Gel-One® CROSS-LINKED HYALURONATE

For **mild** to **moderate**Osteoarthritis of the knee









Effective Pain Relief

100% cross-linked gel, offering increased cushioning, resistance to diffusion and product durability¹

- Demonstrated greater viscoelasticity than Synvisc/Synvisc-One[®],
 Monovisc[®] and non-crosslinked HA, leading to better shock absorption and product durability¹
- Proven 91-day joint residency time¹
- Proven 26 weeks of pain relief³

Counter Force Provided by HA

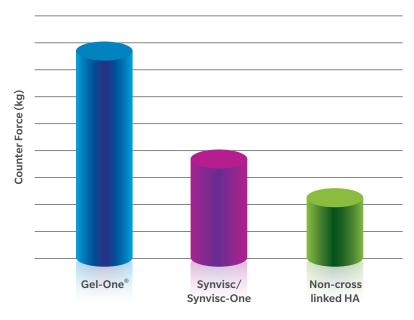
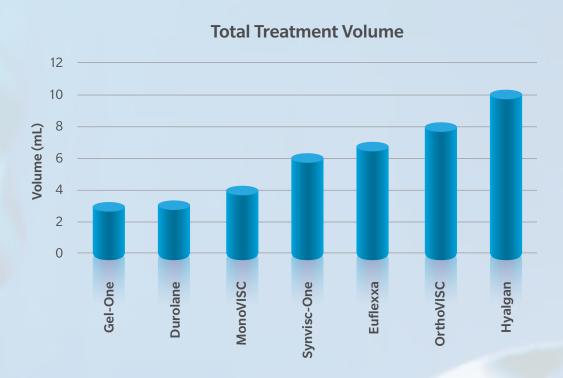


Figure 1: Counter force performance of Gel-One, Synvisc/ Synvisc-One, and non-cross linked HA

Easy-to-Use

Single injection with only 3mL treatment volume²

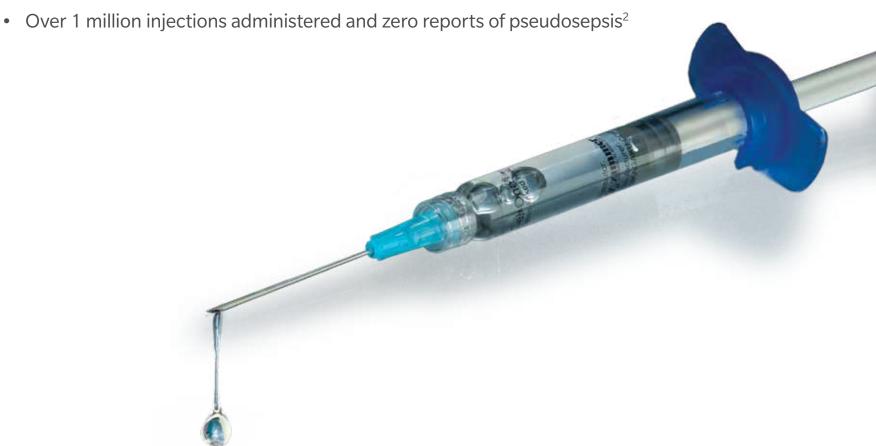
- Patient-friendly treatment requiring only one visit for effective pain relief
- Provides a joint-friendly treatment requiring only 3mL for effective treatment² and chondroprotection⁶



Proven Safety Profile

Safe for repeat use with no increased risk of side effects²⁻⁵

- Proven through clinical trials to be as safe as saline^{2,3}
- No known reported incidences of pseudosepsis, a rare, but serious potential side effect of some viscosupplements²
- No increased risk in side effects with multiple treatment cycles^{2,3,5}



References

- 1. Data on file at Seikagaku corporation.
- 2. Strand, V. et al. A multicenter, randomized controlled trial comparing a single intra-articular injection of Gel-One, a new cross-linked formulation of hyaluronic acid, to phosphate buffered saline for treatment of osteoarthritis of the knee. Osteoarthritis and Cartilage. 20: 350-356, 2012.
- 3. Strand, V., et al. Effectiveness and Safety of a Multicenter Extension and Retreatment Trial of Gel-200 in Patients with Knee Osteoarthritis. Cartilage. 3(4): 297-304, 2012.
- 4. Lot release testing for protein bacterial endotoxin, and DNA (viscosity decline) performed by Seikagaku Corporation.
- 5. Strand, V., et al. Evidence for safety of retreatment with a single intra-articular injection of Gel-200 for treatment of osteoarthritis of the knee from the double-blind pivotal and open-label retreatment clinical trials. BMC Musculoskeletal Disorders. 17:240, 2016.
- 6. K. Yoshioka *et al.* Pharmacological effects of novel cross-linked hyaluronate, Gel-200, in experimental animal models of osteoarthritis and human cell lines. Osteoarthritis and Cartilage 2014; 22:879-887.

Indications For Use:

Gel-One Hyaluronate is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, nonsteroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, e.g., acetaminophen.

Important Safety Information

Before using Gel-One Hyaluronate, ask your patients if they are allergic to hyaluronan products, cinnamon, or products from birds, such as feathers, eggs, and poultry. Gel-One Hyaluronate is only for injection into the knee, performed by a doctor or other qualified healthcare professional. Gel-One Hyaluronate injection should not be used in the presence of skin disease or infection around the area where the injection will be given. Gel-One Hyaluronate has not been tested to show pain relief in joints other than the knee or for conditions other than OA. Gel-One Hyaluronate has not been tested in patients who are pregnant, mothers who are nursing, or anyone under the age of 21. Strenuous or prolonged weight-bearing activities after treatment are not recommended. The effectiveness of repeat treatment cycles of Gel-One Hyaluronate has not been established. The side effects most commonly seen after injection of Gel-One Hyaluronate in the clinical trial were knee pain, swelling and/or knee effusion. These reactions are generally mild and do not last long. For complete instructions for use, see the package insert and visit www.zimmerbiomet.com. Gel-One Hyaluronate is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics, e.g., acetaminophen.



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For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit www.zimmerbiomet.com for additional product information.

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