



# **SynoJoynt™ 1% Sodium Hyaluronate**

SynoJoynt 1% sodium hyaluronate is a high molecular weight, non-crosslinked sodium hyaluronate derived from bacterial fermentation. SynoJoynt HA is 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 such as acetaminophen.

# Excellent Safety and Tolerability<sup>1</sup>

- In a 6 month clinical trial, SynoJoynt 1% sodium hyaluronate demonstrated a safety profile similar to saline and Euflexxa® 1% sodium hyaluronate (Ferring Pharmaceuticals)
- Proven safety and efficacy in a 3-dose regimen
- No pseudoseptic reactions were reported for SynoJoynt HA during the clinical study
- The incidence of arthralgia, the most commonly reported side effect, was similar to saline

### **Key Attributes**

- Non-avian source
- Not crosslinked
- Stable molecular weight of 2.5 million da
- Unique J code: J7331



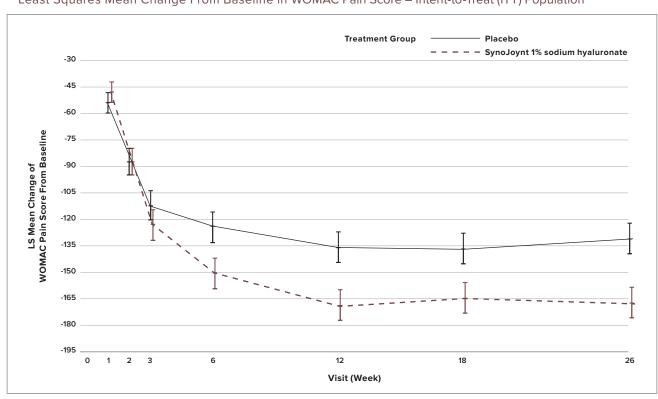
The safety and effectiveness of SynoJoynt™ 1% sodium hyaluronate was evaluated in a double-blind, prospective, multisite, randomized, three-arm, parallel group, pivotal trial in adults.1 The primary objective of the study was to evaluate the effectiveness of 3 weekly intra-articular 2 mL doses of SynoJoynt HA, as compared to a placebo, injected into the target knee of subjects with knee OA.

Primary effectiveness endpoint was the change in baseline in the WOMAC arthritis pain score in the target knee at 26 weeks. Secondary effectiveness endpoints were the mean changes from baseline in the WOMAC pain, stiffness, and physical function scores over time. In total, 595 patients were treated and 543 completed the study. Demographics of participants were similar across study groups.

- From week 6 through week 26, SynoJoynt 1% sodium hyaluronate demonstrated statistically significant decreases in WOMAC pain scores, demonstrating superiority to the placebo
- At the 26-week timepoint, the mean changes in pain scores, stiffness, and physical function were significantly greater for SynoJoynt 1% sodium hyaluronate compared to the placebo
- Over time, the mean change in physical function was similar to Euflexxa 1% sodium hyaluronate



#### Least Squares Mean Change From Baseline in WOMAC Pain Score – Intent-to-Treat (ITT) Population



# Ordering Information

-	Product Description	Item Number
	SynoJoynt™ 1% Sodium Hyaluronate	82197-0721-16

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#### Indications for Use

SynoJoynt is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients that have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

## Contraindications, Warnings, and Precautions

- SynoJoynt is contraindicated in patients with known hypersensitivity (allergy) to hyaluronate preparations or gram-positive bacterial proteins.
- · Do not administer SynoJoynt to patients with infections or skin diseases in the area of the injection site or joint.
- The safety and effectiveness of the use of SynoJoynt has not been tested in pregnant women, nursing mothers or children.
- The safety and effectiveness of the use of SynoJoynt in joints other than the knee, or for use concomitantly with other intra-articular (IA) injections, have not been established.
- See package insert for full prescribing information including indications, contraindications, warnings, precautions, and adverse events.

#### Reference

1. US Food and Drug Administration. Summary of Safety and Effectiveness Data for SynoJoynt. Accessed January 11, 2022. https://www.accessdata.fda.gov/cdrh\_docs/pdf17/P170016B.pdf.



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