

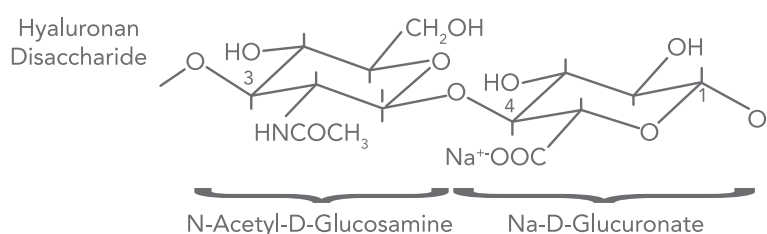
Sinovial[®]

(highly purified intra-articular hyaluronic acid)

DESCRIPTION

Hyaluronic acid (HA) is a very important component of the articular cartilage and has a significant role in maintaining the articular homeostasis. The concentration of HA in the synovial fluid of human knee is about 2.5-4.0 mg/ml in normal conditions, while in patients suffering from osteoarthritis (OA) its concentration is considerably reduced. HA contributes to lubrication of the joint, elasticity, hydration, shock absorption and nutrition for the joint tissue.

In pathological conditions there is a reduction of the HA synthesis by the synoviocytes and the production of a form of HA which is not able to guarantee the metabolic balance, with consequent impact on the articulation. The substitution of the damaged fluid with an intra-articular injection of HA ("Viscosupplementation") having the same properties of the original synovial fluid is able to restore the physiological conditions of the joint.



Besides a purely mechanical effect due to the viscosity of the product, the intra-articular injection of HA is thought to provide a range of biological actions including anti-inflammatory, analgesic, anabolic and chondroprotective effects. The term "Viscoinduction" has been coined to describe the phenomenon of the clinical benefits of HA exceeding that of a physical

lubricant/cushioning effect alone. Viscoinduction ensures that the beneficial effect is maintained for several months despite HA short half-life.

Intra-articular HA is recommended by the current EULAR and OARSI guidelines for the management of knee and hip OA.¹⁻³

PRODUCT CHARACTERISTICS

- **Sinovial[®]** is a medical device constituted by a physiological solution of HA sodium salt in sterile syringe for intra-articular injections ready to use.⁴
- HA is obtained from a cell strain of *Streptococcus equi* through a multiphase biofermentation process which ensures a highly purified final product with a defined molecular weight (MW 800-1200 KDalton).^{4,5}
- **Sinovial[®]** is totally free from animal proteins.^{4,5}
- **Sinovial[®]** is a substitute of synovial fluid, which allows the re-establishment of the physiological and rheological properties of the affected joints.
- **Sinovial[®]** is indicated for pain or reduced mobility due to degenerative diseases, post-traumatic diseases or joint alterations.^{4,6-10}
- **Sinovial[®]** is also a viscosuppletive treatment for small joints (e.g. wrist, hand, foot and the temporo-mandibular joint) and tendon sheath (e.g. in case of stenosing tenosynovitis/trigger finger).^{11,13}
- The administration of **Sinovial[®]** results in a marked pain reduction, improvement of the articular mobility, decreased use of rescue medication.^{4, 6-13}
- The effects of **Sinovial[®]** are already evident starting from the 1st injection and last up to 6 months, suggesting a long-lasting carry-over effect of the treatment.^{4, 6, 7, 10}



KEY POINTS

A) Formulations

Sinovial® is available as ready-to-use formulations in **different volumes and concentrations** for a personalized treatment according to the localization and the degree of the disease:

- **Sinovial® One 2%** (50mg HA in 2.5mL)
- **Sinovial® Forte 1.6%** (32mg HA in 2mL)
- **Sinovial® 0.8%** (16mg HA in 2mL)
- **Sinovial® Mini** (8mg HA in 1mL)

B) Source of hyaluronic acid

Hyaluronic acid is produced through an innovative multiphase biofermentation process (from a cell strain of *S. equi*), to obtain a highly purified product.⁵

IBSA Hyaluronic acid is not contaminated by products derived from animals, eliminating any possible risk of allergy or the transmission of any pathogenic agents (e.g. viruses or prions).⁵

C) Molecular weight

Hyaluronic acid in the ready-to-use product is in the range of 800-1200 KDa. Evidences from large animal models of OA show that

HAs with MW between 500-1000 KDa are more effective than high MW HAs for the restoration of the rheological properties of synovial fluid and in reducing synovial inflammation.¹⁴

IN SUMMARY

Sinovial® represents an effective and safe approach for the management of OA and other clinical conditions when a viscosupplementation is required. The injection of HA contributes to restore the physiological conditions of the joint and the tendon with a consequent reduction of pain and improvement of articular mobility.

Other IBSA's intra-articular hyaluronic acid trademarks: Intragel®/Yaral®

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