OSTENIL® TENDON

Restore Tendon Function

TRB CHEMEDICA (UK) LTD

OSTENIL® TENDON
an innovative approach in the treatment of painful tendinopathy

OSTENIL® TENDON was developed to treat pain and restricted mobility in tendon disorders caused, for example, by overuse or inappropriate biomechanical stress.

It is a conservative treatment based on the biomechanical properties of hyaluronic acid (HA) on the tendons and surrounding structures.

OSTENIL® TENDON CHARACTERISTICS:

2 ml pre-filled syringe for single use	For peritendinous or intrasheath injection
Hyaluronic acid 2% (40 mg/2 ml)	High concentration for prolonged activity
HA obtained from bacterial fermentation	Highly purified, natural, non-chemically modified HA No avian proteins
Mannitol 0.5% (10 mg/2 ml)	Antioxidant effect Protects HA from degradation by free radicals[1]
Syringe equipped with a Luer-Lok™ cap	Safe needle attachment
Terminal sterilization by moist heat	Sterile syringe in the blister to facilitate aseptic use

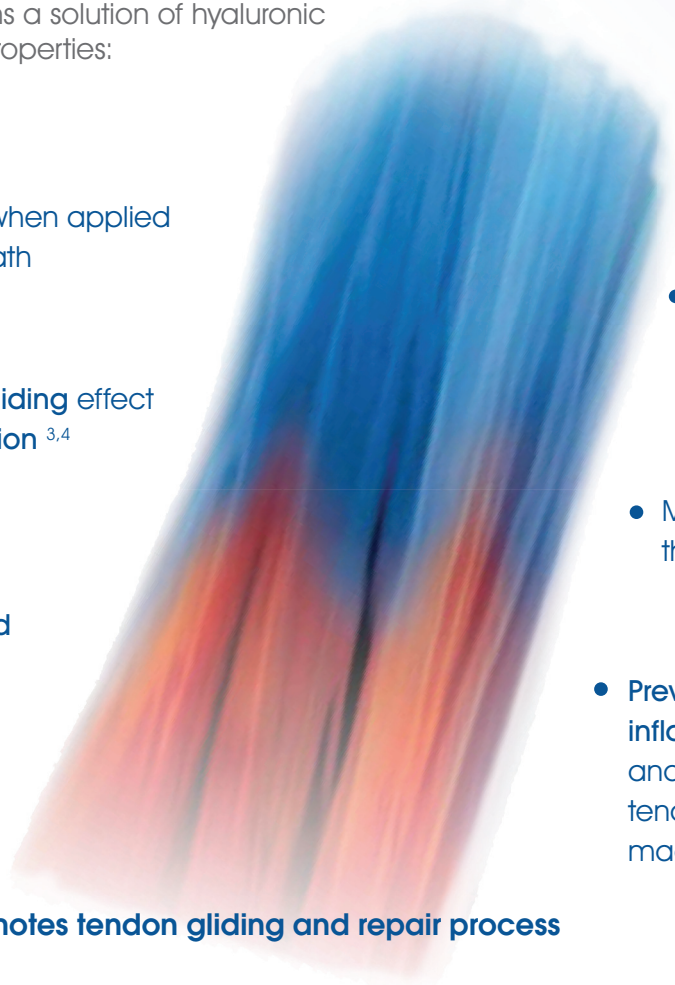
OSTENIL® TENDON is designed for optimum efficacy and safety in the treatment of tendon disorders

1.Mendoza G et al. Carbohydr Res 2007;342:96-102

OSTENIL® TENDON helps to maintain tendon biomechanical properties

OSTENIL® TENDON contains a solution of hyaluronic acid which has unique properties:

- Acts as a **lubricant** when applied into the tendon sheath or peritendinously [2]
- Enhances **tendon gliding** effect and **reduces adhesion** [3,4]
- Promotes **tendon recovery** and **wound healing process** [5,6]



