OSTENIL® TENDON

Product characteristics

HIGH CONCENTRATION	FREE OF ANIMAL PROTEINS	PHYSIOLOGICAL
2.0 % sodium hyaluronate (40 mg/2 ml)	Sodium hyaluronate obtained by biofermentation	Isotonic solution with a physiological pH
READY-TO-USE	**SAFE NEEDLE ATTACHMENT**	**FACILITATION OF ASEPTIC USE**
2 ml pre-filled syringe	Latex-free syringe equipped with a Luer lock	Sterile in the blister

The advantages of Ostenil Tendon

- Is a conservative treatment based on the viscoelastic properties of hyaluronic acid[6]
- Is superior to extracorporeal shock wave therapy,[4] one of the most frequently used treatments for tendinopathy
- Is an alternative to corticosteroid injection[5]

OSTENIL® TENDON

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2. Nestorova R, Todorov P, Petranova T, Kolarov Z. Effectiveness of hyaluronic acid «Ostenil Tendon» in partial thickness rotator cuff tears of the shoulder. Osteoporos Int. 2016;27(Suppl 1):179. Abstract No.: P299.
3. 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.
4. 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.
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7. 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.

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OSTENIL® TENDON

Sodium Hyaluronate 2.0 %

RELIEVE PAINFUL TENDINOPATHIES

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Our solution for the treatment of tendinopathies

Tendinopathies are the most common tendon disorder mainly caused by overuse or inappropriate loading of tendons. The resulting inflammation and/or degenerative changes can lead to pain and loss of function.

Ostenil Tendon has been developed for the treatment of pain and restricted mobility in tendon disorders.

Based on the biomechanical properties of hyaluronic acid, Ostenil Tendon has demonstrated efficacy and safety in treating rotator cuff/supraspinatus tendinopathy,[1,2] Achilles tendinopathy,[3,4] tennis elbow,[3,5] and peroneal tendinopathy[3].

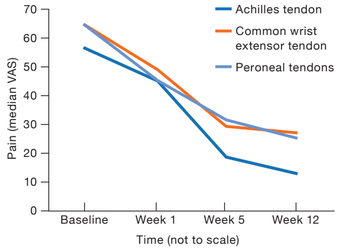
How to inject Ostenil Tendon

Ostenil Tendon should be injected into the tendon sheath (intrasheath injection) or around the affected tendon (peritendinous injection) using a suitable needle (e.g., 25–27 G). The injection should be performed at the site of most intense pain. Ultrasound guidance is highly recommended during injection.

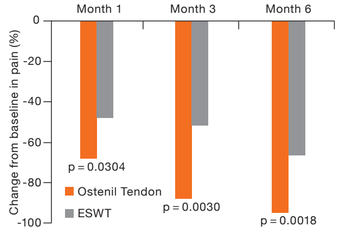
It is recommended to administer Ostenil Tendon once a week for a total of two injections. Several tendons can be treated at the same time and the treatment cycle can be repeated as required.

Proven efficacy and safety for patients

RAPID AND SUSTAINED PAIN RELIEF [1-3]

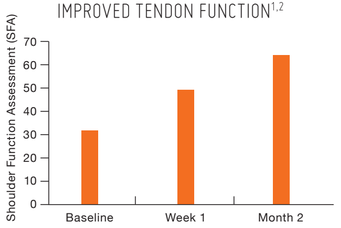


Two injections of Ostenil Tendon significantly relieved tendinopathic pain ($p < 0.0001$ at Weeks 5 and 12 compared with baseline).[3]



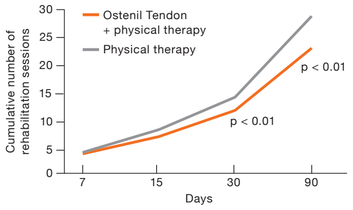
Ostenil Tendon significantly reduced pain for up to six months, and was superior to extracorporeal shock wave therapy (ESWT).[4]

IMPROVED TENDON FUNCTION[1,2]



Ostenil Tendon significantly improved the functional activity of the shoulder at two months after the initiation of treatment ($p < 0.001$).[1]

QUICK REHABILITATION[7]



The cumulative number of rehabilitation sessions was significantly lower for patients treated with physical therapy in combination with Ostenil Tendon injections than for those treated with physical therapy alone ($p < 0.01$ after 90 days of follow-up).[7]

GOOD TOLERABILITY[3,4,7]

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 one 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-Lock 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. As with all invasive treatments in very rare cases an infection may occur. Hence, 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 OSTENIL® TENDON in children, pregnant and lactating women as well as in acute traumas, the 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 and this may be associated with a risk of infection. 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: 2017-03.

The text of this information may vary depending on the country where the product is authorised. In this case, the national authorisation prevails.