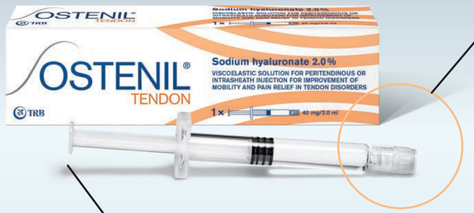
Composition



OSTENIL® Tendon
is provided as a pre-filled syringe containing 2 mL 2% sodium hyaluronate solution.

2 mL isotonic solution
contains **40 mg sodium hyaluronate** and sodium chloride, disodium phosphate, sodium dihydrogen phosphate, mannitol and water for injections.

Dosage and **administration**

- **OSTENIL® Tendon** can be administered into the tendon sheath (intrasheath injection) or around the affected tendon (peritendinous injection) using a suitable needle (e.g. 25-27 G).
- Inject OSTENIL® Tendon 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.
- Ultrasound guidance is highly recommended during injection.

*Scan here to see how **OSTENIL® Tendon** is administered*

COMPOSITION
40 mg sodium hyaluronate, sodium chloride, disodium phosphate, sodium dihydrogen phosphate, mannitol, water for injections, in a 2 mL syringe.

INDICATION
For the treatment of pain and restricted mobility in tendons with or without tendon sheath, like Achilles, epicondylus humeri, supraspinatus, patella, peroneal, biceps brachii tendons, as well as the illiotibial band.

CONTRA-INDICATIONS
OSTENIL® Tendon should not be used in patients with ascertained hypersensitivity to one of its constituents.

UNDESIRABLE EFFECTS
In very rare cases, local secondary phenomena such as discomfort, pain, feeling of heat, itching, bruising, redness and swelling may occur following treatment with OSTENIL® Tendon. As with all invasive treatments, in very rare cases an infection may occur.

PRECAUTIONS
The treatment with OSTENIL® Tendon is not recommended in children, pregnant and lactating women or in acute traumas. The general precautions for peritendinous and intrasheath injections must be observed, this includes thorough disinfection of the injection site and other measures to avoid infections. 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. Do not use if the pre-filled syringe or the sterile blister are damaged. Any solution not used immediately after opening must be discarded. Store between 2 °C and 25 °C in a dry place, protected from light. OSTENIL® Tendon is a medical device. To be used by a physician experienced and trained in peritendinous and intrasheath injections only.

References

1. Abate M, Schiavone C, Salini V. The use of hyaluronic acid after tendon surgery and in tendinopathies. *Biomed Res Int*. 2014;2014:783632.
2. Lynen N. [Treatment of chronic tendinopathies with peritendinous hyaluronan injections under sonographic guidance - an interventional, prospective, single-arm multicenter study]. *OUP*. 2012;1(10):1-11. German.
3. Lynen N, De Vroey T, Spiegel I, Van Ongeval F, Hendrickx NJ, Stassijns G. Comparison of peritendinous hyaluronan injections versus extracorporeal shock wave therapy in the treatment of painful Achilles' tendinopathy: a randomized clinical efficacy and safety study. *Arch Phys Med Rehabil*. 2017;98(1):64-71.
4. Gorelick L, Rozano-Gorelick A, Saab A, Ram E. Single hyaluronate injection in the management of insertional Achilles tendinopathy in comparison to corticosteroid injections and non-invasive conservative treatments. *Scholars Bull*. 2015;1(1):16-20.
5. Flores C, Balius R, Alvarez G, Buil MA, Varela L, Cano C, et al. Efficacy and tolerability of peritendinous hyaluronic acid in patients with supraspinatus tendinopathy: a multicenter, randomized, controlled trial. *Sports Med Open*. 2017;3(1):22.
6. Understanding Post-Injection Inflammation. Accessed January 27, 2023. https://myhealth.ucsd.edu/Search/3,90744

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OSTENIL® TENDON
Sodium Hyaluronate 2%

GET BACK IN THE GAME. NOW.

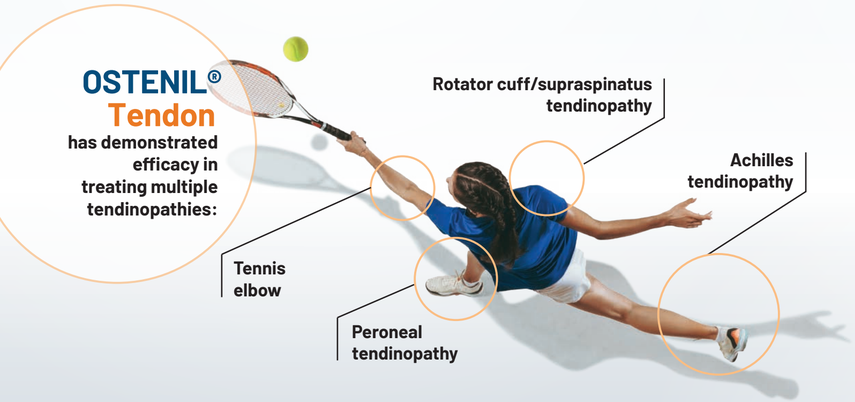
FOR THE TREATMENT OF PAIN AND RESTRICTED MOBILITY IN TENDON DISORDERS.

