Gelsyn-3

(sodium hyaluronate)

New Product Slideshow

MPR

Introduction

- **Brand name:** Gelsyn-3
- **Generic name:** Sodium hyaluronate
- **Pharmacological class:** Hyaluronan
- **Strength and Formulation:** 0.84%; per 2mL; solution for intra-articular injection
- **Manufacturer:** Bioventus
- **How supplied:** Single-use pre-filled syringe—1 (with needle)
- **Legal Classification:** Rx

GELSYN-3


REF GS3111
GELSYN-3™
3 injection hyaluronic acid treatment
bioventus
Intra-articular Hyaluronic Acid
1 pre-filled syringe containing 16.8 mg/2 mL
Hyaluronic Acid Sodium Salt

Indications

- Treatment of pain in **osteoarthritis of the knee** in patients who have failed to respond adequately to conservative nonpharmacologic therapy and simple analgesics (eg, acetaminophen)

Dosage & Administration

- Remove synovial fluid or effusion before injection
- Give as a single intra-articular injection
- **>21yrs:** 2mL in one knee only once weekly for 3 weeks

Contraindications

- Knee joint infections
- Skin diseases or infections in area of the injection site

Considerations for Special Populations

- **Pregnancy:** Not established
- **Nursing mothers:** Not established
- **Pediatric:** ≤21 years: not established

Warnings/Precautions

- **Do not** inject by intravascular route
- Severe intra-articular effusion
- Lymphatic or venous stasis in leg
- Advise patients to avoid strenuous or prolonged weight-bearing activities for approximately 48hrs following injection

Interactions

- **Avoid** use of disinfectants containing quaternary ammonium salts; hyaluronan can precipitate in their presence

- Concomitant other intra-articular injections: not studied

Adverse Reactions

- Injection site pain
- Arthralgia
- Joint effusion/warmth/stiffness/swelling
- Arthritis
- Gait disturbance
- Arthropathy

Clinical Trials

- The safety and efficacy of Gelsyn-3 was evaluated in a prospective, randomized, double-blind, active control (commercial hyaluronan), non-inferiority study conducted across 23 centers in Europe (n=380)

Clinical Trials

- Patients were administered 2mL intra-articular injections of either Gelsyn-3 or commercial hyaluronan once weekly for 3 consecutive weeks with follow-up visits scheduled for Weeks 4, 12 and 26

- The **primary efficacy variable** for this study was the Western Ontario McMaster Universities (WOMAC) pain subscore at Week 26

Clinical Trials

- Safety variables included averse events, pain and local tolerability at the injection site, and global tolerability as assessed by both patient and investigator

- For the primary outcome measure, the protocol-defined **8mm non-inferiority margin** was met for all time points

Clinical Trials

- The 95% lower-bound confidence interval in pain subscore reduction from baseline for the overall 26-week WOMAC pain subscore for the ITT patient population -1.4
- Overall WOMAC pain subscore mean reduction from baseline was **30.8mm** (56%) for the Gelsyn-3 treatment group vs. **29.4mm** (53%) for the commercial hyaluronan group
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/gelsyn-3/drug/34622/