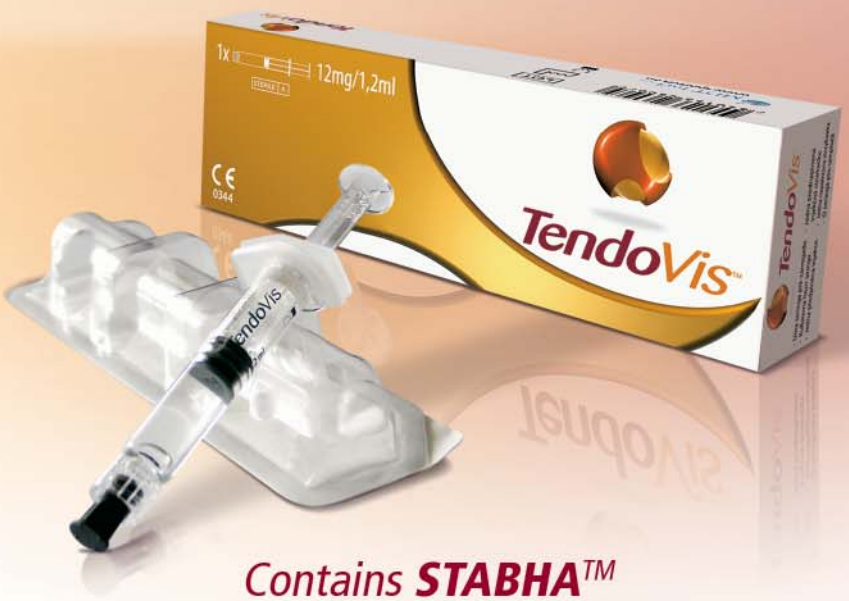
TendoVis™

Keeping active people active

Designed for soft tissue injuries



*Contains **STABHA**™*

***S**oft **T**issue **A**dapted **B**iocompatible **H**yaluronic **A**cid*

TendoVis™

Keeping active people active

TO RELIEVE PAIN AND PROMOTE FUNCTION IN DAMAGED TENDONS AND LIGAMENTS.

> Presentation

TendoVis™ is a clear solution of sterile 1% sodium hyaluronate in a phosphate buffered saline contained in a pre-filled syringe for peri-articular injection into the soft tissue surrounding tendons and ligaments.
Sodium hyaluronate is a long chain polysaccharide made up of repeating disaccharide units, which occurs naturally in the body. ***TendoVis***™ has a pH and osmolality biocompatible with the soft tissue.
1.2ml of ***TendoVis***™, 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.

> Uses

TendoVis™ is intended to relieve pain and optimise recovery of tendons and ligaments damaged by acute or chronic injury.
TendoVis™ sodium hyaluronate augments the sodium hyaluronate naturally present in the soft tissue surrounding damaged tendons and ligaments and provides support, lubrication and hydration to the affected site thereby providing the ideal environment for healing of the damaged tissue.
TendoVis™ has been demonstrated to relieve pain and optimise recovery in the ankle following first or second degree sprain, to relieve chronic pain and disability of the elbow with lateral epicondylalgia and to relieve pain in patients with symptomatic rotator cuff tendinopathy.

> Contra-indications

Patients with known sensitivity to sodium hyaluronate.

> Dosage and Administration

Peri-articular injection of ***TendoVis***™ should only be made by a Healthcare Professional trained in the specific peri-articular injection technique.
The contents of the syringe are sterile and should be injected using a sterile needle of an appropriate size for the injection site.
The area to be treated should be disinfected before injection.
Discard the syringe and needle after single use.

> Ankle Sprains

One 1.2ml peri-articular injection of ***TendoVis***™ preferably within 48 hours of the first or second degree ankle sprain and a second injection 2 to 3 days following the first injection, 27 gauge needle is recommended. 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.

> Lateral Epicondylalgia

One 1.2ml peri-articular injection of ***TendoVis***™ at the lateral elbow epicondyle site followed by a second injection at the same site one week after the first injection, 27 gauge needle is recommended.
Identify the tenderest point of the epicondyle by gentle palpation.
Position the needle at 45 degrees to the point of maximal pain of the lateral epicondyle. After puncture of the skin, angle the needle parallel to the skin and insert it towards the point of maximal pain on the lateral epicondyle. Inject half the contents as the needle is with drawn to the skin without exiting the skin.
Rotate the needle 180 degrees (opposite direction) and insert the needle parallel to the skin towards the point of maximal pain on the lateral epicondyle. Inject the remaining contents on withdrawing of needle. Remove the needle from the skin.
Flex and extend the elbow five times and then internally and externally rotate five times.

> Rotator Cuff Tendinopathy

One 1.2ml peri-articular injection of ***TendoVis***™ into the subacromial space of the shoulder just above the tendon followed by a second peri-articular injection after 14 days, 22 gauge needle is recommended. Seat the patient in an upright position, arm relaxed at the side and externally rotated. Use of an ultrasound probe positioned on the lateral shoulder directed in the plane of the supraspinatus tendon to guide the injection is recommended.
Locate the acromion, greater tubercle, head of the humerus and subacromial cleft. Introduce the needle into the cleft 1cm posterior and 2cm distal to the antereo-lateral acromial edge. Advance the needle horizontally and in a partly medial direction under the acromion process. When no resistance to the plunger is felt inject ***TendoVis***™ over the head of the humerus into the subacromial space taking great care not inject into the tendon.

> Warnings and Precautions

TendoVis™ should only be injected by a Healthcare Professional trained in the procedure. ***TendoVis***™ 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. ***TendoVis***™ should not be re-sterilised as the device performance may be compromised which could cause serious harm to the patient's health and safety. ***TendoVis***™ must not be injected into blood vessels because sodium hyaluronate has the potential to occlude the vessels, which could result in embolism or infarction. ***TendoVis***™ should not be injected into a haematoma. Direct injection into tendons should be avoided as this can lead to rupture. Use of an ultrasound probe to guide the injection will minimise this risk. Do not inject into the soft tissue of patients if the area of the injection site is 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 ***TendoVis***™ in human pregnancy and lactation. The safety and effectiveness of ***TendoVis***™ has not been tested for children below 18. 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. Do not use after the expiry date.

> Adverse Reactions

Mild erythema that should resolve with time.

> Incompatibilities

TendoVis™ 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. Do not use after expiry date.

MDT Int'l s.a.