

SportVis™

To relieve pain and optimise recovery of the ankle following first or second degree sprain.

To relieve chronic pain and disability of the elbow with lateral epicondylalgia.

Presentation :

SportVis™ is a clear solution of sterile 1% sodium hyaluronate in a phosphate buffered saline contained in a pre-filled syringe for :

- a series of two peri-articular injections into the soft tissue of the ankle; one peri-articular injection preferably within 48 hours of the injury and a second peri-articular injection 2 to 3 days following the first injection.
- a peri-articular injection in the elbow epicondyle followed by a second injection as may be required one week after the first injection.

Sodium hyaluronate is a long chain polysaccharide made up of repeating disaccharide units, which occurs naturally in the body.

SportVis™ has a pH and osmolality biocompatible with the soft tissue.

1.2ml of SportVis™, sterilised by filtration, is enclosed within a glass, ready to use, disposable syringe. The syringe is packed within a blister pack and an outer cardboard carton.

Dosage and Administration :

Peri-articular injection of SportVis™ should only be made by a Healthcare Professional trained in the technique.

The dosage regimen is :

- one peri-articular injection preferably within 48 hours of the first or second degree ankle sprain and a second injection 2 to 3 days following the first injection.
- one peri-articular injection at the lateral elbow epicondyle site followed by a second injection at the same site one week after the first injection.

The contents of the syringe are sterile and should be injected using a sterile needle of an appropriate size (27 gauge needle is recommended). The area to be treated should be disinfected before injection.

Ankle Sprains

Peri-articular injections should be delivered during a single penetration along the anterior talofibular ligament using clinical landmarks.

The injection is delivered along 3 planes from antero-posterior, medial and lateral to the proximal ligamentous landmark.

1.2ml of SportVis™ is injected preferably within 48 hours of the injury and a second injection of 1.2ml is given 2 to 3 days after the first injection.

Lateral Epicondylalgia

Peri-articular injections identify the tenderest point of the epicondyle by gentle palpation.

Insert the needle at 90 degrees to the point of maximal pain on the lateral epicondyle. After insertion to the epicondyle, angle the needle at 45 degrees (or thereabout) and inject half the contents as the needle is withdrawn to the skin (without exiting the skin).

Insert the needle to 45 degrees in the opposite direction to the epicondylar point of maximum pain and inject the remaining contents on withdrawing of the needle outward. The needle is removed from the skin. The elbow is flexed and extended five times and then internally and externally rotated five times.

Discard the syringe and needle after single use.

Uses :

SportVis™ is intended to relieve pain and optimise recovery of the ankle following first or second degree sprain.

SportVis™ is intended as well to relieve chronic pain and disability of the elbow after lateral epicondylalgia.

SportVis™ sodium hyaluronate augments the sodium hyaluronate naturally present in the soft tissue of the ankle joint or elbow tissue thereby providing the ideal environment for healing of the damaged tissue.

Contra-indications :

Patients with known sensitivity to sodium hyaluronate.

Warnings and Precautions :

SportVis™ should only be injected by a healthcare professional trained in the procedure.

SportVis™ pre-filled syringes are single use. The contents of the syringe should be used for one injection only. Any remaining sodium hyaluronate should be discarded. If a syringe is retained for a subsequent injection there is a risk of contamination resulting in the possible infection of the patient and/or foreign body reaction.

SportVis™ must not be injected into blood vessels because sodium hyaluronate has the potential to occlude the vessels, which could result in embolism or infarction.

Do not inject into the soft tissue of patients if the area of the injection site is inflamed, infected or where there is evidence of acute or chronic skin disease.

Sodium hyaluronate is manufactured by fermentation of *Streptococcus Equi* and rigorously purified. However, the healthcare professional should consider the immunological and other potential risks that can be associated with the injection of any biological material.

There is a risk of infection at the injection site as with any peri-articular procedure.

There is no evidence of the safety of SportVis™ in human pregnancy and lactation. Administration during pregnancy and lactation is at the discretion of the healthcare professional.

The safety and effectiveness of SportVis™ has not been tested for children. Administration to children below 18 is at the discretion of the healthcare professional.

SportVis™ should not be injected into a haematoma. Needles should not be reused because SportVis™ may become turbid due to precipitation in the presence of cationic agents such as benzalkonium chloride or detergents residual in the needle following re-sterilisation.

Follow national or local guidelines for the safe use and disposal of needles. Obtain prompt medical attention if injury occurs.

Do not use if packaging has been damaged.

Adverse Reactions :

Mild erythema that should resolve with time.

Incompatibilities :

SportVis™ has not been tested for compatibility with other substances for peri-articular injection. Therefore the mixing or simultaneous administration with other peri-articular injectables is not recommended.

Storage :

Store between 2°C and 25°C. Do not freeze. Protect from light. Do not use if sterile packaging has been damaged. Sterile product for single use only. Do not use after expiry date.

Manufacturer : Hyaltech Ltd