Early Efficacy of Intra-articular HYADD® 4 (HYMOVIS®) Injections for Symptomatic Knee Osteoarthritis

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Background

■ Real-world clinical practice, retrospective study of 937 eligible patients from the ANTIAGE National Registry (Italy)

■ Demonstrates safety and efficacy of HYMOVIS in patients with mild to severe symptomatic knee osteoarthritis (OA)

Study Objective

The aim of the study was to evaluate the clinical efficacy and safety of HYMOVIS (HYADD 4), a hydrogel based on a hyaluronic acid derivative, in patients with symptomatic knee osteoarthritis.

Study Design

■ A retrospective observational study to evaluate the clinical efficacy and tolerability of two intra-articular (IA) HYMOVIS injections (24 mg/3 mL) administered 1 week apart in everyday clinical practice, for the treatment of symptomatic knee OA

■ Data were obtained from the ANTIAGE National Registry, a nonprofit database of clinical data on the effects of ultrasound-guided IA viscosupplementation

■ Patients were evaluated on a visual analog scale (VAS) for pain at rest and on movement at 1, 3, 6, 9, and 12 months from baseline

■ Total WOMAC scores, NSAIDs/acetaminophen use, and patient satisfaction with therapy were evaluated at 1, 3, and 6 months from baseline

■ A total of 937 eligible patients (age range, 41-80 years) with Kellgren-Lawrence grades II to IV knee OA were included at baseline

■ Symptomatic knee arthritis was diagnosed according to the American College of Rheumatology (ACR) criteria

Results

Statistically significant improvements in VAS pain and mean WOMAC scores.

■ VAS scores for pain at rest and pain on movement improved significantly 6 months and 12 months from baseline

■ Total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores improved at 6 months from baseline

Figure 1. Trend in pain scores and WOMAC scores after Two HYMOVIS injections

* Indicates statistically significant change from baseline

### Results Table

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Month 1</th>
<th>Month 3</th>
<th>Month 6</th>
<th>Month 9</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>VAS Pain</td>
<td>56.9</td>
<td>31.8</td>
<td>24.9</td>
<td>24.1</td>
<td>25.3</td>
<td>26.9</td>
</tr>
<tr>
<td>VAS Move</td>
<td>72.1</td>
<td>49.3</td>
<td>38.4*</td>
<td>37.9</td>
<td>38.4</td>
<td>38.9*</td>
</tr>
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Number of evaluable patients: n = 937, n = 821, n = 743, n = 698, n = 137, n = 106

WOMAC scores, 0-96 points

Arthrex®
Reductions in the use of NSAIDs or acetaminophen during study

- 48.8% (n = 457) of patients reported the use of either nonsteroidal anti-inflammatory drugs (NSAIDs) or acetaminophen at least twice a week at baseline
- Patients treated with HYMOVIS® demonstrated decreased use of NSAIDs/acetaminophen
- At 6 months, only 19.6% (n = 37) of evaluable patients reported use of NSAIDs or acetaminophen more than twice per week

Improvements in patient satisfaction with HYMOVIS therapy

- Satisfaction with therapy in terms of pain reduction and improvement in joint function was assessed via 3 possible patient responses to a subjective evaluation:
  1. Improvement
  2. No change
  3. Worsening
- Improvements in patient satisfaction with pain reduction and joint function from IA HYMOVIS injections were demonstrated as soon as 1 month and remained stable over 6 months

Safety

- Arthralgia was the most frequently reported adverse event (11.2%), which was self-limiting and resolved within 2 days of onset (12-36 hours) with no adverse event observed 4 weeks post-injection
- There were no reported allergic reactions or systemic effects (e.g., inflammatory/pseudoseptic reactions) related to study treatment

Conclusion

In this large-scale, real-world, clinical practice retrospective study of 937 eligible patients included in an international registry, HYMOVIS demonstrated significant improvements in VAS pain scores, total WOMAC scores, and NSAID/acetaminophen use in patients with mild to severe knee OA.
Reference


Indication

HYMOVIS® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics (eg, acetaminophen).

Important Safety Information

HYMOVIS is contraindicated in patients with known hypersensitivity (allergy) to hyaluronate preparations or gram-positive bacterial proteins. Do not administer HYMOVIS to patients with infections or skin diseases in the area of the injection site or joint.

The safety and effectiveness of the use of HYMOVIS has not been tested in pregnant women, nursing mothers, or children. The safety and effectiveness of the use of HYMOVIS in joints other than the knee, or for use concomitantly with other intra-articular (IA) injections has not been established. The effectiveness of repeat treatment cycles of HYMOVIS has not been established. Arthralgia, transient pain, or swelling may occur after the IA injection. The incidence of arthralgia in the clinical study for HYMOVIS was equivalent to the control group. No serious adverse reactions or pseudoseptic reactions were reported. Transient increases in inflammation following any IA hyaluronan injection have been reported in some patients with inflammatory joint conditions.

See package insert for full prescribing information including adverse events, warnings, precautions, and side effects at [www.Hymovis.com](http://www.Hymovis.com).

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