- Acts as a **transport medium** for nutrients to reach the avascular portions of the tendon [7]
- Masks the nociceptors and thus provides **pain relief** [8,9]
- **Prevents the free passage of inflammatory cells** [10,11] and molecules through the tendon sheath due to its macromolecular meshwork

OSTENIL® TENDON promotes tendon gliding and repair process

2. Akasaka T et al. Clin Biomech 2006;21:810–5
3. Kumar N et al. Trends Biomater. Artif. Organs 2009;23(1):34-45
4. St Onge R et al. Clin Orthop Relat Res 1980;146:269-75
5. Chen WY, Abatangelo G. Wound Repair Regen 1999;7:79–89
6. Yagishita K et al. Arthroscopy 2005;21:1330–6.
7. Hagberg L et al. J Hand Surg [Br] 1992;17(B):167-71.
8. Gotoh S et al. Ann Rheum Dis 1993;52:817–22
9. Balazs EA. Cells Tissues Organs 2003;174:49–62
10. Gaughan EM et al. Am J Vet Res 1991;52(5):764–72
11. Amiel D et al. J Hand Surg 1989;14A:837–43

OSTENIL® TENDON

Rapid symptom relief in painful tendinopathy

A total of 35 patients suffering from Achilles mid-portion tendinopathy, lateral epicondylitis or peroneal tendinopathy for at least 6 weeks, received 2 injections of OSTENIL® TENDON with an interval of 1 week between injections. [12]

Rapid pain relief

The decrease in pain was rapid and was maintained until the end of the study, 3 months after the end of treatment ($p<0.0001$). *(Fig. 1)*

Patient satisfaction boosted by return to normal activities

The patient questionnaire showed significant improvements in 'activities of daily life', 'leisure activities' ($p<0.0001$) and also in 'ability to work' ($p<0.0018$) after the first injection which persisted until the end of the study. [12]

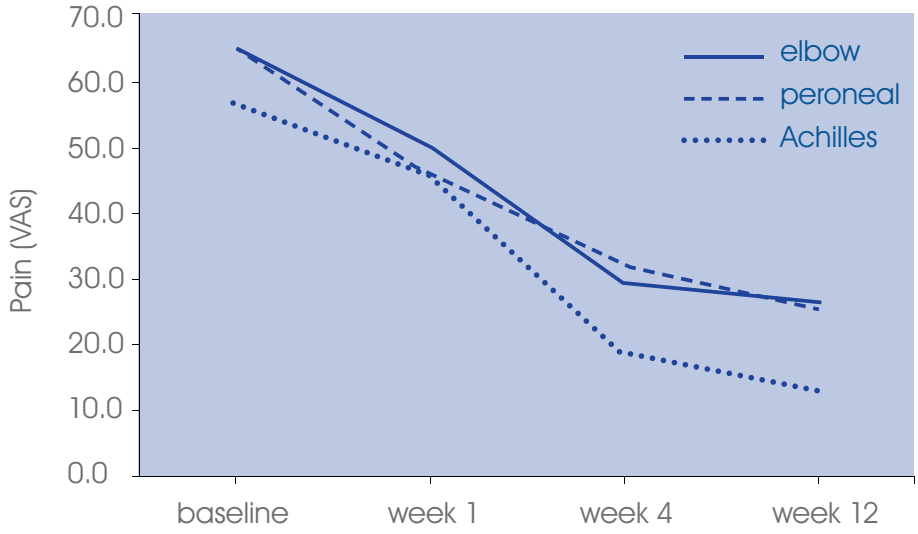


Fig. 1

After 2 injections of OSTENIL® TENDON, pain relief was significant and maintained for 3 months (end of study).

12 TRB Chemedica data on file

Sustained relief of pain with increased functionality of the shoulder

23 patients with symptomatic shoulder peri-arthritis and sono-graphically confirmed partial thickness tears of the Supraspinatus Tendon (SSP), were treated with an image guided injection of OSTENIL® TENDON to the affected area. The same procedure was repeated one week later. VAS Scores and the Shoulder Function Assessment (SFA) scale (0-70) were evaluated at each visit - baseline (first injection), at week two (second injection), and two months after baseline evaluation.

