Instructions for Use Synvisc-One

DESCRIPTION

Synvisc-One (hylan G-F 20) is a sterile, nonpyrogenic, elastoviscous fluid containing hylans. Hylans are derivatives of hyaluronan (sodium salt of hyaluronic acid) and consist of repeating disaccharide units of N-acetylglucosamine and sodium glucuronate. Hylan A has an average molecular weight of approximately 6,000,000 daltons and hylan B is a hydrated gel. Hylan G-F 20 contains hylan A and hylan B (8.0 mg ± 2.0 mg per ml) in buffered physiological sodium chloride solution (pH 7.2 ± 0.3).

CHARACTERISTICS

Synvisc-One is biologically similar to hyaluronan. Hyaluronan is a component of synovial fluid which is responsible for its elastovicosity. The mechanical (elastoviscous) properties of hylan G-F 20 are, however, superior to those of synovial fluid and hyaluronan solutions of comparable concentration. Synvisc-One has an elasticity (storage modulus G') at 2.5 Hz of 111 ± 13 Pascals (Pa) and a viscosity (loss modulus G") of 25 ± 2 Pa. Elasticity and viscosity of knee synovial fluid of 18- to 27-year-old humans measured with comparable method at 2.5 Hz are G' = 117 ± 13 Pa and G" = 45 ± 8 Pa. Hylans are degraded in the body by the same pathway as hyaluronan, and breakdown products are nontoxic.

INDICATIONS AND USAGE

Synvisc-One:

- is a temporary replacement and supplement for synovial fluid.
- is beneficial for patients in all stages of knee pathology.
- is most effective in patients who are actively and regularly using the affected knee.
- achieves its therapeutic effect through viscosupplementation, a process whereby the physiological and rheological states of the arthritic knee tissues are restored.

Viscosupplementation with Synvisc-One is a treatment to decrease pain and discomfort, allowing more extensive movement of the knee. *In vitro* studies have shown that hylan G-F 20 protects cartilage cells against certain physical and chemical damage.

Synvisc-One is only intended for intra-articular use by a physician to treat pain associated with osteoarthritis of the knee.

CONTRAINDICATIONS

- If venous or lymphatic stasis is present, Synvisc-One should not be injected into the knee.
- Synvisc-One should not be used in infected or severely inflamed knees or in patients having skin diseases or infections in the area of the injection site.

WARNINGS

- Do not inject intravascularly.
- Do not inject extra-articularly or into the synovial tissues and capsule. Adverse events, generally in the area of the injection, have occurred following extra-articular injection of Synvisc*.
- Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because hyaluronan can precipitate in their presence.
- Some cases of skin necrosis have been reported after intra-articular use of hyaluronic acid. Patients should be instructed to contact their treating physician if signs of skin disorder (such as change of color or open sores) appear.

PRECAUTIONS

- Synvisc-One should not be used if there is a large intra-articular effusion prior to the injection.
- As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities following the intra-articular injection, and resume full activities within a few days.
- Synvisc-One has not been tested in pregnant women or children under 18 years of age.
- Synvisc-One contains small amounts of avian protein and should not be used in patients with related hypersensitivities.

ADVERSE EVENTS

- Adverse events involving the injected knee: transient pain and/or, swelling and/or effusion in the injected knee may occur after intraarticular injections of Synvisc-One. Cases of acute inflammation, characterized by joint pain, swelling, effusion and sometimes joint warmth and/or stiffness, have been reported following an intra-articular injection of Synvisc-One. Analysis of synovial fluid reveals aseptic fluid with no crystals. This reaction often responds within a few days to treatment with Non Steroidal Anti Inflammatory Drugs (NSAIDS), intra-articular steroids and/or arthrocentesis. Clinical benefit from the treatment may still be apparent after such reactions.
- Intraarticular infections did not occur in any of the clinical trials of Synvisc/Synvisc-One and have been reported only rarely during clinical use of Synvisc.
- Hypersensitivity reactions including anaphylactic reaction, anaphylactoid reaction, anaphylactic shock and angioedema have been reported.
- The post marketing experience has identified the following systemic events to occur rarely with Synvisc administration: rash, hives, itching, fever, nausea, headache, dizziness, chills, muscle cramps, paresthesia, peripheral oedema, malaise, respiratory difficulties, flushing and facial swelling.
- In the controlled clinical trial with Synvisc-One, the frequency and types of adverse events were similar between the group of patients that received Synvisc-One and the group that received placebo.

DOSAGE AND ADMINISTRATION

- Remove synovial fluid or effusion before injecting Synvisc-One.
- Do not use Synvisc-One if package is opened or damaged.
- Inject at room temperature.
- To remove the syringe from the blister (or tray), take hold of it by the body, without touching the plunger rod.
- Administer using strict aseptic procedures, taking particular care when removing the tip cap.
- Twist the grey tip cap before pulling it off, as this will minimise product leakage
- Use an 18 - 20 gauge needle.
- To ensure a tight seal and prevent leakage during administration secure the needle tightly while firmly holding the Luer hub.
- Do not over tighten or apply excessive leverage when attaching the needle or removing the needle guard, as this may break the tip of the syringe.
- Do not resterilise Synvisc-One.
- Inject into the synovial space only.
- The syringe contents are for single use only.

DOSAGE GUIDELINES

The recommended treatment regimen is one injection in the knee. The injection may be repeated 6 months after the first injection, if justified by the patient's symptoms.

DURATION OF EFFECT

Hylan G-F 20 treatment affects only the injected knee; it does not produce a general systemic effect.

Prospective clinical data in knee osteoarthritis patients have shown benefit of treatment up to 26 weeks, following a single Synvisc-One injection.

CONTENT PER ml

Each 1 ml contains: hylan 8.0 mg, sodium chloride 8.5 mg, disodium hydrogen phosphate 0.16 mg, sodium dihydrogen phosphate hydrate 0.04 mg, water for injection q.s.

HOW SUPPLIED

The contents of the syringe are sterile and nonpyrogenic. Store between +2°C and +30°C. Do not freeze. Synvisc-One is supplied in a 10 ml glass syringe containing 6 ml hylan G-F 20.

*Synvisc (hylan G-F 20) is a 3 x 2 ml treatment regimen supplied in a 2.25 ml syringe. Synvisc is administered by intra-articular injection once a week (one week apart) for a total of three injections.

For use in Canada only

For orders, product information, product and medical complaints call 1-800-265-7927.

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