NeoVisc® HA 1.5%

Hyaluronic acid sodium salt solution for intra-articular injection

NeoVisc®+ 2mL
NeoVisc® ONE 4mL

Product description
NeoVisc® HA 1.5% products (NeoVisc®+ 2 mL and NeoVisc® ONE 4 mL) are sterile, non-pyrogenic, viscoelastic solutions manufactured with hyaluronic acid sodium salt, obtained by bacterial fermentation from a fraction of high molecular weight. Hyaluronic acid, a polysaccharide of the glycosaminoglycan family, is naturally present in many human tissues such as cartilage and synovial fluid; it is continuously secreted into the joint space and represents a major component of the synovial fluid, to which it provides its characteristic viscosity and elasticity. Such properties are fundamental for the lubricating and shock absorbing functions exerted by the fluid in normal joints to protect cartilage and soft tissues against mechanical injuries.

In traumatic and degenerative joint disorders, an insufficient amount of hyaluronic acid and a loss of viscosity occur in synovial fluid, resulting in an impairment of joint function and in a painful symptomatology. Extensive data in the literature indicate that intra-articular administration of hyaluronic acid is capable of restoring the viscoelastic properties of the synovial fluid, with alleviation of pain and improvement of joint mobility.

NeoVisc® HA 1.5% are treatments for temporary synovial fluid replacement in patients affected by degenerative or mechanical arthropathy of the knee, which causes an alteration of the functional performances of the synovial liquid. Intra-articular injection of NeoVisc® HA 1.5% reduces pain symptoms and improves knee joint functionality, up to 6 months.

Composition
Principal component: Hyaluronic acid sodium salt 1.5%
Other components: Sodium chloride, Disodium hydrogen phosphate dodecahydrate, Sodium dihydrogen phosphate dihydrate, Water for injection.

Intended use
NeoVisc® HA 1.5% is a temporary synovial fluid replacement to be administered by intra-articular injection.

Indications
NeoVisc® HA 1.5% is indicated for the treatment of pain and improvement of joint functionality in patients affected by degenerative (age-related changes) or mechanical arthropathy (related to overuse) of the knee.

Dosage and Administration - NeoVisc®+ 2 mL
NeoVisc®+ is intended for intra-articular injection only.
Product administration should be performed exclusively by licensed physicians (e.g. orthopaedic surgeon, rheumatologist, physiatrist, radiologist, sports doctors, etc.).
Injection must be strictly intra-articular. Intra-articular injection must be performed according to the usual standard technique, using precise, anatomical localization. Inject NeoVisc®+ using a suitable sterile needle (for example 18 or 20 G), in the affected joint at weekly intervals for 3 weeks.
Subsequent cycles may be performed if necessary, even if no systematic collection of clinical data is available.
All the rules regarding the asepsis and the injection technique shall be followed. Remove any joint effusion, if present, before administration.
The sterility on the outer surface of the syringe makes the use of the product suitable for the operating room.

Dosage and Administration - NeoVisc® ONE 4 mL
NeoVisc® ONE is intended for intra-articular injection only.
Product administration should be performed exclusively by licensed physicians (e.g. orthopaedic surgeon, rheumatologist, physiatrist, radiologist, sports doctors, etc.).
Injection must be strictly intra-articular. Intra-articular injection must be performed according to the usual standard technique, using precise, anatomical localization. Remove any joint effusion, if present, before the administration.
Inject NeoVisc® ONE using a suitable sterile needle (for example 18 or 20 G) in the affected joint. Further treatments after the first application may be needed to maintain the benefit of the treatment over time, depending upon the individual patient needs. As demonstrated by clinical studies, a second injection of NeoVisc® ONE should be administered no sooner than six months after the first injection. All the rules regarding the asepsis and the injection technique shall be followed.
The sterility on the outer surface of the syringe makes the use of the product suitable for the operating room.

Contraindications
Do not administer to patients with ascertained individual hypersensitivity to the product components.
Do not administer in cases where there are infections or skin diseases in the area of the injection site.
Do not administer to patients with active synovitis.

Use in specific populations
The safety and efficacy of NeoVisc® HA 1.5% in pregnant women, lactating women who are breast feeding, or in subjects less than 18 years of age have not been established and therefore its use is contraindicated in these patient populations.

Warnings and Precautions
Do not use in case of package damage.
Do not use the product after the expiry date reported on the package.
The expiry date refers to the product kept in its original package at a temperature not exceeding 25° C.
The syringe is for single use, that means it should to be used once only for a single patient. Inject the contents in one joint only.
For the first 24 hours after injection, the patient is permitted to continue all routine activities of daily living but is recommended not to overuse the treated joint.
The assembled syringe must be discarded immediately after use, regardless of whether the solution has been completely administered.
If this product is reprocessed and/or reused, Fidia Farmaceutici cannot guarantee performance, functionality, material structure, cleanliness or sterility of the product. Reuse could lead to illness, infection and/or serious injury to the patient or user.
After use, dispose according to applicable national practice. Keep out of reach of children.

Undesirable effects
Local pain, swelling, heat and redness may occur sporadically at the injection site. Such symptoms are generally mild and transient. Following intra-articular injection, application of an ice pack onto the treated joint for five to ten minutes will reduce the incidence of these events.
Local or systemic allergic reactions may occur in subjects with hypersensitivity to the product components.
More marked inflammatory reactions, sometimes with sodium pyrophosphate crystals, have been occasionally reported in association with intra-articular injections of hyaluronate.
As for any intra-articular treatment, septic arthritis may occur rarely when general precautions for injections are not observed or the site of injection is not aseptic.

Interactions
Do not use concomitantly with disinfectants containing quaternary ammonium salts, because hyaluronic acid can precipitate in their presence.
In order to prevent any possible interactions, avoid the contemporary administration of NeoVisc® HA 1.5% with other intra-articular products.

Storage
Store at a temperature not exceeding 25° C.

How supplied
NeoVisc® HA 1.5% is presented in pre-filled syringes containing either 30 mg/2 mL or 60 mg/4 mL hyaluronic acid sodium salt sterilised by using steam, in a blister sterilised by ethylene oxide.
It is available in three packaging configurations:

NV002	Package contains 1x **NeoVisc®+** 2 mL volume in a 2.25 mL syringe
NV002X3	Package contains 3x **NeoVisc®+** 2 mL volume each in a 2.25 mL syringe
NV004	Package contains 1x **NeoVisc®ONE** 4 mL volume in a 5 mL syringe

Manufacturer:
FIDIA Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme (PD) Italy

Distributor:
Aralez Pharmaceuticals Canada Inc.
Mississauga, Ontario
1-866-391-4503

Date of the latest revision of the instructions for use: September 2020

Consult instructions for use

Use by date

LOT Batch code

Do not reuse

STERILE Sterilised using steam

STERILE EO Sterilised using ethylene oxide

STERILE Sterile

Do not use if package is damaged

Temperature upper limit

Manufacturer

PI012-00

NeoVisc® (acide hyaluronique 1,5 %)

33000346/A

NeoVisc® HA 1.5%