Disclaimer:

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STERILE A

2°C

INSTRUCTIONS FOR USE

Sodium Hyaluronate FOR INTRA-ARTICULAR INJECTION
Non-surgical use 15 mg/mL Sterile Injection

DESCRIPTION: ORTHOVISC and ORTHOVISC mini are a sterile, non-pyrogenic solution of sodium hyaluronate.

ORTHOVISC and ORTHOVISC mini contain 15 mg/mL of sodium hyaluronate (NaHA) dissolved in physiological saline. The kinematic viscosity of the solution is adjusted to 20,000–70,000 centistokes, and the osmolarity is approximately 340 milliosmoses.

CHARACTERISTICS: Sodium hyaluronate is a high molecular weight polymer composed of sodium glucuronate and N-acetylglucosamine. Sodium hyaluronate is ubiquitously distributed throughout the tissues 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 viscoelastic support maintaining a separation between tissues. Different sodium hyaluronate preparations may have different molecular weights, but are thought to have the same chemical structure. The sodium hyaluronate in ORTHOVISC and ORTHOVISC mini has a molecular weight greater than one million Daltons. ORTHOVISC and ORTHOVISC mini are non-inflammatory and non-pyrogenic.

Sodium hyaluronate preparations have been shown to be biocompatible, non-antigenic, and do not interfere with normal wound healing processes.

INDICATIONS: ORTHOVISC and ORTHOVISC mini are indicated as a viscoelastic supplement or a replacement for synovial fluid in human joints. ORTHOVISC and ORTHOVISC mini are well suited for treatment of the symptoms of human synovial joint dysfunctions such as osteoarthritis.

The actions of ORTHOVISC and ORTHOVISC mini are lubrication and mechanical support.

DIRECTIONS FOR USE:

NOT FOR INTRAVENOUS INJECTION.

The required amount of ORTHOVISC or ORTHOVISC mini is slowly infused through a sterile, disposable, ISO/ANSI-conforming, non-rigid hubbed hypodermic needle of suitable gauge into the selected joint space. 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 volume will vary depending upon the size of the joint space, not to exceed 2 mL for the knee and other large joints, or 1 mL for small joints. It is the physician’s responsibility to determine the appropriate volume and ensure that the joint is not overfilled.

The recommended treatment regimen is 3 injections spaced one week apart for each treatment course. To not exceed one treatment course for any individual joint in any 6-month period.

Any joint effusion present should be removed before injecting ORTHOVISC or ORTHOVISC mini.

DO NOT OVEFILL JOINT SPACE.

CONTRAINDICATIONS:

The following pre-existing conditions may constitute relative or absolute contraindications to the use of ORTHOVISC or ORTHOVISC mini:

• known sensitivity to any of the ingredients contained in ORTHOVISC or ORTHOVISC mini,
• pre-existing infections of the skin in the region of the intended injection site,
• known infection of the index joint,
• known systemic bleeding disorders.

ORTHOVISC and ORTHOVISC mini may contain trace amounts of gram positive bacterial proteins and are contraindicated for patients with a history of such allergies.

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 intra-articular synovial joint spaces should inject sodium hyaluronate for this application. An excess amount of sodium hyaluronate is not to be used and the patient should be monitored closely. The space should not be overfilled. If pain increases during the injection procedure, the injection should be stopped and the needle withdrawn. Patients experiencing abnormal sequelae to the administration of ORTHOVISC or ORTHOVISC mini should consult with a physician immediately.

ADVERSE REACTIONS: Sodium hyaluronate is a natural component of the tissues of the body. ORTHOVISC and ORTHOVISC mini have been shown to be non-inflammatory. Since sodium hyaluronate molecules are non-inflammatory, any inflammatory response is considered to be caused by the injection procedure itself. Mild to moderate episodes of transient swelling and discomfort have occasionally been observed following intra-articular injection of sodium hyaluronate preparations. The relationship of this occurrence to ORTHOVISC and ORTHOVISC mini has not been established. There are minimal risks associated with the procedure of injecting substances into joints in general, primarily infections and bleeding.

HOW SUPPLIED: ORTHOVISC is a sterile viscoelastic preparation supplied in a disposable glass syringe containing 2.0 mL (appropriate for larger joints such as the knee) of sodium hyaluronate dissolved in physiological saline. ORTHOVISC mini is a sterile viscoelastic preparation supplied in a sterile glass syringe containing 1.0 mL (appropriate for smaller joints) of sodium hyaluronate dissolved in physiological saline. Each mL of ORTHOVISC and ORTHOVISC mini contains 15 mg of sodium hyaluronate, 5 mg of sodium chloride and q.s. Sterile Water for Injection USP. ORTHOVISC and ORTHOVISC mini are sterile filtered and aseptically filled. The contents of the syringe are sterile if the syringe is intact. ORTHOVISC and ORTHOVISC mini should be stored at 2°C to 25°C, and should be allowed to reach room temperature approximately 20-45 minutes prior to use.

DO NOT USE IF INNER (POUCH) PACKAGING IS OPEN OR DAMAGED.

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.

DO NOT RESTERILIZE: 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.

ORTHOVISC is a registered trademark of Anika Therapeutics, Inc.

REFERENCES: