Mitek Sports Medicine

ORTHOVISC®

High Molecular Weight Hyaluronan

Please see Important Safety Information on back cover and Package Insert.

HA, hyaluronic acid; OA, osteoarthritis.

*CONTENT = CONCENTRATION × VOLUME.

† According to SmartTRAK Financial Dashboard - Full Year, 2020.[8]

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ORTHOVISC® High Molecular Weight Hyaluronan provides

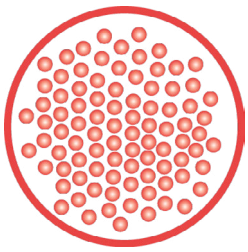
HIGH HA CONTENT

Provides more HA to the knee joint than currently available 3-injection series of HA[1-7,‡]

HA content of multi-injection therapies[2-7,‡,§]

ORTHOVISC[2]

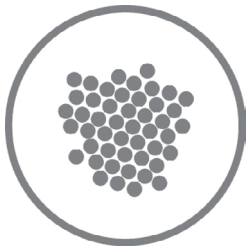
HA Content: 90 mg



Bacterial fermentation
MW: 1.0-2.9 M

Synvisc®[2,3]

HA Content: 48 mg

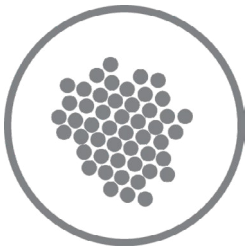


Each ORTHOVISC injection has 88% more HA than each Synvisc injection

Avian formulation
MW: 6 M[||]

Gelsyn-3®[2,4]

HA Content: 50 mg

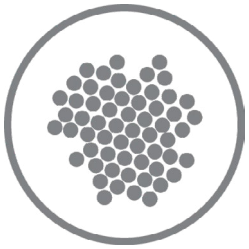


Each ORTHOVISC injection has 80% more HA than each Gelsyn-3 injection

Bacterial fermentation
MW: 1.1 M

Euflexxa®[2,5]

HA Content: 60 mg

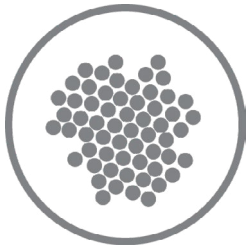


A 3-injection treatment of ORTHOVISC has 50% more HA than a 3-injection treatment of Euflexxa

Bacterial fermentation
MW: 2.4-3.6 M

Hyalgan®[2,6]

HA Content: 60 mg

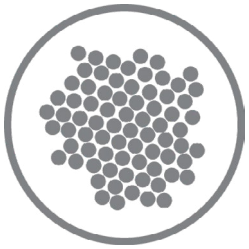


Each ORTHOVISC injection has 50% more HA than each Hyalgan injection

Avian formulation
MW: 0.5-0.73 M

Supartz FX®[2,7]

HA Content: 75 mg



Each ORTHOVISC injection has 20% more HA than each Supartz FX injection

Avian formulation
MW: 0.62-1.2 M

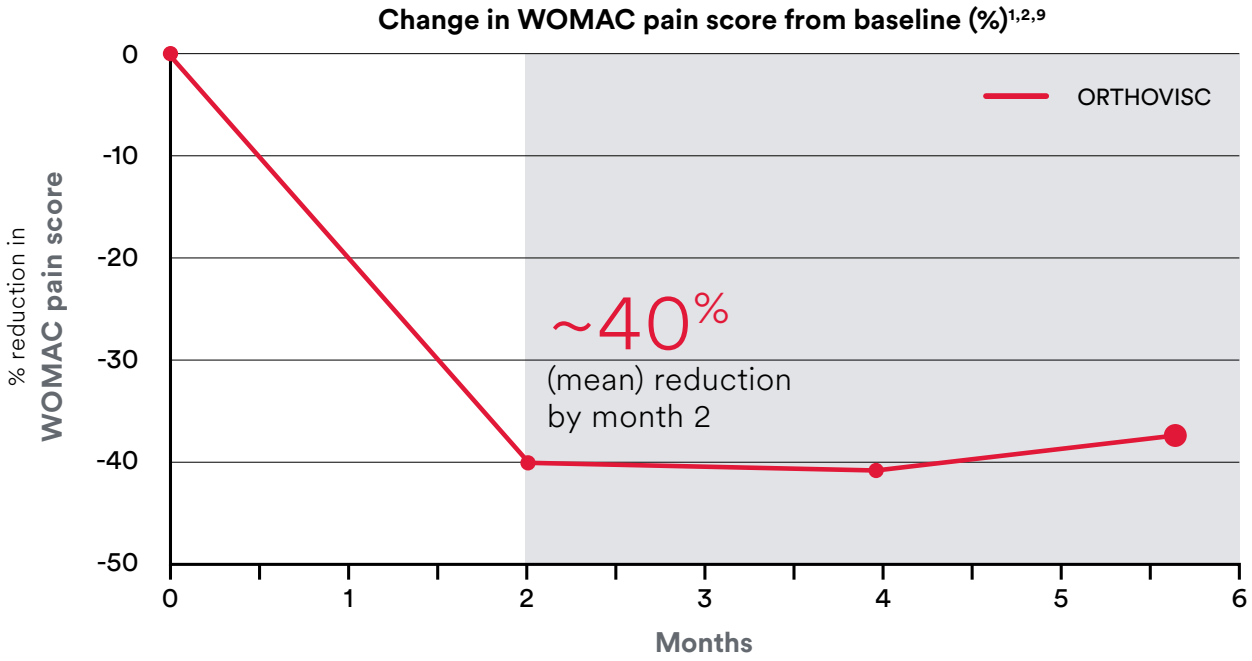
ORTHOVISC is a bacterial-fermented formulation that had no incidence of pseudosepsis events reported in clinical trials.[2,¶]

