SynoJoynt™ 1% Sodium Hyaluronate Frequently Asked Questions (FAQs)

PLEASE NOTE: FAQs RELATED TO SYNOJOINT HA MAY APPEAR ON THE LABEL OF THE DEVICE AND BE DELIVERED BY ANY REPRESENTATIVE (CUSTOMER SERVICE, COMMERCIAL/SALES, MARKETING, MEDICAL/CLINICAL, REGULATORY/COMPLIANCE, ETC)

1. What is SynoJoynt HA?

SynoJoynt HA is a sterile, nonpyrogenic, clear, viscoelastic solution of hyaluronan contained in a single-use, prefilled syringe. It is a viscous solution of sodium hyaluronate in buffered physiological sodium chloride. SynoJoynt HA has a high molecular weight fraction (approximately 2,500,000 Da). Synojoynt HA is nonavian, non-crosslinked, and derived from bacterial fermentation.

2. What is the indication for SynoJoynt injections?

SynoJoynt HA is indicated for the treatment of pain from osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative, nonpharmacologic therapy and simple analgesics (eg, acetaminophen).

3. What is the mechanism of action of SynoJoynt HA?

A singular mechanism of action for all HA products, including SynoJoynt, is still unknown. Synovial fluid is largely comprised of HA and serves to lubricate and provide cushioning to joint surfaces, particularly the knee, during movement. OA causes the breakdown of synovial fluid, making it less effective at lubricating and cushioning joint surfaces. Intra-articular administration of SynoJoynt HA can reduce the symptoms by restoring the levels of HA in the intra-articular space.

4. How is SynoJoynt HA administered?

SynoJoynt HA is administered by injection into the articular joint space by a health care professional using aseptic technique.

5. How is SynoJoynt HA different than other HA preparations?

SynoJoynt HA is a 3-injection regimen HA product for the treatment of knee OA pain. It is non-crosslinked and derived from bacterial fermentation rather than an avian source. It is a high-molecular–weight HA product (2,500,000 Da).

6. When should SynoJoynt HA be used?

The goal of viscosupplementation, including SynoJoint HA, is to augment the viscosity and elasticity of native synovial fluid. SynoJoynt HA is indicated for the treatment of knee pain due to OA in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics. It is appropriate for patients with active lifestyles who also suffer from knee OA pain.

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7. When shouldn't SynoJoynt HA be used?

SynoJoynt™ HA is contraindicated in patients who have a known hypersensitivity to hyaluronan preparations. Do not administer SynoJoynt HA to patients with active knee joint infections or patients with infections and/or skin diseases in the area of injection. Safety and effectiveness have not been tested in pregnant women, nursing mothers, or children. The use of SynoJoynt HA in joints other than the knee or for use with other intra-articular injections has not been established.

WARNINGS:

- Do not concomitantly use disinfectants containing quaternary ammonium salts or chlorhexidine for skin preparations because hyaluronan can precipitate in their presence.
- Do not inject SynoJoynt HA intravascularly, as this may cause systemic adverse events.

8. How long will pain relief last after a SynoJoynt HA injection?

In a double blind, placebo-controlled pivotal clinical study, Synojoynt HA demonstrated improvements in pain, stiffness, and function over baseline at time points from 6 to 26 weeks.[1]

9. How long does it take for a patient to see pain relief after an injection of SynoJoynt HA?

Notable clinical improvement occurred and was sustained at 6, 12, 18, and 26 week time points.[1]

10. Can SynoJoynt HA be administered in both knees at the same time?

Patients with bilateral knee pain can receive SynoJoynt HA injections in both knees. A separate syringe and needle should be used for each knee. Reimbursement should be confirmed with the patient's insurance carrier to verify payor coverage prior to administration of SynoJoynt HA.

11. What is the treatment cycle for SynoJoynt HA?

SynoJoynt HA is approved for 3 injections administered once a week for 3 weeks.

12. Can patients receive fewer than the 3 injections in the treatment cycle?

SynoJoynt HA was approved as a 3-injection regimen for treating OA pain, with one injection administered per week for 3 weeks. The efficacy of fewer than 3 injections has not been studied.

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13. Can patients take other medications while receiving SynoJoynt™ HA injections?

There are no known drug interactions related to the intra-articular use of SynoJoynt HA and medications delivered systemically. SynoJoynt HA interference with anti-inflammatory agents or simple analgesics has not been reported. Safety and efficacy of the combined use of SynoJoynt HA and other intra-articular injectables have not been established.

14. Can SynoJoynt HA be used in any other joints to treat OA pain?

SynoJoynt HA is indicated for the treatment of knee OA pain in patients who have failed to respond adequately to conservative nonpharmacologic treatment or simple analgesics (eg, acetaminophen). The safety and effectiveness of SynoJoynt HA use in joints other than the knee has not been established.

15. What are the most common side effects?

The most common side effects reported in the double blinded, placebo-controlled pivotal clinical study were injection site pain (1%), arthralgia (2%), and injection site joint effusion (0.5%).

16. What size needle should be used?

Administer SynjoJoynt HA injections using a 21 ga-23 ga needle.

17. How should SynoJoynt HA be stored?

Store SynoJoynt HA in its original packaging, between 36° and 77° F. SynoJoynt HA has a shelf life of 2 years.

18. How do I report product complaints?

To report product complaints and adverse events or ask product-related questions, call Product Surveillance at (800) 934-4404 or email complaints@arthrex.com.

Reference

1. SynoJoynt. Directions for use. Hanmi Pharmaceuticals; 2021.