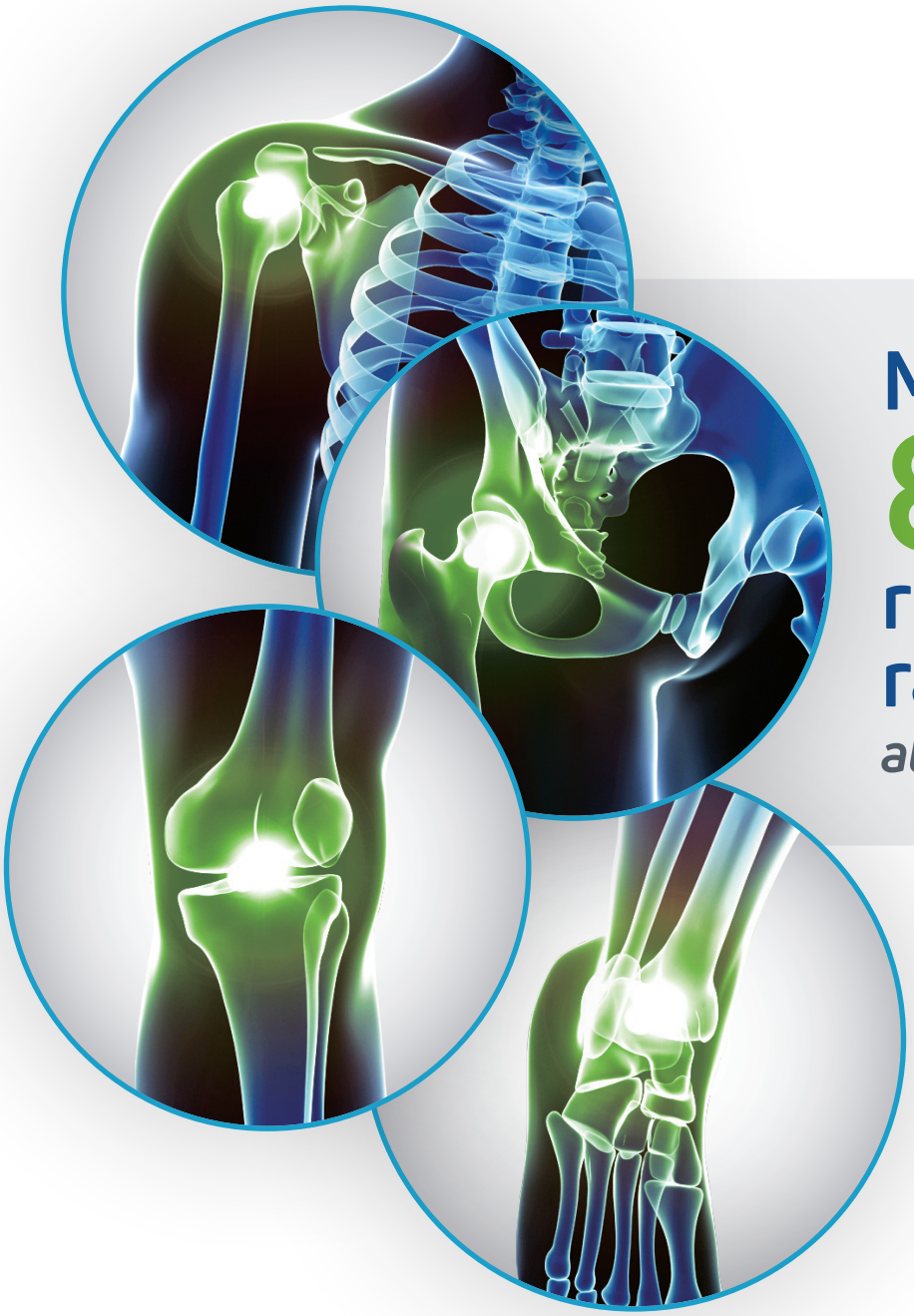
ANIKA

Monovisc™

Hyaluronic Acid Single Injection

Product Brochure



Minimum 80% responder rate

at 6 months[1-4]

Long-lasting pain relief for shoulder, hip, knee & ankle

The market-leading single injection viscosupplement utilised to treat joint pain caused by osteoarthritis.

