VISCO-3™ Sodium Hyaluronate

Safe and Effective pain relief for knee OA[1, 2]

A double-blind, multi-center, randomized, controlled trial was conducted in which VISCO-3 Sodium Hyaluronate* was compared to Euflexxa® 1% Sodium Hyaluronate (NCT 02110238). The study enrolled a total of 421 subjects.

Safety[2]

Safety analysis included all subjects who received at least one injection (n = 211 Euflexxa, n = 209 VISCO-3). There was no significant difference in the total Treatment-Emergent Adverse Events (TEAEs) with VISCO-3 Sodium Hyaluronate compared to Euflexxa (Table 1). A total of seven serious adverse events (SAE) were reported, however none were considered to be related to the study devices. **There were no reports of pseudoseptic events or allergic reactions in the study.**

Table 1: Overall Summary of Treatment-Emergent Adverse Events (TEAEs)

Category	Euflexxa (N=211) n(%)	VISCO-3 (N=209) n(%)
Subjects with ≥ 1 TEAE	109 (51.7)	107 (51.2)
Subjects with ≥ 1 TEAE related to study device	14 (6.6)	9 (4.3)
Subjects with ≥ 1 serious adverse event (SAE)	6 (2.8)	1 (0.5)

The most common device related adverse events in the VISCO-3 group were arthralgia (1%), joint swelling (1.4%) and injection site pain (1%).

In addition, literature has shown that repeated treatment cycles of the VISCO-3 Sodium Hyaluronate formulation contain no evidence of an increased safety risk. The frequency and severity of adverse events occurring during repeat treatment cycles did not increase over that reported for a single treatment cycle.

Effectiveness[2]

The analysis of effectiveness was based on the 384 evaluable patients over the 12 week time point. The effectiveness of the treatments was measured as WOMAC VAS pain subscale change from base line (CFB). The Key effectiveness outcomes are presented below (Table 2).

Table 2: Effectiveness Analysis; CFB of WOMAC VAS Pain Subscale Through Study Duration

Average over Weeks 3, 6, and 12	Euflexxa (N=189)	VISCO-3 (N=195)	CFB Difference
Baseline WOMAC VAS Pain (mm) (Mean[SD])	58.40 (8.977)	57.83 (9.654)	
LS Mean (standard error [SE]) of change from Baseline (CFB)	30.15 (1.303)	26.85 (1.270)	-3.30 (1.762)
95% CI	27.59-32.71	24.35-29.35	-6.77-0.17

The mean baseline WOMAC VAS pain subscale was 57.83 in the VISCO-3 Sodium Hyaluronate group and 58.40 in the Euflexxa Sodium Hyaluronate group. The least squares mean for CFB for VISCO-3 Sodium Hyaluronate minus that of the control gives a WOMAC VAS subcale sore of -3.30 mm.

VISCO-3 Sodium Hyaluronate demonstrated non-inferior pain relief compared to patients treated with Euflexxa. This is concluded based upon the fact that the lower bound of the 95% CI (-6.77 mm) is greater than -8 mm. On average, patients treated with VISCO-3 Sodium Hyaluronate saw a 52% reduction in pain at week 12 compared to baseline.

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INDICATIONS FOR USE:

VISCO-3 Sodium Hyaluronate 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 and simple analgesics, e.g., acetaminophen.

CONTRAINDICATIONS SAFETY INFORMATION:

Before using VISCO-3 Sodium Hyaluronate, ask your patients if they are allergic to hyaluronan products, or products from birds such as feathers, eggs, and poultry. Do not administer to patients with known hypersensitivity to sodium hyaluronate preparations. Use caution when injecting VISCO-3 Sodium Hyaluronate into patients who are allergic to avian proteins, feathers and egg products. VISCO-3 Sodium Hyaluronate is only for injection into the knee, performed by a doctor or other qualified health care professional. VISCO-3 Sodium Hyaluronate injection should not be used in the presence of a skin disease or infection around the area where the injection will be given. VISCO-3 Sodium Hyaluronate has not been tested to show pain relief in joints other than the knee and for conditions other than OA. VISCO-3 Sodium Hyaluronate has not been tested in patients who are pregnant, mothers who are nursing, or anyone under the age of 21. Strenuous or pro-longed weight-bearing activities after treatment are not recommended. The effectiveness of repeat treatment cycles of VISCO-3 Sodium Hyaluronate has not been established. The side effects most commonly seen after injection of VISCO-3 Sodium Hyaluronate in the clinical trial were knee pain, swelling, and/or fluid build-up around the knee. These reactions are generally mild and do not last long. Other conditions, including but not limited to skin redness and rash, knee stiffness were also reported. For complete instructions for use, see the package insert and visit www.zimmerbiomet.com.

References

1. Non-Inferiority Study Comparing 3 Weekly Injections of SUPARTZ® vs 3 Weekly Injections of Euflexxa® for Knee OA. https://clinicaltrials.gov/ct2/show/NCT02110238?term=Supartz&rank=2.
2. VISCO-3 Sodium Hyaluronate Summary of Safety and Effectiveness Data (SSED)

*In this study (NCT02110238), VISCO-3 is called Supartz.

**SSED refer to Euflexxa as 'commercially available hyaluronan'.

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