

Gel-One[®] Cross-Linked Hyaluronate

Proven Safety Profile

Gel-One[®] offers a **proven safety profile** and is **safe for repeat use** with no increased risk of side effects.¹⁻⁴



Retreatment Safety

Gel-One has demonstrated an excellent safety profile in multiple clinical trials, having a safety profile equivalent to that of saline.^{1,2}

Additionally, a retreatment trial showed that there was no increased risk of adverse events related to multiple treatment cycles of Gel-One.¹ These results support **a favorable safety profile** for Gel-One with **no increased risk in side effects with multiple treatment cycles.**¹⁻³

No Known Reported Incidences of Pseudosepsis²

Results from a multicenter, randomized trial indicate that treatment with Gel-One offers statistically significant and clinically meaningful improvements both in pain and physical function in patients with knee osteoarthritis (OA), demonstrating the multidimensional effectiveness of this therapy.

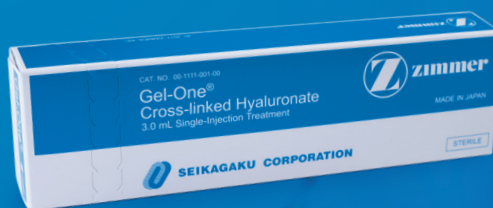
Since launch, over 1 million injections have been administered with **no known reported incidences of pseudosepsis**, a rare, but serious potential side effect of some viscosupplements.² The **absence of pseudosepsis or allergic reactions** and the low incidence of treatment-associated adverse events further support a favorable safety profile for this product for the treatment of symptomatic OA of the knee.²

As Safe as Saline²

In the same trial, the safety profile following a single Gel-One injection was comparable to phosphate buffered saline.



**Learn More
About the Benefits
of Gel-One**



References

1. 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.
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. Lot release testing for protein bacterial endotoxin, and DNA (viscosity decline) performed by Seikagaku Corporation.
4. 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.

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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