FAIR AND CONSISTENT PRICING HELPS YOU MAKE THE DIFFERENCE.

TriVisc®

3 injection hyaluronic acid regimen

trivisc.com

Fair and Consistent Pricing Helps You Make the Difference

For osteoarthritis knee pain, it's your skill that makes viscosupplements work. With TriVisc you get a clinically proven 3 injection product with the advantage of fair and consistent pricing — for you and your patients.

OrthogenRx prices it's products in a way that is affordable and reflective of the value they bring to patients and providers.

Reimbursement Code:
J7329

Pure[1]

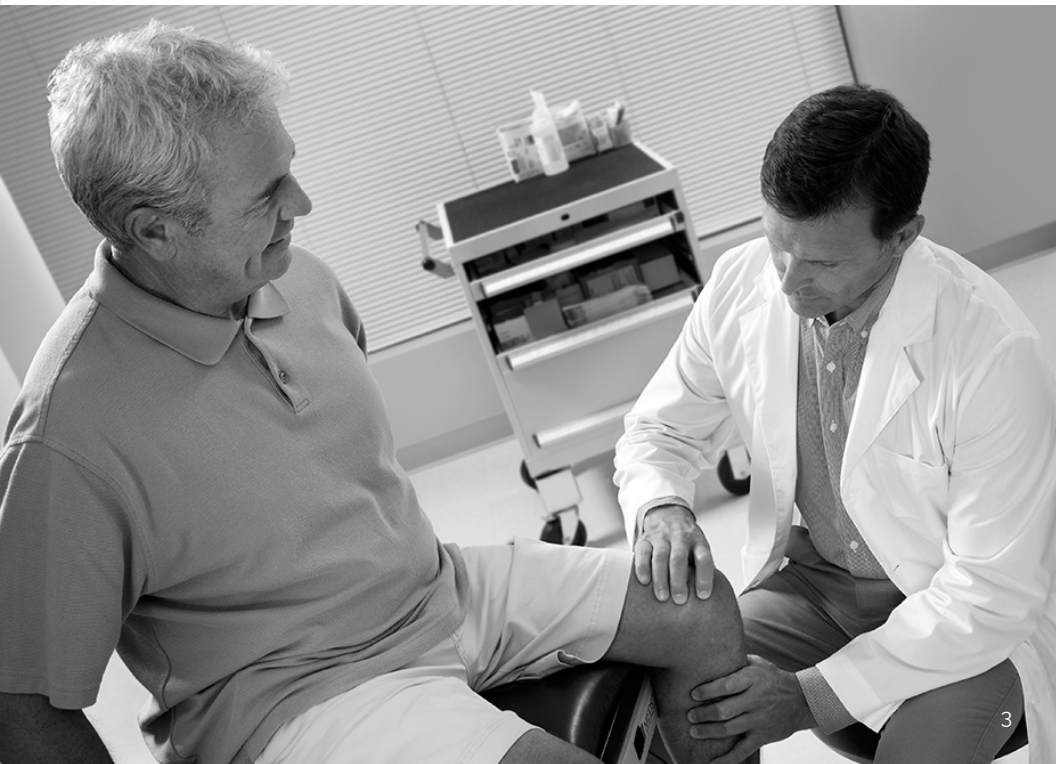
- Highly purified HA produced by bacterial biofermentation technology
- Removes the risk of avian allergies and sensitivities
- Consistent viscolastic properties, safe for repeat injection cycles
- Fully automated manufacturing process minimizes the risk of contamination and human error

Trusted

35 million doses administrated worldwide[1]

Determined to be non-inferior to Visco-3®[2] and Euflexxa®[3]
Supported by published clinical data

- TriVisc exhibited improvement in WOMAC, VAS and patient satisfaction compared to baseline[4,5]



TriVisc®

Description

TriVisc is a sterile, viscoelastic non-pyrogenic solution of purified, high molecular weight sodium hyaluronate. Each 2.5 mL of TriVisc contains 10mg/mL of sodium hyaluronate dissolved in a physiological saline. The sodium hyaluronate is derived from bacterial fermentation. Sodium hyaluronate is a poly-saccharide containing repeating disacchride units of glucuronic acid and N-acetylglucosamine.

Indications and Usage

TriVisc 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

TriVisc is administered by intra-articular injection. A treatment cycle consists of three injections given at weekly intervals. Injection of subcutaneous lidocaine or similar local anesthetic may be recommended prior to injection of TriVisc.

Important Safety Information

TriVisc 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 to simple analgesics (e.g. acetaminophen).