Results

Pain (VAS) during active movement was significantly reduced from baseline values following the first injection (29%), with a further significant reduction in pain at 2 months follow-up. (84%) *(Fig.2)*
The SFA index had a statistically significant improvement for all criteria, from 31 at baseline to 64 at 2 months follow-up. *(Fig.4)*
78% (n=18) of patients had a complete recovery or improved structure of the SSP which was US demonstrated. *(Fig. 3)*
No adverse events were reported. No subjects withdrew from the study during the treatment phase.[13]

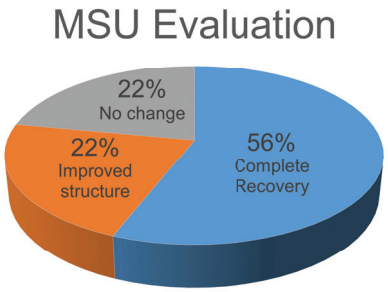


Fig. 3

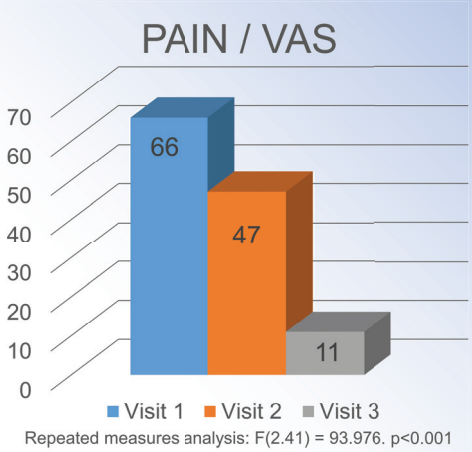


Fig. 2

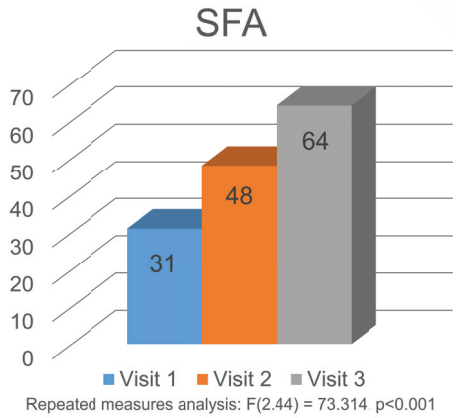


Fig. 4

13 Nestorova et al. WCO-IOF-ESCEO 2014 Seville, Spain, P289

Which pathologies can be treated with OSTENIL® TENDON ?

Many tendinopathies can be treated with OSTENIL® TENDON, including:

- **SHOULDER** — Rotator cuff (supraspinatus) tendinopathy; Bicipital tendinopathy
- **ELBOW** — Lateral epicondylalgia; Medial epicondylalgia
- **KNEE** — Patellar tendinopathy
- **ANKLE and FOOT** — Achilles tendinopathy; Posterior tibial tendinopathy; Peroneal tendinopathy

Why 2% hyaluronic acid ?

Administration of HA with a high molecular weight at high concentration results in a higher concentration of HA in the sheath fluid or around the tendon for a longer period of time. A 2% HA concentration will result in less new extracellular matrix formation and hence less adhesion. [4,14]

How to inject OSTENIL® TENDON

OSTENIL® TENDON is injected into the tendon sheath (intrasheath injection) or around the affected tendon (peritendinous injection) using a suitable needle (e.g. 25-27 G). Injection should be made at the site of most intense pain. Ultrasound guidance is recommended during injection.

Intrasheath injection:
In tendons with a sheath, inject OSTENIL® TENDON into the tendon sheath in the affected area.

Peritendinous injection:
In tendons without a sheath, inject the solution along the tendon, but not in the tendon.

