

Monovisc®

Cross-linked Sodium Hyaluronate for Intra-Articular Injection

Clinically proven long-lasting pain relief for 6 months¹²

HIGH CONCENTRATION OF HA (22 mg/mL)³

Creates a high viscosity environment to replicate healthy joint function

OPTIMAL HIGH MOLECULAR WEIGHT HA

Results in greater pain reduction and longer duration of effect than low molecular weight $\rm HA^{4,5}$

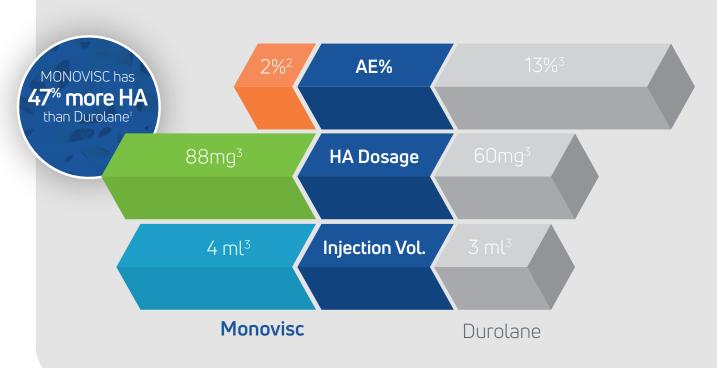
LIGHTLY CROSS-LINKED HA

Leads to longer residence time in joint and better viscoelasticity of synovial fluid¹

ULTRA PURE NON-AVIAN HMW HA

Produced via bacterial fermentation³ - no serious adverse events (AE) related to Monovisc were reported and only a 2% rate of mild injection site reactions were reported⁶

Not all HAs are the same



Monovisc clinical data overview

Patients experienced a **57.2% improvement** in WOMAC pain from baseline at 3 weeks¹

Delivers a **65% improvement** in WOMAC pain at Week 26 relative to baseline (p = 0.0352)²

Delivers an **85% responder rate** in the OMERACT-OARSI Responder Index through 26 Weeks⁶

Can be safely re-administered as prescribed to continue to help **protect** the joint and **reduce** the pain of OA⁷

Monovisc may **delay** the need for total knee replacement⁸

Key Publications

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

Stephanie C. Petterson, Kevin D. Plancher;

Published in: Knee Surgery, Sports Traumatology, Arthroscopy, Aug 2018

Intraarticular Injection of a Cross-Linked Sodium Hyaluronate Combined with Triamcinolone Hexacetonide (Cingal) to Provide Symptomatic Relief of Osteoarthritis of the Knee: A Randomized, Double-Blind, Placebo-Controlled Multicenter Clinical Trial Laszlo Hangody, Robert Szody, Piotr Lukasik, et al.; Published in: Cartilage, May 2017

Monovisc 0702 Pivotal Clinical Trial.

FDA Monovisc Summary of Safety and Effectiveness Data, 2014

Description Monovisc is a sterile, non-pyrogenic, sodium hyaluronate solution, lightly cross-linked with a proprietary chemical cross-linker. Contains lightly cross-linked sodium hyaluronate (NaHA) dissolved in phosphate-buffered saline at physiological osmolality Manufactured from ultra-pure, high molecular weight sodium hyaluronate produced by bacterial fermentation. Application Monovisc Cross-Linked Sodium Hyaluronate Injection is a single, intra-articular injection of crosslinked sodium hyaluronate designed to treat the symptoms of osteoarthritis in the knee. Directions for use The required amount of Monovisc is injected through a sterile, disposable hypodermic needle of suitable gauge into the selected joint space. How supplied Monovisc is a sterile viscoelastice supplement provided in a disposable glass syringe. Each syringe contains 4 mL lightly cross-linked sodium hyaluronate dissolved in phosphate-buffered saline. Storage Store at 2°C to 25°C. Refer to the Instructions for Use for complete product information.

1. Petterson SC, Plancher KD. Knee Surg Sports Traumatol Arthrosc (2018). https://doi.org/10.1007/s00167-018-5114-0 10.1177/1947603517703732. 2. Hangody L, Szody R, Lukasik P, et al. Cartilage 2017 May; doi: 10.1177/1947603517703732. 3. Instructions for use for Monovisc, Durolane. 4. Balazs, E.A. (2004)Viscosupplementation for treatment of Osteoarthritis: From Initial Discovery to Current Status and Results. Surgical Technology International 5. American Academy of Orthopaedic Surgeons. Academy A, AAOS. Treatment of osteoarthritis of the knee—evidence-based guidelines. Am Acad Orthop Surg Board Dir 2013;973;. Doi: 10.5435/JAAOS-21-09-571 6. CINGAL 13-01, a randomized, double-blind, placebo-controlled, active comparator Phase III study. 7. FDA Monovisc Summary of Safety and Efficacy Data (SSED). Application Number: P090031. 8. Altman, R., et. al. Hyaluronic Acid Injections Are Associated with Delay of Total Knee Replacement Surgery in Patients with Knee Osteoarthritis: Evidence from a Large U.S. Health Claims Database.

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