

HIGH MOLECULAR WEIGHT

SHOCK ABSORBER



Used to prevent pain and motion limitation caused by osteoarthritis for all synovial joints

Reviscon 20 mg
The ideal concentration for OA treatment

20 mg HA (1.0%) in 2 ml solution
3-5 injections with one week intervals
Bacterial fermentation
3.0 M Da molecular weight
35,000 mPa.s viscosity



Preservation free

Reviscon Plus 32 mg
To meet the highest expectations with a medium concentration of sodium hyaluronate

32 mg HA (1.6%) in 2 ml solution
1-3 injections with one week intervals
Bacterial fermentation
3.0 M Da molecular weight
250,000 mPa.s viscosity



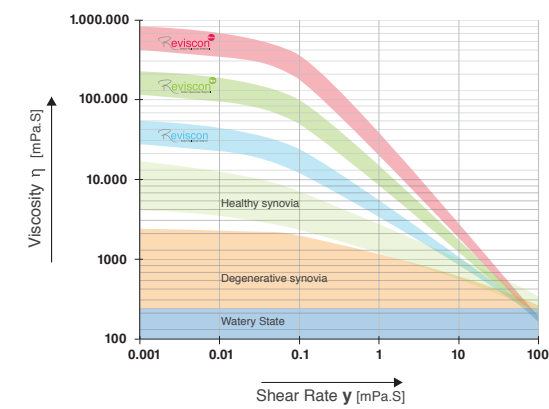
Preservation free

STRUCTURED NaHA Pattern



VISCOSITY

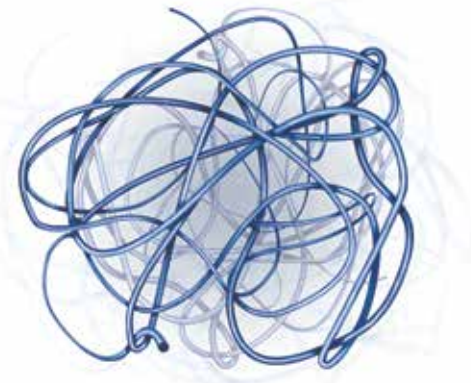
Excellent Rheological Pattern



Excellent rheological profile is designed for greater zero shear viscosity resulting in efficient pain relief and dynamic elasticity at higher shear rates for enduring mobility.

MOLECULAR WEIGHT

One of the highest molecular weight

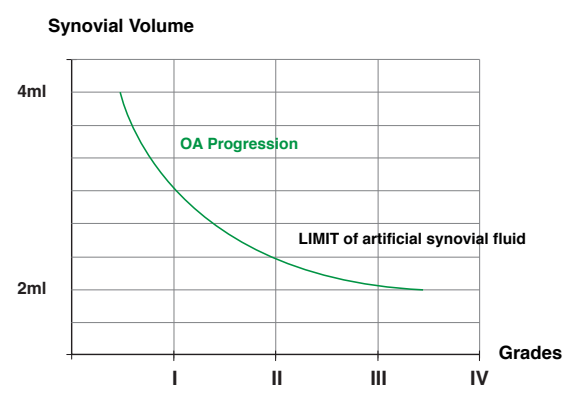


Reviscon Line contains one of the highest molecular weight of sodium hyaluronate with unique cohesive energy characteristics. With longer chain of HA Reviscon Line Provides;

- Better shock absorbtion
- High lubrication
- Long-lasting efficiency

CONCENTRATION

Well designed concentrations



Reviscon Line offers a range with 2.0 ml and 2.4 ml solutions.

