SYNOTECH

Rx Only

1. INFORMATION FOR PRESCRIBERS:

SYNOTECH is a High Molecular Weight Viscoelastic Hyaluronan solution for intra-articular injection, 40mg/2mL, prefilled sterile syringe.

CAUTION:

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

2. DESCRIPTION:

SYNOTECH is a sterile, non-pyrogenic, viscoelastic hydrogel contained in a single-use syringe. SYNOTECH is based on high molecular weight (average 1 800 000 daltons) ultra-pure non-crosslinked Sodium Hyaluronate having a pH of 6.8-7.8. Each one mL of SYNOTECH contains 20mg of sodium Hyaluronate dissolved in physiological saline. The hyaluronan in SYNOTECH is derived from bacterial fermentation. Sodium Hyaluronate is a poly-saccharide containing repeating disaccharide units of glucuronic acid and N-acetylglucosamine.

3. INDICATIONS:

SYNOTECH 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 or simple analgesics (e.g, acetaminophen).

4. CONTRAINDICATIONS:

- Do not administer to patients with known hypersensitivity (allergy) to Hyaluronate preparations.
- Do not administer to patients with known hypersensitivity (allergy) to gram positive bacterial proteins.
- Do not administer to patients with infections or skin diseases in the area of the injection site or joint.

5. WARNINGS:

- Do not use disinfectants containing quaternary ammonium salts for skin preparation prior to administration of SYNOTECH as hyaluronan can precipitate in their presence.
- Transient increases in inflammation following any intra-articular hyaluronan injection have been reported in some patients with inflammatory joint conditions.
- Intravascular injections of SYNOTECH may cause systemic adverse events.

6. PRECAUTIONS:

General

- Strict aseptic injection technique should be employed during the administration of SYNOTECH.
- The safety and effectiveness of the SYNOTECH in joints other than the knee have not been tested.
- The safety and effectiveness of repeat treatment cycles of SYNOTECH has not been established.
- The safety and effectiveness of the use of SYNOTECH concomitantly with other intra-articular (IA) injections have not been established.
- STERILE CONTENTS. The pre-filled syringes are intended for single-use only. The contents of the syringe are sterile and should be used immediately after opening. Discard any unused SYNOTECH. Do not re-sterilize.
- Do not use SYNOTECH if the package has been opened or damaged.
- SYNOTECH should be stored in its original packaging at room temperature (below 77°F/25°C). DO NOT FREEZE. Do not use after expiration date indicated on packaging. Shelf life is 48 months.
- It is recommended to remove joint effusion, if present, before injecting SYNOTECH.
- Only properly licensed medical professionals trained in accepted injection techniques for delivering agents into the knee joint should inject SYNOTECH for the indicated use.
- Transient pain or swelling may occur after the intra-articular injection.
- It is recommended that patients avoid strenuous or prolonged (i.e. more than one hour) physical activities within 48 hours following the intra-articular injections.

7. USE IN SPECIFIC POPULATIONS:

- Pregnancy: The safety and effectiveness of the use of SYNOTECH in pregnant women has not been tested.
- Nursing Mothers: It is not known if SYNOTECH

is excreted in human milk. The safety and effectiveness of the use of the product in lactating women has not been tested.
- Pediatrics: The safety and effectiveness of the use of SYNOTECH have not been tested in children (21 years of age or younger).

8. POTENTIAL ADVERSE EFFECTS OF THE DEVICE ON HEALTH:

Below is a list of the potential adverse effects (e.g., complications) associated with use of this device and, in general, associated with intra-articular injection devices for the treatment of pain in osteoarthritis of the knee:

- Infection, Arthralgia (Knee pain), Arthrosis, Joint (knee) disorder, Joint (knee) swelling, Joint (knee) effusion, Joint (knee) stiffness, Pain in Limb, Tendonitis, Paraesthesia, Phlebitis, Pruritus, Injection site erythema, Injection site edema, Injection site pain, Injection site reaction, Arthropathy, Bakers Cyst, Bursitis, Localized osteoarthritis, Aggravated osteoarthritis, Immune Response

Incidences of rash, headache, dizziness, chills, hives, nausea, muscle cramps, peripheral edema, and malaise have also been reported in association with intra-articular injections.

Reported device-related Adverse events

The most commonly reported adverse event associated with the intra-articular injection was arthralgia.

9. DETAILED DEVICE DESCRIPTION:

SYNOTECH is a proprietary high molecular weight (average molecular weight 1 800 000 daltons) hyaluronic acid (HA) based viscosupplementation intended for the treatment of pain in patients with osteoarthritis (OA) of the knee who have failed to respond to conservative non-pharmacological therapy and simple analgesics. The device is administered as a three-to-five weekly injection regimen under aseptic conditions.

SYNOTECH has a hyaluronan concentration of 20mg/mL, dissolved in physiologic saline. It is supplied in a 3.0mL syringe containing 2.0mL (40 mg) of SYNOTECH. The contents of the syringe are sterile and non-pyrogenic.

SYNOTECH is engineered by modification of hyaluronan (hyaluronic acid or 'HA') with proprietary process without chemical crosslinking and results in a highly viscoelastic hydrogel with increased lubricating and shock absorption properties. This results in a natural hyaluronan similar to the hyaluronan found in the synovial fluid present in the human joint. This Sodium Hyaluronate is derived from bacterial fermentation (Streptococcus equi).

10. HOW SUPPLIED:

SYNOTECH is supplied in a single-use 3.0 mL syringe containing 2.0mL dose of treatment to be injected in weekly intervals. Each syringe package is labelled SYNOTECH for ready identification. The contents of the syringe are sterile and non-pyrogenic. The syringe components contain no latex.

11. DIRECTIONS FOR USE:

SYNOTECH is intended to be injected into the knee joint as three to five intra-articular injection regimen. Standard intra-articular injection site preparation and strict aseptic administration technique must be followed.

1. Using an 18-20 gauge needle, it is recommended to remove synovial fluid or effusion before injecting SYNOTECH. Do not use the same syringe for removing synovial fluid and for injecting SYNOTECH.
2. Remove the protective rubber cap on the tip of the syringe and securely attach a needle (18-20 gauge) to the tip. Twist the tip cap before pulling it off, as this will minimize product leakage.
3. Do not overtighten or apply excessive leverage when attaching the needle or removing the needle guard, as this may break the tip.
4. Inject the full 2mL in one knee only (do not overfill the joint). If treatment is bilateral, a separate syringe should be used for each knee.
5. Administer the following injections of SYNOTECH in weekly intervals after the first injection following the same guidelines.

12. MANUFACTURED FOR:

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