structure which are deposited within the collagen network of cartilage. Hydration of aggrecan molecules provides resilience and elastic strength to cartilage. Viscoelasticity of synovial fluid is due mainly to rheological properties of hyaluronate solution. In osteoarthritis, the concentration of hyaluronate is decreased, resulting in a loss of viscoelastic properties of synovial fluid. NeoVisc® is a specific high molecular weight hyaluronate, free of avian proteins, in a phosphate buffered saline for synovial fluid replacement/replenishment.

Indication: As a replacement/replenishment for synovial fluid, following arthrocentesis.

Blister Pack Directions: To be opened by a Physician only. To access syringe, grip tab at top and peel off one strip as needed.

Administration: Using aseptic technique, administer 6 mL (60 mg) intra-articularly to the affected joints. Repeat depending on clinical response.

Precautions: Do not administer to patients with known hypersensitivity reactions. Transient short duration pain may occur following intra-articular injection.

No contraindications to hyaluronate solutions have been reported with intra-articular injections.

Warning: Do not inject intra-vascularly.

All medical procedures carry some risk. After intra articular injections of NeoVisc, the injected joint may experience: transient pain, and/or swelling, and/or effusion. In cases of large effusions; it is important to remove and analyze the fluid to rule out infection or crystalline arthropathies. Expect these reactions to abate within a few days, often overnight. After such reactions there may still be clinical benefit from the treatment.

Supplied: Each mL contains sodium hyaluronate 10 mg.
Each 6 mL single dose disposable syringe contains 60 mg of sodium hyaluronate.
Only the contents of the syringe are sterile.

Storage: Store 2 - 25°C. DO NOT FREEZE.
Bring contents to room temperature before use.

LOT Batch Number	Expiry date	For single use only	Refer to instruction leaflet	STERILE A Sterile by aseptic processing and sterile filtration
2°C 25°C Store at 2 - 25° C	Manufacturer	Do not use if package is damaged	EC REP Authorized representative	REF Catalogue Number

Aralez Pharmaceuticals
Aralez Pharmaceuticals Canada Inc.,
7100 West Credit Avenue,
Mississauga, ON, Canada
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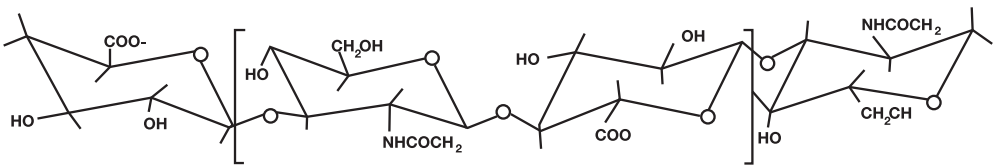
310-03 Rev 2

REF 6902-S

NeoVisc®

Sterile Sodium Hyaluronate Solution 1.0%
Synovial Fluid Replacement/Replenishment

Description: Sodium hyaluronate in NeoVisc® is a naturally occurring linear polysaccharide composed of repeating disaccharide unit of D-glucuronic acid and N-acetyl-D-glucosamine linked by ß1-3 and ß1-4 glycosidic bond.



N-Acetylglucosamine **D-Glucuronic Acid**

Hyaluronate maintains the structure of proteoglycan molecules. Proteoglycans bind hyaluronate chains to form large aggregates in the range of 10^8 Daltons. The linking proteins of aggregates stabilize the macromolecular structure which are deposited within the collagen network of cartilage. Hydration of aggrecan molecules provides resilience and elastic strength to cartilage. Viscoelasticity of synovial fluid is due mainly to rheological properties of hyaluronate solution. In osteoarthritis, the concentration of hyaluronate is decreased, resulting in a loss of viscoelastic properties of synovial fluid. NeoVisc® is a specific high molecular weight hyaluronate, free of avian proteins, in a phosphate buffered saline for synovial fluid replacement/replenishment.

Indication: As a replacement/replenishment for synovial fluid, following arthrocentesis.

Blister Pack Directions: To be opened by a Physician only. To access syringe, grip tab at top while supporting neighbouring strip and peel off one strip as needed. To separate individual blister packs, fold on perforation and bend back and forth several times prior to tearing.

Administration: Using aseptic technique, administer 2 mL (20 mg) intra-articularly to the affected joints. Continue with one injection per week for a total of 3 to 5 injections. Repeat every 6 to 8 months, depending on clinical response.

Precautions: Do not administer to patients with known hypersensitivity reactions. Transient short duration pain may occur following intra-articular injection.

No contraindications to hyaluronate solutions have been reported with intra-articular injections.

Warning: Do not inject intra-vascularly.

All medical procedures carry some risk. After intra articular injections of NeoVisc, the injected joint may experience: transient pain, and/or swelling, and/or effusion. In cases of large effusions; it is important to remove and analyze the fluid to rule out infection or crystalline arthropathies. Expect these reactions to abate within a few days, often overnight. After such reactions there may still be clinical benefit from the treatment.

Supplied: Each mL contains sodium hyaluronate 10 mg.
Each 2 mL single dose disposable syringe contains 20 mg of sodium hyaluronate. Three syringes in a box.
Only the contents of the syringe are sterile.

Storage: Store 2 - 25°C. DO NOT FREEZE.
Bring contents to room temperature before use.

LOT Batch Number	Expiry date	For single use only	Refer to instruction leaflet	STERILE A Sterile by aseptic processing and sterile filtration
2°C 25°C Store at 2 - 25° C	Manufacturer	Do not use if package is damaged	EC REP Authorized representative	REF Catalogue Number

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