- No pressure in the joint
- No side effects or swelling

Reviscon Line provides high impact on optimum volume

Single
Injection

Reviscon Mono 48 mg
Excellent high viscosity for long-lasting efficiency by single injection

48 mg HA (2.0%) in 2.4 ml solution
1 injection
Bacterial fermentation
3.0 M Da molecular weight
900,000 mPa.s viscosity
Therapeutical effect of single injection is 6 months



Preservation free

with STRUCTURED NaHA PATTERN



Reviscon
Sodium Hyaluronate 10 mg/ml

Reviscon Plus
Sodium Hyaluronate 16 mg/ml

Reviscon Mono
Sodium Hyaluronate 20 mg/ml

The Solution For Multiple Requirements



1-Takahashi K, Georger BS, Hawwood F, Kubo T, Hirasawa Y, Amiel D. The effects of hyaluronan on matrix metalloproteinases-3 (MMP-3), interleukin-1beta (IL-1beta), and tissue inhibitor of metalloproteinase-1 (TIMP-1) gene expression during the development of osteoarthritis. *Osteoarthritis and Cartilage* 2005;13:216-24.
2-Goldberg VM, Buckwalter JA. Hyaluronans in the treatment of osteoarthritis of the knee: evidence for disease-modifying activity. *Osteoarthritis and Cartilage* 1997;16:23-9.
3-Pozo MA, Balazs EA, Belmonte C. Reduction of sensory responses to passive movements of inflamed knee joints by hyaluronan, a hyaluronan derivative. *Experimental Brain Research* 1997;116:23-9.
4-Namiki O, Toyoshima H, Morisaki N. Therapeutic effect of intra-articular injection of high molecular weight hyaluronic acid on osteoarthritis of the knee. *International Journal of Clinical Pharmacology, Therapy, and Toxicology* 1982;20(11):501-7.

Reviscon 1.0%, 20 mg	Reviscon Plus 1.6%, 32 mg	Reviscon Mono 2.0%, 48 mg
Product: Reviscon 1.0% viscoelastic sodium hyaluronate solution for intra-articular injection.	Product: Reviscon Plus 1.6% viscoelastic sodium hyaluronate solution for intra-articular injection.	Product: Reviscon Mono 2.0% viscoelastic sodium hyaluronate solution for intra-articular injection.
Each product consists of 2.0 ml of viscoelastic solution in a single-use glass syringe for intra-articular use.	Each product consists of 2.0 ml of viscoelastic solution in a single-use glass syringe for intra-articular use.	Each product consists of 2.4 ml of viscoelastic solution in a single-use glass syringe for intra-articular use.
- 1.0 ml of Reviscon 1.0% contains 10.0 mg sodium hyaluronate, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate and water for injection.	- 1.0 ml of Reviscon Plus 1.6% contains 16.0 mg sodium hyaluronate, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate and water for injection.	- 1.0 ml of Reviscon Mono 2.0 % contains 20.0 mg sodium hyaluronate, sodium chloride, disodium hydrogen phosphate, sodium dihydrogen phosphate and water for injection.

Description:
Reviscon is sterile, non-pyrogenic, clear, non-inflammatory, highly purified sodium hyaluronate of high molecular weight, dissolved in a buffered physiological saline solution. The highly-purified sodium hyaluronate is obtained from bacteria by fermentation. Reviscon is a product for the relief of the pain and stiffness of the knee joint and other synovial joints in patients with degenerative and traumatic changes to the synovial joint. Reviscon has a pH of 6.8 to 7.6 and osmolality of 300 to 350 mOsm/kg, similar to the synovial fluid.

Properties and efficacy:
All synovial joints especially the weight –bearing joints, contain viscoelastic sodium hyaluronate. This substance has lubrication and shock absorbing properties, allowing these joints to move normally and painlessly. In patients with degenerative joint disease (osteoarthritis), the viscoelasticity of the synovial fluid is significantly impaired, causing the mechanical stress on the joint and the breakdown of the articular cartilage to greatly increase resulting in limited and painful joint movement. Intraarticular administration of high purity sodium hyaluronate, which has very good viscoelastic properties, can improve the quality of the joint's lubrication. The lubrication and shock absorbing properties of this product reduce pain and improve joint mobility. This effect may last for several months following recommended treatment cycle of intra-articular injections.

Indications:
Reviscon is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacological therapy and simple analgesics (e.g. acetaminophen(paracetamol)).