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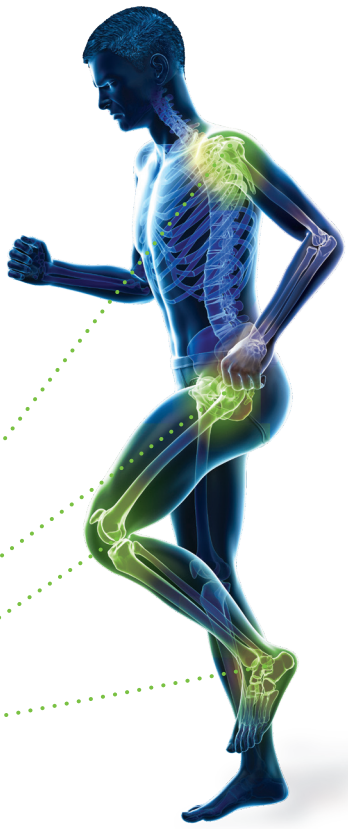
Extended indications

Monovisc is now indicated for the treatment of the symptoms of mild to moderate osteoarthritis of the shoulder, hip, knee, and ankle joints.*



Extended residence time

Patented cross-linking process slows down degradation to stay in the joint longer so its actions last longer, leading to longer pain relief.[5]

Responder rate at 6 months

***Shoulder* – 95.8%**[3]

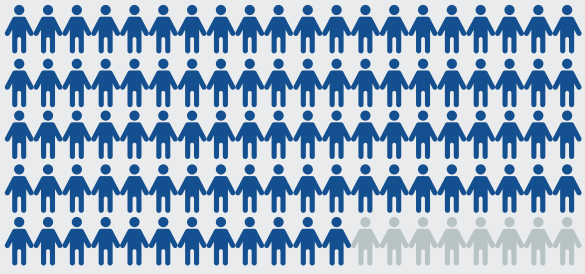
***Hip* – 80%**[2]

***Knee* – 85%**[1]

***Ankle* – 84%**[4]

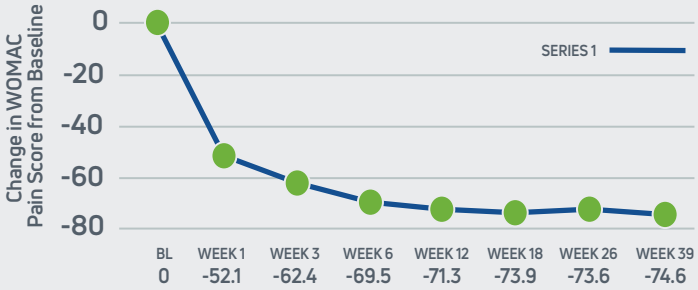
Extended pain relief

Up to 39 weeks of clinically proven efficacy with a single injection in the knee[6]



92.4% of patients whose knee joints were treated with Monovisc responded positively in the areas of pain, stiffness, and physical function at 39 weeks.

Percentage change in WOMAC Pain Score from Baseline at 39 weeks



*Monovisc 17-02: percentage change from baseline in WOMAC Pain Score

Monovisc is formulated to mimic the properties of endogenous HA[7,8]

In human joints, endogenous HA is present in the cartilage extracellular matrix and synovial fluid and has several functions, including:

Mechanical effect
HA binds well to water, producing a viscous, jelly-like consistency that provides lubrication and acts as a shock absorber within the joint.

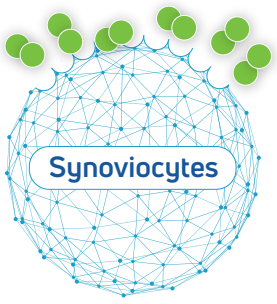
Analgesic effect
HA diminishes nerve impulses and the sensitivity of nociceptive nerve endings.[9]

Anti-inflammatory effect
HA plays an important role in reducing joint inflammation and pain caused by injury or tissue degeneration.[8,9]

Chondroprotective effect
HA has a biomechanical structure that protects cartilage when surrounding chondrocytes.[8]

Monovisc *aims to improve the rheological properties of the synovial fluid, thereby promoting mechanical, analgesic, anti-inflammatory, and chondroprotective effects.*[10-12]

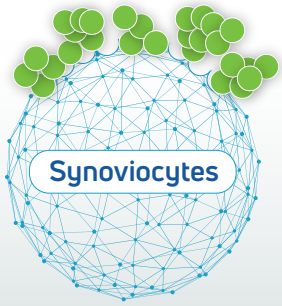
Optimal high molecular weight HA[13,14]