Medical Devices Regulation MDR APPROVED

Accelerate tendinopathy recovery with **OSTENIL® Tendon**

Tendinopathy is characterised by inflammation and degeneration of the tendon, resulting in pain and reduced mobility. Tendinopathies are the most frequent tendon disorders and occur due to overuse or strain of the tendon. Athletes and people who engage in repetitive motions in their jobs are at higher risk of developing tendinopathy.

Preclinical studies demonstrate that **hyaluronic acid (HA)** positively impacts cell turnover and collagen deposition to aid tendon repair. Additionally, it can reduce scar formation following tendon repair, promote tissue healing, improve tendon gliding, and reduce the likelihood of tendon adhesion to the surrounding tissue.[1]



How **OSTENIL® Tendon** works:

OSTENIL® Tendon is a pharmaceutical grade 2% sodium hyaluronate solution indicated for the treatment of pain and restricted mobility in tendons with or without a tendon sheath.

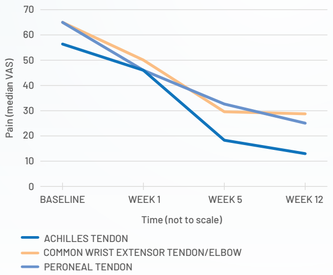
OSTENIL® Tendon injection around the tendon is an effective first line option as a monotherapy or in combination with physical therapy and/or painkillers.

OSTENIL® Tendon contains sodium hyaluronate, the sodium salt form of HA. Sodium hyaluronate is highly soluble in water and has a physiological pH.

Clinical data

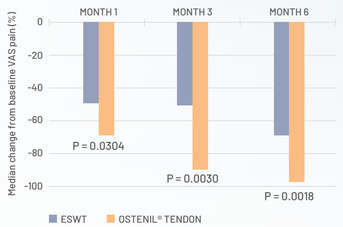
OSTENIL® Tendon reduces pain, improves long-term function and helps patients return faster to their pre-injury activity

Rapid, sustained pain relief in different tendinopathies



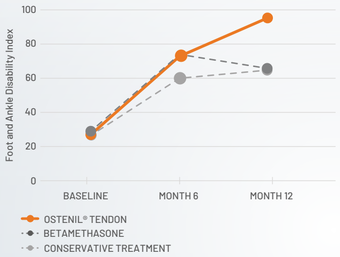
OSTENIL® Tendon significantly relieved tendinopathic pain, as measured on the visual analog scale (VAS), in the Achilles tendon (n=19), the common wrist extensor tendon (n=14), and the peroneal tendon (n=2; $p < 0.0001$ at weeks 5 and 12 compared with baseline).[2]

Superior pain relief to extracorporeal shock wave therapy



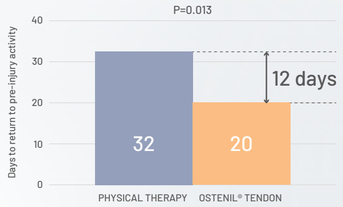
OSTENIL® Tendon significantly reduced pain for up to six months (n=29), providing superior pain relief compared with extracorporeal shock wave therapy (ESWT, n=30).[3]

Improved long-term tendon function compared with corticosteroid treatment



OSTENIL® Tendon injection improved the functional activity of the Achilles tendon for up to 12 months after treatment. Patients treated with OSTENIL® Tendon see progressive functional improvements, whereas corticosteroid treatment is associated with worsening function after 6 months.[4]

37.5% faster return to pre-injury activity compared with physiotherapy alone



OSTENIL® Tendon in combination with physical therapy enabled patients to return to work or sport after just 20 days (n=39), compared with a recovery period of 32 days for those only receiving physical therapy (n=41).[5]

Safety

No known interactions or contraindications. **OSTENIL® Tendon** can be safely used alongside other therapies and treatments.

OSTENIL® Tendon has an excellent safety profile. In very rare cases (less than 1 in 10,000) local secondary phenomena such as discomfort, pain, feeling of heat, itching, bruising, redness, and swelling may occur following treatment with **OSTENIL® Tendon**.* As with all invasive treatments, in very rare cases an infection may occur.

The biofermentation-derived hyaluronic acid in **OSTENIL® Tendon** is identical to endogenous hyaluronic acid. The product is free from animal proteins, minimising the risk of allergic reaction.

** Secondary phenomena such as discomfort, pain, feeling of heat, itching, bruising, redness and swelling are commonly observed injection-site reactions .*[6]

FREE FROM PROHIBITED SUBSTANCES

OSTENIL® Tendon conforms to the World Anti-Doping Agency in-competition rules and is free from prohibited substances. **OSTENIL® Tendon** can be used in and out of competition without the requirement for a therapeutic use exemption.

MADE IN SWITZERLAND

With 25 years of experience producing injectables, our manufacturing processes are compliant to the highest possible pharmaceutical standards globally. We are constantly reviewing and improving our quality standards to stay ahead of regulatory changes and to guarantee that our products meet the highest safety standards. **Manufactured in Vouvry, Valais, Switzerland.**

MDR APPROVED

The European Union Medical Devices Regulation (MDR) was established to ensure a high standard of safety and quality of medical devices. **OSTENIL® Tendon** has successfully passed the EU MDR review and clearance process and is available for use in the EU market.