Contraindications:
Do not administer to patients with known hypersensitivity to hyaluronate preparations. Intra-articular injections are contraindicated in cases of present infections or skin diseases in

the area of the injection site to reduce the potential for developing septic arthritis.

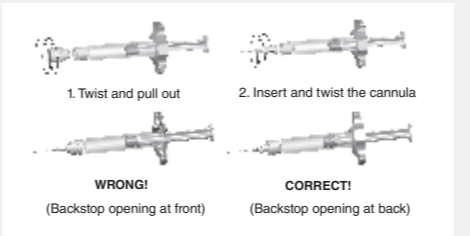
Side Effects:
Following the use Reviscon, patients may experience local symptoms in the joint being treated (pain, sensation of heat, reddening and swelling). The following adverse events have been reported for similar products: mild or moderate arthralgia, in rare cases skin rash, aseptic joint effusions, pruritus and muscular cramps. Further adverse events that have been observed in very rare cases are: allergic reactions, anaphylactic shock, hemarthrosis, phlebitis, pseudosepsis, severe acute inflammatory reaction (SAIR), nasopharyngitis, joint stiffness, tendonitis, bursitis, fever and myalgia.

Warnings and Precautions:
- Reviscon is intended for single use only. The reuse of the product creates a potential infection risk for patients or users.
- Sodium hyaluronate is manufactured by bacterial fermentation and rigorously purified. However the physician should consider the immunological and other potential risks that can be associated with the injection of any biological material.
- Do not reuse syringe. Any repeat usage of the syringe carries a risk of contamination and infection of the patient.
- Do not re-sterilize the pre-filled syringe. Performance will be impaired.
- Do not use if package is damaged or opened.
- Do not use after the expiry date printed on the pack.
- In order to avoid overuse of treated joints patients should be advised to relative rest (but no immobilisation) for 24h after each injection.
- Dispose of the syringe and cannula in accordance with accepted medical practice and applicable national, local and institutional requirements.
- There is no evidence concerning the safety of Reviscon in human pregnancy, lactation and the children under 18 years of age. Administration during pregnancy and lactation is at the discretion of the doctor.

Interaction with other agents:
Sodium hyaluronate is incompatible with quaternary ammonium compounds such as benzalkonium chloride solutions. Therefore, Reviscon pre-filled syringes must never come into contact with surgical instruments rinsed with these solutions.

Dosage and Administration:
FOR INTRAARTICULAR INJECTION. FOR SINGLE USE ONLY.




Reviscon should only be used by a physician for intra-articular injection. Use an appropriate size of the needle (19 to 20 gauge is recommended) and length of the needle depending on the joint to be treated. The administration periods vary due to the concentration of products. Multiple joints may be treated simultaneously and treatment cycles may be repeated. In order to avoid intra-articular infection strict aseptic injection technique has to be applied. It is recommended that an ice-pack be placed on the joint undergoing treatment for 5-10 minutes in order to prevent pain and swelling. In the case of effusion accompanied by severe pain the fluid must be removed from the affected joint.



Storage:
Store Reviscon between 2°C and 25°C. Protect from light and shocks. Do not freeze.

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High molecular weight NaHA Line

			
	Reviscon 20 mg	Reviscon Plus 32 mg	Reviscon Mono 48 mg
Substance	Sodium Hyaluronate (NaHA)	Sodium Hyaluronate (NaHA)	Sodium Hyaluronate (NaHA)
Concentration	20 mg HA (1.0%)	32 mg HA (1.6%)	48 mg HA (2.0%)
Volume	2 ml	2 ml	2.4 ml
Frequency	3-5 injections with one week intervals	1-3 injections with one week intervals	1 injection only
Origin	Bacterial fermentation	Bacterial fermentation	Bacterial fermentation
Molecular Weight	3.0 M Da	3.0 M Da	3.0 M Da
Zero Shear Viscosity	35,000 mPa.s	250,000 mPa.s	900,000 mPa.s