**Synvisc-One® Clinical Summary**

**In a saline-controlled trial, Synvisc-One® delivered superior pain relief**

*Statistically significant difference from saline control group in primary end point over 26 weeks*

**Knee Patient Baseline**

Most participants in the study had radiographically confirmed Kellgren-Lawrence grade II or III OA at baseline. Patients initially received arthrocentesis and then either one 6-mL injection of Synvisc-One or one 6-mL injection of placebo (saline). Follow-up visits to gauge effectiveness occurred at weeks 1, 4, 8, 12, 18, and 26.

The safety and efficacy of Synvisc-One in locations other than the knee, or for conditions other than osteoarthritis, or in combination with other intra-articular injectables, or in severely inflamed knee joints have not been established.

**Synvisc-One® Knee Injection Efficacy**

Over 70% of patients responded to Synvisc-One

**Walking pain response rates**

![Graph showing walking pain response rates](image)

Greater magnitude of pain relief with Synvisc One

**Walking pain relief**

![Graph showing walking pain relief](image)

Important Safety Information: SYNVISC and Synvisc-One are contraindicated in patients with known hypersensitivity to hyaluronan products or patients with infections in or around the target knee. Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because hyaluronan can precipitate in their presence.

Please see accompanying full Important Safety Information and Prescribing Information.
Patients with Device-Related Adverse Events in the Injected Knee

<table>
<thead>
<tr>
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<th>Synvisc-One N=123 n(%)</th>
<th>Saline Control N=130 n(%)</th>
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<tbody>
<tr>
<td>Any Device-Related Adverse Events</td>
<td>7 (5.7%)</td>
<td>4 (3.1%)</td>
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* Defined as related to either the study injection or the study treatment

The most commonly reported adverse events were arthralgia, arthritis, arthropathy, injection site pain, and joint effusion. The following reported adverse events are among those that may occur in association with intra-articular injections, including Synvisc-One: arthralgia, joint stiffness, joint effusion, joint swelling, joint warmth, injection site pain, arthritis, arthropathy, and gait disturbance.

**Safety results**

No incidence of pseudoseptic reactions reported for the duration of the SOUND study²,³

- Zero serious adverse events related to study treatment
- No increased risk of adverse events with repeat exposure to Synvisc-One*
- The most commonly reported adverse events were arthralgia, arthritis, arthropathy, injection site pain, and joint effusion

* In the repeat treatment phase of the pivotal clinical study involving 160 patients, 77 patients received a second injection of Synvisc-One.

**References**


Important Safety Information: SYNVISC and Synvisc-One are contraindicated in patients with known hypersensitivity to hyaluronan products or patients with infections in or around the target knee. Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because hyaluronan can precipitate in their presence.

Please see accompanying full Important Safety Information and Prescribing Information.
**Indication**

SYNVISC® (hylan G-F 20) and Synvisc-One® (hylan G-F 20) are indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen.

**Important Safety Information**

SYNVISC and Synvisc-One are contraindicated in patients with known hypersensitivity to hyaluronan products or patients with infections in or around the target knee.

Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because hyaluronan can precipitate in their presence. Do not inject SYNVISC or Synvisc-One extraarticularly, into the synovial tissues, into the fat pad or joint capsule, or intravascularly.

The safety and efficacy of Synvisc-One in locations other than the knee, or for conditions other than osteoarthritis, or in combination with other intra-articular injectables, or in severely inflamed knee joints have not been established. Use caution when injecting SYNVISC or Synvisc-One in patients allergic to avian proteins, feathers, or egg products; who have evidence of lymphatic or venous stasis in the leg to be treated; or who have severe inflammation in the knee to be treated. Remove any synovial fluid or effusion before injecting SYNVISC or Synvisc-One. Strict adherence to aseptic technique must be followed to avoid joint infection. The safety and effectiveness of SYNVISC and Synvisc-One have not been established in children (≤21 years old) or in pregnant or lactating women. Patients should be advised to avoid strenuous or prolonged weight-bearing activities for approximately 48 hours after treatment.

**For SYNVISC**

In clinical trials, the most commonly reported adverse events were transient pain, swelling, and joint effusion in the injected knee. The following reported adverse events are among those that may occur in association with intra-articular injections, including Synvisc: arthralgia, joint stiffness, joint effusion, joint swelling, joint warmth, injection site pain, arthritis, arthropathy, and gait disturbance.

**For Synvisc-One**

The most commonly reported adverse events were arthralgia, arthritis, arthropathy, injection site pain, and joint effusion. The following reported adverse events are among those that may occur in association with intra-articular injections, including Synvisc-One: arthralgia, joint stiffness, joint effusion, joint swelling, joint warmth, injection site pain, arthritis, arthropathy, and gait disturbance.