IT'S YOU THAT MAKES HYALURONIC ACID WORK.

GenVisc®850

5 injection hyaluronic acid regimen

orthogenrx.com

In a field where hyaluronic acids are often considered to be the same, GenVisc 850 is different because it has a unique reimbursement code and gives you the regimen options for you to decide what's best for each individual patient. It's you after all, that makes GenVisc 850 work.

Reimbursement Code: J7320

Flexible Dosing:

Approved for 5 injections, but some patients may benefit from as few as 3 injections.

Proven

GenVisc 850 is approved in 64 countries with over 45 million syringes distributed worldwide.[1†]

- GenVisc 850 has the largest and longest duration double blind clinical study of hyaluronic acids for knee osteoarthritis.[2]
- GenVisc 850 has been published in over 30 clinical studies.[3]

Safe[4]

- Safe as saline placebo
- Free of avian proteins
- Demonstrated safe for repeat injection cycles

Effective

- Provides significant pain relief with results that last[5]
- Demonstrated improvement in pain relief up to 30 weeks post first injection cycle[3]
- Demonstrated improvement of total WOMAC index at 30 weeks: Pain, stiffness and functional capacity[2]

GenVisc® 850

Description

GenVisc 850 is a sterile, viscoelastic non-pyrogenic solution of puri-fied, high molecular weight sodium hyaluronate (average of 850,000 daltons and a range of 620,000 - 1,170,000 daltons) having a pH of 6.8-7.8. Each 2.5 mL of GenVisc 850 contains 10mg/mL of sodium hyluronate dissolved in a physiological saline (1.0% solution). The sodium hyluronate is derived from bacterial fermentation. Sodium hyluronate is a poly-saccharide containing repeating disacchride units of glucuronic acid and N-acetylglucosamine.

Indications and Usage

GenVisc 850 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.

Directions for Use

GenVisc 850 is administered by intra-articular injection. A treatment cycle consists of five injections given at weekly intervals. Some patients may experience benefit with three injections given at weekly intervals. Injection of subcutaneous lidocaine or similar local anesthet-ic may be recommended prior to injection of GenVisc 850.

Important Safety Information

GenVisc 850 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 to simple analgesics (eg, acetaminophen)

GenVisc 850 is contraindicated in patients with known hypersensitivity to hyaluronate preparations. Intra-articular injections are contraindi-cated in cases of present infections or skin diseases in the area of the injection site to reduce the potential for developing septic arthritis

The effectiveness of a single treatment cycle of less than 3 injections has not been established In a clinical trial of 297 patients, the frequen-cy of adverse events in the rst treatment cycle was 2.9%, which was identical to the frequency in the saline-control group

GenVisc® 850

The most commonly reported adverse events in the GenVisc 850 group included injection site pain (6), allergic reaction (3), arthralgia (2), and bleeding at the injection site (2).

In a clinical study of 513 completed GenVisc 850 treatment cycles, and a total of 487 completed PBS treatment cycles, the frequency of adverse events between the groups was the same, and did not increase over the course of the three retreatment cycles.

Caution

Federal law restricts this device to sale by or on the order of a physician (or a properly licensed practitioner.)

Warnings

Do not concomitantly use disinfectants containing quaternary ammonium salts for skin perparation because sodium hyluronate can precipitate in their presence.

Precautions

Remove joint effusion, if present, before injecting GenVisc 850. Do not use GenVisc 850 if the package is opened or damaged. Store in the original packaging (protected from light) below 86°F (30°C.) DO NOT FREEZE. Do not use after expiration date indicated on package. The shelf life of GenVisc 850 is 36 months. The effectiveness of a single treatment cycle of less than 3 injections has not been established. The effectiveness of repeat treatment cycles of GenVisc 850 has not been established. Strict aseptic administraiton technique must be followed to avoice infections in the injection site. The safety and effectiveness of the use of GenVisc 850 in joints other than the knee have not been established. The safety and effectiveness of the use of GenVisc 850 concomitantly with other intra-articular injectable products have not been established.

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GenVisc® 850

Information for Patients

Transient pain and/or swelling of the injected joint may occur after intra-articular injection of GenVisc 850. As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities or prolonged (i.e., more than 1 hour) weight-bearing activities such as jogging or tennis within the 48 hours that follow the intra-articular injection. **Use in Specific Populations Pregnancy:** The safety and effectiveness of GenVisc 850 have not been established in pregnant women. **Nursing Mothers:** It is not known if GenVisc 850 is excreted in human milk. The safety and effectiveness of GenVisc 850 have not been established in lactating women. **Pediatrics:** The safety and effectiveness of GenVisc 850 have not been demonstrated in children (21 years of age or younger).

