NEW

OSTENIL® TENDON

Sodium Hyaluronate 2%

Restore Tendon Function

- Viscoelastic solution for peritendinous or intrasheath injection
- Reduce pain and improve tendon mobility in painful tendinopathy
- Enhance tendon gliding and prevent formation of adhesions

TRB CHEMEDICA (UK) LTD

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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-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 clinician only.

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