TriVisc is contraindicated in patients with known hypersensitivity to hyaluronate preparations. Intra-articular injections are contraindicated 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 frequency of adverse events in the first treatment cycle was 2.9%, which was identical to the frequency in the saline-control group.

TriVisc®

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

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 preparation because sodium hyluronate can precipitate in their presence.

Precautions

Remove joint effusion, if present, before injecting TriVisc. Do not use TriVisc 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 TriVisc is 42 months. The effectiveness of a single treatment cycle of less than 3 injections has not been established. Transient increases in inflammation following any intra-articular hyaluronan injection have been reported in some patients with inflammatory joint conditions. The effectiveness of repeat treatment cycles of TriVisc has not been established. Strict aseptic administration technique must be followed to avoid infections in the injection site. The safety and effectiveness of the use of TriVisc in joints other than the knee have not been established. The safety and effectiveness of the use of TriVisc concomitantly with other intra-articular injectable products have not been established.

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Information for Patients

Transient pain and/or swelling of the injected joint may occur after intra-articular injection of TriVisc. 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 TriVisc have not been established in pregnant women. **Nursing Mothers:** It is not known if TriVisc is excreted in human milk. The safety and effectiveness of TriVisc have not been established in lactating women. **Pediatrics:** The safety and effectiveness of TriVisc has not been demonstrated in children (21 years of age or younger).

Adverse Events

The primary clinical performance testing to assess the safety of TriVisc were two clinical studies, the AMELIA[1] and Yong Ping[2] studies, used to establish reasonable assurance of the safety of established in the approval of another intra-articular hyaluronan (HA) under P1400053 (P140005 HA). TriVisc is composed of identical chemical formulation to this HA and differs only in that less of the device is injected (3 weekly injections of 2.5 ml for TriVisc instead of 5 weekly injections). Thus, the clinical studies used to provide evidence of the reasonable assurance of the safety of the HA under P140005 are directly applicable to TriVisc as well. The primary evidence of the safety under P140005 was provided by the comparison of the P140005 HA to PBS in the AMELIA study. In this study, four cycles of 5 injections of the P140005 HA or PBS were administered at regular intervals. The first three cycles were administered at intervals of 6 months. The fourth and last cycle was administered after 1 year after the 3rd cycle. Patients were followed for 1 year after the last injection. The population of patients evaluated for the safety of the P140005 HA included 306 subjects (153 HA, 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 (4). None of the related adverse events were assessed as severe. In the HA treatment group, the 15 adverse events reported as related adverse events 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 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 (1), and arthritis (1).

Clinical Studies

The primary clinical performance testing to demonstrate effectiveness of TriVisc, as per the application of Section 216 of the Food and Drug Administration Modernization Act (1997), is obtained from the Summary of Safety and Effectiveness Data (SSED) for a viscosupplement approved under Premarket Application (PMA) supplement P980044/S27. A clinical study was performed to establish a reasonable assurance of safety and effectiveness of three weekly intra-articular injections of the viscosupplement approved under P980044/S27. The clinical study evaluated the treatment of pain due to OA of the knee in patients who had failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics . The study was performed in the United States (US) under IDE (Investigational Exempt Device) G130271. Data from this clinical study were the basis for the approval decision of this viscosupplement under P980044/S27.

TriVisc Coverage

- Medicare Reimbursement assistance
- Covered under Part B of Medicare
- Reimbursed under a unique reimbursement code: J7329
- OrthogenRx Reimbursement Hotline: 1-877-517-5445
- OrthogenRx Reimbursement Navigator: orthogenrx.aspnprograms.com
- OrthogenRx Order Fax Line: 1-614-533-5475
- OrthogenRx Email: TriVisc@cordlogistics.com

TriVisc Is Easy To Order

- OrthogenRx Customer Service Number: 1-877-517-5445
- Product Code: 50653-0006-04
- 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

TriVisc Support Hotline: 1-877-517-5445

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TriVisc Support Hotline: 1-877-517-5445
OrthogenRx Customer Service Number: 1-877-517-5445
OrthogenRx Order Fax Line: 1-614-553-5475
OrthogenRx Email: TriVisc@cordlogistics.com
Product Code: 50653-0006-04

References

1. FDA summary of safety and effectiveness data (SSED). TriVisc®
2. TriVisc Package Insert
3. Ulucay, I. et al. Acta Orthop Traumatol Turc 2007;41: 337-342. The use of arthroscopic debridement and viscosupplementation in knee osteoarthritis.
4. Dıraçöglu, D. et al. J Back and Musculo Rehab. 2016;16: 53. Single versus multiple dose hyaluronic acid: Comparison of the results.

TriVisc®
3 injection hyaluronic acid regimen

orthogenRx®
multi-regimen hyaluronic acids

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