Adverse Events

The primary evidence of safety is provided by the comparison of GenVisc 850 to Phosphate Buffered Saline (PBS) in the AMELIA (Navarro, Spain) study. Four cycles of 5 injections of GenVisc 850 or PBS were administered with an interval of 6 months for the first three cycles and 1 year for the fourth cycle. Patients were followed for 1 year after the last injection. The population of patients evaluated for the safety of GenVisc 850 included 306 subjects (153 GenVisc 850, 153 PBS). In each treatment group, 127 subjects experienced at least one adverse event during the study and 22 patients (11 in each treatment group) experienced at least one adverse event that was reported as possibly, probably or certainly related to the device, Table 1. None of the related adverse events were assessed as severe. For the first cycle of 5 injections in the GenVisc 850 treatment group, the 15 adverse events reported as related were pain at the injection site (6), allergic reaction (3), arthralgia (2), bleeding at the injection site (2), bleeding (1) and heaviness (1). In the first cycle of 5 injections for the PBS treatment group, the 14 adverse events reported as related were bleeding at the injection site (6), allergic reaction (3), pain at the injection site (2), arthralgia (2), and arthritis.

GenVisc® 850

Clinical Studies

The results of the Yong Ping study and the Bayesian longitudinal analysis summarized below confirm that the clinical performance of GenVisc 850 was superior to a saline placebo control and similar to that of Supartz/Supartz FX. The Yong Ping study was a randomized controlled, multicenter clinical trial that demonstrated non-inferiority of GenVisc 850 to Supartz/Supartz FXX through 6 weeks. The Bayesian longitudinal analysis included data from four randomized controlled trials, two of which included comparisons of GenVisc 850 to saline and two of which included comparisons of Supartz/Supartz FX to saline. The results of this Bayesian longitudinal analysis demonstrated the superiority of GenVisc 850 to saline placebo control.

GenVisc 850 Coverage

- Medicare Reimbursement assistance
- Covered under Part B of Medicare
- Reimbursed under a unique reimbursement code: J7320
- OrthogenRx™ Reimbursement Hotline: 1-844-GENVISC (436-8472)
- OrthogenRx Reimbursement Verification Fax Line: 1-866-227-9248
- OrthogenRx Order Fax Line: 1-614-553-5475
- OrthogenRx Email: GenVisc@cordlogistics.com

GenVisc 850 Is Easy To Order

- OrthogenRx™ Customer Service Number: 1-844-GENVISC (436-8472)
- Product Code: 50653-0006-01
- Supplied as a sterile, non-pyrogenic solution in 3mL prefilled syringe
- Each syringe contains sodium hyaluronate 25.0 mg with a stability established to 36 months

GenVisc 850 Support Hotline
1-844-GENVISC (1-844-436-8472)
Fax: (866) 227-9248

GenVisc® 850

OrthogenRx Customer Service Number:
1-844-GENVISC (1-844-436-8472)
OrthogenRx Order Fax Line: 1-614-553-5475
OrthogenRx Email: GenVisc@cordlogistics.com
Product Code: 50653-006-01

References

1. FDA summary of safety and effectiveness data (SSED). GenVisc® 850. http://www.accessdata.fda.gov/cdrh_docs/pdf14/p140005b.pdf. Accessed April 17, 2018.

2. Navarro-Sarabia F, Coronel P, Collantes E, Navarro FJ, de la Serna AR, Naranjo A, Gimeno M, Herrero-Beaumont G; AMELIA study group. A 40-month multicentre, randomised placebo-controlled study to assess the efficacy and carry-over effect of repeated intra-articular injections of hyaluronic acid in knee osteoarthritis: the AMELIA project. Ann Rheum Dis. 2011;70: 1957-62.

3. GenVisc 850 Patient Package Insert

4. GenVisc 850 Package Insert

5. Blanco FJ, Fernández-Sueiro JL, Pinto-Tasende JA, Fernández-López JC, Ramallal M, Freire A et al. Intra-articular hyaluronan treatment of patients with knee osteoarthritis waiting for replacement surgery. The Open Arthritis Journal 2008; 1: 1-7.

† The Adant® formulation is approved in 63 countries outside the US. Adant is manufactured by TEDEC-MEIJI FARMA and is authorized to be marketed and distributed under the trademark GenVisc850.

GenVisc850

5 injection hyaluronic acid regimen

orthogenRx®

multi-regimen hyaluronic acids

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