For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory

Abridged Prescribing Information

Hylan Polymer A & B G-F 20 prefilled syringe -8mg/ml

SYNVISC - ONE®

COMPOSITION

Content per ml (hylan G-F 20):
Each 1 ml contains: hylan polymer 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.

THERAPEUTIC INDICATIONS

Hylan G-F 20 (Synvisc-One) is indicated:

For the treatment of pain in osteoarthritis of the knee in patients who have failed to respond adequately to conservative non pharmacologic therapy and to simple analgesics.
For the treatment to decrease pain and discomfort allowing more extensive movement of the Knee

DOSAGE AND ADMINISTRATION

Synvisc-One is administered as a single intra-articular injection. Remove synovial fluid or effusion before injecting hylan G-F 20.Strict aseptic administration technique must be followed. When using fluoroscopic guidance, ionic or non-ionic contrast agent may be utilized. No more than 1 ml of contrast agent should be used per 2 ml of hylan G-F 20. . The recommended treatment regimen is one injection in the one knee.

SAFETY-RELATED INFORMATION

Contraindications: Synvisc-One should not be used in patients with known hypersensitivity (allergy) to hyaluronan (sodium hyaluronate) preparations. Synvisc-One should not be injected into the joint if there is venous or lymphatic stasis in the limb to be injected. Synvisc-One should not be used in infected or severely inflamed joints or in patients having skin disease or infections in the area of the injection site.

Pregnancy and Lactation: The safety and effectiveness of Synvisc-One has not been established in pregnant women. It is not known if Synvisc-One is excreted in human milk. The safety and effectiveness of Synvisc-One have not been established in lactating women.

Warnings and Precautions: Do not inject Synvisc-One intravascularly. Intravascular injections may cause systemic adverse events. Do not inject Synvisc-One 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-One. 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. Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation because hyaluronan can precipitate in their presence. Remove any synovial fluid or effusion prior to injecting Synvisc-One.
As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities for approximately 48 hours following the intra-articular injection, and resume full activities within a few days. Synvisc-One have not been tested in pregnant women or children ≤ 21 year of age. Synvisc-One contains small amounts of avian protein and should not be used in patients with related hypersensitivities. Do not inject anesthetics or other medications into the knee joint during Synvisc therapy.

Adverse Reactions: Adverse events involving the injected joint that may occur after intra-articular injections of Synvisc-One are Transient pain, Transient swelling and/or Effusion. Hypersensitivity reactions including anaphylactic reaction, anaphylactoid reaction, anaphylactic shock and angioedema have been reported. Cases of acute inflammation, characterized by joint pain, swelling, effusion and sometimes joint warmth and/or stifness, have been reported following an intra-articular injection of Synvisc-One.

For full prescribing information please contact Sanofi Healthcare India Private Limited, Sanofi House, CT Survey No 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai 400072

Source: CCDS version 4 dated 16th Jun 2022

Updated: Jul 2023