MW ≤ 500,000

Low Binding Affinity

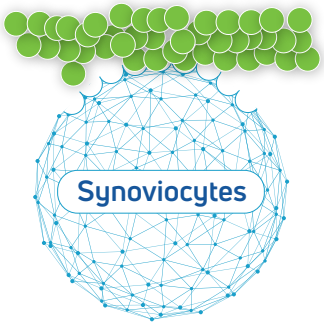
Limited stimulation of biosynthesis of HA



500,000 < MW < 4,000,000

Optimal Binding Affinity

Stimulation of biosynthesis of HA[14]



MW ≥ 4,000,000

Steric Hindrance

Limited stimulation of biosynthesis of HA

1,000,000 Da < 2,900,000 Da

MONOVISC

Monovisc™

High Concentration of HA (22 mg/ml)[10]

Creates a high viscosity environment to replicate healthy joint function[15]

Lightly Cross-Linked HA[10]

Leads to longer residence time in joint and better viscoelasticty of synovial fluid[5]

Optimal High Molecular Weight HA

Results in greater pain reduction and longer duration of effect than low molecular weight HA[15,16]

Ultra Pure Non-Avian HMW HA

Produced by bacterial fermentation with complaint data under Post Market Surveillance over 14 years demonstrating an excellent safety profile in all joints with a very low patient reaction complaint rate of 0.01%[10,17]

Indications

Monovisc is indicated as a viscoelastic supplement or a replacement for synovial fluid in human knee, hip, shoulder, and ankle joints. Monovisc is well suited for the treatment of the symptoms of mild to moderate osteoarthritis of the knee, hip, shoulder, and ankle joints for patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. In clinical studies, Monovisc has been proven to have a duration of effect of at least six months and a second injection six months after the first injection was shown to be safe.

***** CE marked for use in shoulder, hip, knee and ankle indicating approval for use in the EU and other countries recognising the CE mark. Please refer to your regional IFU.

1 Petterson SC, Plancher KD. Single intra-articular injection of lightly cross-linked hyaluronic acid reduces knee pain in symptomatic knee osteoarthritis: a multicenter, double-blind, randomized, placebo-controlled trial; Knee Surgery, Sports Traumatology, Arthroscopy. **2** 18-01 Data on File (hip). **3** 18-02 Data on File (shoulder). **4** 18-03 Data on File (ankle). **5** Anika Data on File. **6** 17-02 Data on File. **7** Vincent HK, Percival SS, Conrad BP, et al. Hyaluronic Acid (HA) Viscosupplementation on Synovial Fluid Inflammation in Knee Osteoarthritis: A Pilot Study. Open Orthop J. 2013 Sep 20;7:378-84. doi:10.2174/1874325001307010378. PMID: 24093052; PMCID: PMC3788189.**8** Garantziotis S, Savani RC. Hyaluronan biology: a complex balancing act of structure, function, location and context. Matrix Biol. 2019 May;78-79:1-10. **9** Synovial Fluid Inflammation in Knee Osteoarthritis: A Pilot Study. Open Orthop J. 2013 Sep 20;7:378-84. doi: 10.2174/1874325001307010378. PMID: 24093052; PMCID: PMC3788189. **10** Monovisc IFU. **11** Brandt KD, Smith GN, Simon LS. Intra-articular injection of hyaluronan as treatment for knee osteoarthritis. Arthritis Rheum 2000;43:1192-1203. **12** de Rezende MU, de Campos GC. VISCOSUPPLEMENTATION. Rev Bras Ortop. 2015 Dec 6;47(2):160-4. **13** Smith MM, Ghosh P. The synthesis of hyaluronic acid by human synovial fibroblasts is influenced by the nature of the hyaluronate in the extracellular environment. Rheumatol Int. 1987; 7(3):113-22. **14** Ghosh P, Guidolin D. Potential mechanism of action of Intraarticular Hyaluronan Therapy in Osteoarthritis: Are the effects Molecular Weight Dependent?; Seminars in Arthritis and Rheumatism,
Vol 32, No 1 (August), 2002: pp 10-37. **15** de Rezende MU, de Campos GC. VISCOSUPPLEMENTATION. Rev Bras Ortop. 2015 Dec 6;47(2):160-4. doi: 10.1016/S2255-4971(15)30080-X. PMID: 27042615; PMCID: PMC4799378. **16** Nicholls MA, Fierlinger A, Niazi F, et al. The Disease-Modifying Effects of Hyaluronan in the Osteoarthritic Disease State. Clin Med Insights Arthritis Musculoskelet Disord. 2017; 10:1179544117723611. **17** Monovisc CER- Data on File.

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OA Pain Management