INSTRUCTIONS FOR USE
MONOVISC™, Lightly Cross-linked High Molecular Weight Sodium Hyaluronate

DESCRIPTION:

MONOVISC™ is a sterile, non-pyrogenic, sodium hyaluronate solution, lightly cross-linked with a proprietary chemical cross-linker. MONOVISC™ contains 22 mg/mL of lightly cross-linked sodium hyaluronate (NaHA) dissolved in phosphate buffered saline at physiological osmolality. MONOVISC™ is manufactured from ultra pure, high molecular weight sodium hyaluronate produced by bacterial fermentation. Hyaluronic acid is a natural complex polysaccharide of the glycosaminoglycan family.

CHARACTERISTICS:

Sodium Hyaluronate is a high molecular weight polysaccharide composed of sodium glucuronate and N-acetylglucosamine. The sodium hyaluronate in MONOVISC™ is derived from bacterial fermentation. Hyaluronic acid is ubiquitously distributed throughout the tissue of the body and is present in high concentrations in such tissues as vitreous humor, synovial fluid, umbilical cord and dermis. Sodium hyaluronate functions as a tissue lubricant and is thought to play an important role in modulating the interactions between adjacent tissues. It can also act as a viscoeleastic support maintaining a separation between tissues. Different sodium hyaluronate preparations may have different molecular weights, but have the same chemical structure. The MONOVISC™ cross-linked sodium hyaluronate injection is biocompatible, non-inflammatory and non-pyrogenic. Sodium hyaluronate preparations have been shown to be well tolerated in osteoarthritic synovial joints.

APPLICATION:

MONOVISC™ Cross-Linked Sodium Hyaluronate Injection is a single, intra-articular injection of cross-linked sodium hyaluronate designed to treat the symptoms of osteoarthritis.

INDICATIONS:

MONOVISC™ is indicated as a viscoelastic supplement or a replacement for synovial fluid in human joints. MONOVISC™ is well suited for treatment of the symptoms of human joint dysfunctions such as osteoarthritis. The actions of MONOVISC™ are lubrication and mechanical support.

DIRECTIONS FOR USE:

The required amount of MONOVISC™ is injected through a sterile, disposable, hypodermic needle of suitable gauge into the selected joint space. The sterile needle should be attached to the MONOVISC™ syringe by a health care professional using a health care facility-approved aseptic technique. Common needle gauges for injections into the knee are 18-21 gauge. The final needle selection for any procedure is determined by the physician. The health care provider should ensure proper penetration into joint synovial space prior to injecting MONOVISC™.

CONTRAINDICATIONS:

MONOVISC™ is composed of cross-linked sodium hyaluronate and may contain trace amounts of gram positive bacterial proteins. The following pre-existing conditions may constitute relative or absolute contraindications to the use of MONOVISC™:

- Known sensitivity to any of the materials contained in MONOVISC™
- Pre-existing infections of the skin region of the intended injection site
- Known infection of the index joint
- Known systemic bleeding disorders

PRECAUTIONS:

- Those precautions normally considered during injection of substances into joints are recommended.
- Only medical professionals trained in accepted injection techniques for delivering agents to joint spaces should inject sodium hyaluronate for this application.
- The amount of MONOVISC™ necessary to be injected depends on specific site and patient anatomy and needs to be defined by the medical professional performing the procedure. An excess quantity of sodium hyaluronate should not to be used and the patient should be monitored closely.
- The synovial space should not be overfilled.
- If pain increased during the injection procedure, the injection should be stopped and the needle withdrawn.

ADVERSE REACTIONS:

Hyaluronic acid is a natural component of the tissues of the body. MONOVISC™ is thoroughly tested to determine that each batch conforms to the product quality attributes. Since sodium hyaluronate molecules are non-inflammatory, any phlogistic response is considered to be caused by the surgical procedures. Mild to moderate episodes of transient swelling and discomfort have occasionally been observed following intra-articular injection of sodium hyaluronate preparations. General risks associated with the procedure of injecting substances into joints may include infections and bleeding.

HOW SUPPLIED:

MONOVISC™ is a sterile viscoelastic preparation supplied in a disposable glass syringe delivering 4.0 mL. Each mL of MONOVISC™ contains 22 mg/mL of lightly cross-linked sodium hyaluronate (NaHA) dissolved in phosphate buffered saline.
Note: The contents of the syringe are sterile; however, the product tray is non-sterile.

FOR INTRA-ARTICULAR USE. STORE AT 2°C to 25°C. PROTECT FROM FREEZING.

CAUTION: This device is restricted to sale and use by or under the supervision of a physician.

This product is for single patient use only and must not be re-sterilized. Reuse of needles or syringes used to inject this product can result in transmission of infectious agents as well as blood-borne pathogens (including HIV and hepatitis), potentially endangering patients and physicians and staff. Used needles or syringes should be discarded after each injection session and not saved for subsequent sessions on the same patient.

DO NOT USE IF PRODUCT INNER PACKAGING IS OPEN OR DAMAGED.

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