14. Hagberg L et al. J Orthop Res 1991;9(6):792-7

INSTRUCTIONS FOR USE

OSTENIL ® TENDON

Sodium hyaluronate from fermentation 2.0 %.
Viscoelastic solution for peritendinous or intrasheath injection. Sterile by moist heat.

Composition:

1 ml isotonic solution contains 20.0 mg sodium hyaluronate and sodium chloride, disodium phosphate, sodium dihydrogen phosphate, mannitol and water for injections.

Indications:

For the treatment of pain and restricted mobility in tendon disorders.

Contra-indications:

OSTENIL® TENDON should not be used in patients with ascertained hypersensitivity to any of its constituents.

Interactions:

No information on the incompatibility of OSTENIL® TENDON with other medications administered to tendons is available to date.

Undesirable effects:

Local secondary phenomena such as pain, feeling of heat, bruising, redness and swelling may occur following treatment with OSTENIL® TENDON.

Dosage and administration:

Inject OSTENIL® TENDON around the affected tendon or into the affected tendon sheath once a week for a total of 2 injections. Several tendons may be treated at the same time. Repeat treatments may be administered as required.

The content and outer surface of the OSTENIL® TENDON pre-filled syringe are sterile as long as the sterile pack remains unbroken. Take the pre-filled syringe out of the sterile pack, unscrew the Luer-Lok™ cap, attach a suitable needle (for example 25 to 27 G) and secure by turning slightly. Remove any air bubble, if present, before injection.

Precautions:

Caution should be exercised in patients with known hypersensitivity to medicinal products. The general precautions for peritendinous and intrasheath injections should be observed. OSTENIL® TENDON should be instilled accurately into the tendon sheath or around the affected tendon, if necessary under imaging control. Avoid nerve lesions and injections into blood vessels! As no clinical evidence is available on the use of sodium hyaluronate in children, pregnant and lactating women, treatment with OSTENIL® TENDON is not recommended in these cases. Do not use if the pre-filled syringe or the sterile blister are damaged. Any solution not used immediately after opening must be discarded. Otherwise the sterility is no longer guaranteed. Store between 2 °C and 25 °C! Do not use after the expiry date indicated on the box! Keep out of the reach of children!

Characteristics and mode of action:

A tendon is a strong structure of fibrous connective tissue designed to transmit forces from muscle to bone and resist load during muscle contraction. Tendons may be surrounded by different structures: fibrous bands, synovial sheaths, peritendon sheaths, tendon bursae. Overuse or inappropriate biomechanical stress may cause inflammation and/or degenerative changes of the tendon, leading to pain and loss of function. Lubricating the tendon could reduce pain, improve tendon function and reduce the potential for adhesions.

Because of its lubricating and viscoelastic properties OSTENIL® TENDON promotes tendon gliding and the physiological repair process. In addition, due to its macromolecular meshwork OSTENIL® TENDON reduces the free passage of inflammatory cells and molecules.

OSTENIL® TENDON is a transparent solution of natural and highly purified sodium hyaluronate obtained by fermentation and is devoid of animal protein. OSTENIL® TENDON also contains mannitol, a free radical scavenger, which helps to stabilise the chains of sodium hyaluronate. In biocompatibility studies OSTENIL® TENDON was found to be particularly safe.

Presentation:

One pre-filled syringe of 40 mg/2.0 ml OSTENIL® TENDON in a sterile pack.

OSTENIL® TENDON is a medical device.
To be used by a physician only.

Last revision date: November 2011

TRB CHEMEDICA AG
Richard-Reitzner-Allee 1
85540 Haar/München, Germany

OSTENIL® TENDON

OSTENIL® TENDON

Restore Tendon Function

TRB CHEMEDICA (UK) LTD

TRB CHEMEDICA (UK) LTD
9 Evolution - Lymedale Business Park
Hooters Hall Road - Newcastle-under-Lyme
Staffordshire - ST5 9QF
Tel. 0845 330 7556 - Fax 0845 330 7557
email: info@trbchemedica.co.uk
www.trbchemedica.co.uk