HA, hyaluronic acid; MW, molecular weight; OA, osteoarthritis; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

[‡] CONTENT = CONCENTRATION × VOLUME.
[§] Based on 3-injection series.
[||] Represents the hylan A component of Synvisc. The hylan B ∞.[3]
[¶] There is a risk of pseudosepsis-like reactions with any intra-articular injection.

ORTHOVISC® High Molecular Weight Hyaluronan provides

PAIN RELIEF FOR OA OF THE KNEE THAT LASTS UP TO 6 MONTHS[2,9]



Demonstrated WOMAC pain score reduction in patients as early as week 2, with significant reduction at week 7.[1,2,9,10]

In patients with OA of the knee

Improvements in pain were assessed using the WOMAC pain scale, which measured important patient activities, including[2,11]


Walking on a flat surface[11]


Going up and down stairs[11]


At night while in bed[11]


Sitting or lying down[11]


Standing upright[11]

WOMAC is a self-administered questionnaire that measures pain severity, stiffness, and physical function limitations in patients with knee OA.[11]

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ORTHOVISC® High Molecular Weight Hyaluronan

SAFETY PROFILE SIMILAR TO SALINE

Demonstrated in clinical trials even during retreatment[2]

- Bacterial-fermented formulation that had no incidence of pseudosepsis events reported in clinical trials[2,**]
- There were 2 joint effusions during initial treatment and 1 joint effusion during retreatment with ORTHOVISC in clinical trials[2]

Treatment-related adverse events[2,††]

Adverse Events	**ORTHOVISC** (n=562)	**Saline** (n=296)
Any adverse events[§§]	349 (62.1%)	204 (68.9%)
Injection site pain	14 (2.5%)	6 (2.0%)
Injection site reaction NOS	1 (0.2%)	2 (0.7%)
Pain NOS	14 (2.5%)	11 (3.7%)
Arthralgia	71 (12.6%)	51 (17.2%)

In a repeat injection study, the frequency and type of adverse events observed with ORTHOVISC were similar to initial treatment.[2]

NOS, not otherwise specified.

** There is a risk of pseudosepsis-like reactions with any intra-articular injection.
†† Not all adverse events reported in clinical studies are listed. Please refer to the Package Insert for more complete information.
§§ In some cases, patients were involved in more than one adverse event.

Please refer to the Package Insert for more complete Important Safety Information.

Important Safety Information

ORTHOVISC High Molecular Weight Hyaluronan is indicated in the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics, e.g., acetaminophen. In clinical studies, the most commonly reported adverse events were arthralgia, back pain, and headache. Other side effects included local injection site adverse events. ORTHOVISC is contraindicated in patients with known hypersensitivity to hyaluronate formulations or known hypersensitivity (allergy) to gram positive bacterial proteins. ORTHOVISC should not be injected in patients with infections or skin diseases in the area of the injection site. Intra-articular injection of sodium hyaluronate preparations has occasionally been associated with allergic/anaphylactic reactions and transient hypotension, which have generally resolved spontaneously or after conservative treatment.

References: 1. Summary of safety and effectiveness data. US Food and Drug Administration website. Accessed February 28, 2020. https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030019b.pdf. **2.** ORTHOVISC [package insert]. Bedford, MA: DePuy Synthes Mitek Sports Medicine; 2013. **3.** SYNVISC (Hylan G-F 20) [package insert]. Ridgefield, NJ: Genzyme Corporation; 2014. **4.** Gelsyn-3 [package insert]. Durham, NC: Bioventus; 2016. **5.** EUFLEXXA [package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc. **6.** Hyalgan [package insert]. Parsippany, NJ: Fidia Pharma USA Inc.; 2011. **7.** SUPARTZ FX [package insert]. Durham, NC: Bioventus LLC; 2015. **8.** SmartTRAK Financial Dashboard - YTD2021 US Joint Fluid. SmartTRAK, LLC; 2021. **9.** Adapted from ORTHOVISC PMA Module 3, Table 3.6-29. Accessed February 28, 2020. https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030019b.pdf. **10.** Brandt KD, Block JA, Michalski JP, Moreland LW, Caldwell JR, Lavin PT. Efficacy and safety of intraarticular sodium hyaluronate in knee osteoarthritis. ORTHOVISC Study Group. *Clin Orthop Relat Res*. 2001;385:130-143. **11.** WOMAC Patient Survey Form. Accessed August 26, 2021. https://www.hss.edu/files/New_patient_Hip_WOMAC.PDF.

Please refer to the Instructions for Use for a complete list of indications, contraindications, warnings, and precautions.

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