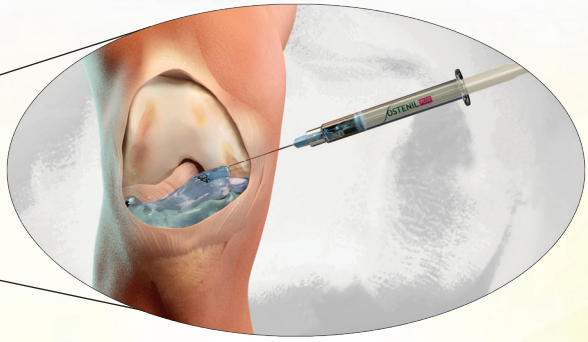
OSTENIL® Range

Reduces Pain
Improves Function



TRB

TRB Chemedica (UK) Ltd

OSTENIL® PLUS:

Simple, safe, effective joint therapy

- HA obtained from bacterial fermentation
- HA 2% (40mg/2ml)
- Molecular weight: 1-2 million Daltons
- Mannitol 0.5% (10mg/2ml)
- 2ml pre-filled syringe
- Terminal sterilisation for optimal safety: the contents and the outer surface of the syringe are sterile.

- **Mannitol-stabilised HA. Mannitol acts as a free radical scavenger which protects HA from rapid depolymerisation.** [1]
- **Sustained efficacy with a single injection offers statistically significant functional improvement.** [2]
- **One injection of OSTENIL® PLUS reduces pain and improves function in knee OA for at least 6 months.** [2]

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

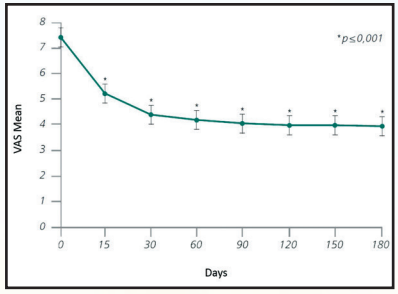
(2) Borràs Verdera A et al. Poster presented at the XXV triennial world congress of the International Society of Orthopaedic and Traumatology. September 6-9, 2011.

OSTENIL® PLUS

OSTENIL® PLUS:

Single intra-articular injection for patient comfort & convenience

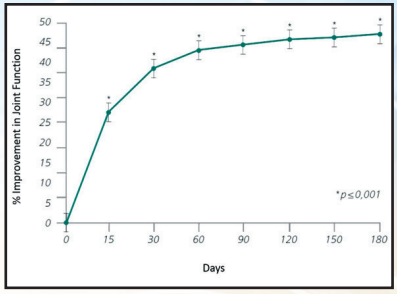
Mean Pain score (VAS)



- Statistically significant reduction (p<0.001) of **joint pain** (VAS).
- **Joint pain** improved by 40.7% on day 30, reaching 46.5% on day 180.

Fig.1
**p<0,001, pairwise comparisons referred to the first visit values (Bonferroni method).*

% Improvement in Joint Function (WOMAC)



- **Joint function** improved by 38.7% (WOMAC) on day 30, reaching 47.5% on day 180

Fig.2
**p<0,001, pairwise comparisons referred to the first visit values (Bonferroni method).*

Clinical trial data [2] demonstrates:

- **Mean scores on all measures reveal a statistically significant improvement within the first 15 days of treatment with OSTENIL® PLUS (Fig.1).**
- **Symptomatic control following a single IA injection of OSTENIL® PLUS persists for at least 6 months.**
- **Treatment was safe and well tolerated. Patient evaluation of treatment: good or very good throughout the study.**

Conclusions

A single intra-articular injection of OSTENIL® PLUS offers statistically significant therapeutic benefit in the treatment of knee osteoarthritis in terms of efficacy, tolerability and convenience.

OSTENIL® PLUS

OSTENIL® PLUS:

Non-inferior to high molecular weight product but at reduced cost

Efficacy of single intra-articular injection of OSTENIL® PLUS is non-inferior to chemically crosslinked Hylan G-F 20 in the treatment of painful tibofemoral osteoarthritis. [3]

Conclusion

This multicentre clinical trial demonstrated no statistically significant difference between one intra-articular injection of 2ml OSTENIL® PLUS compared with 6ml of Hylan on the primary measure of efficiency. Both preparations reduced pain and improved function in patients with painful tibiofemoral OA over 6 months.

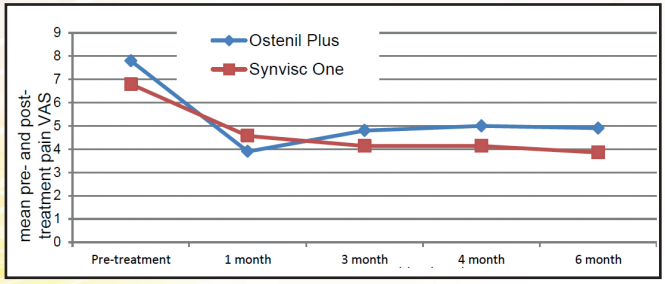


Fig.3

Efficacy of two hyaluronic acid preparations in patients with refractory knee Osteoarthritis. [4]

Conclusions

- Both Synvisc-One ™ and OSTENIL® PLUS significantly improved VAS pain scores for up to 6 months (Fig.3) with no significant statistical difference between the two preparations.
- However, a single injection of OSTENIL® PLUS offers a less expensive but equally effective treatment option.

(3) Maheu E, Avauac B, Dreiser RL, Bardin T (2019) PLoS ONE 14(12): e0226007.
(4) Shaikh M, Reddy V, Pyne D (2015). Rheumatology. 54 i96-i197. 10.1093/rheumatology/kev091.070.

OSTENIL® PLUS

OSTENIL®

Designed for long-term relief in OA

- HA obtained from bacterial fermentation
- HA 1% (20mg/2ml)
- Molecular weight: 1-2 million Daltons
- 2ml pre-filled syringe
- Terminal sterilisation for optimal safety: the contents and the outer surface of the syringe are sterile.

- **Treatment cycle of 3-5 weekly injections into large joints.**
- **OSTENIL® provides long-lasting pain relief and improves function in knee OA patients with excellent tolerability. [5]**
- **12 months effective pain relief for patients suffering from hip OA. [6]**
- **Among patients with advanced OA of the shoulder who either refused or were considered medically unfit for shoulder replacement surgery, OSTENIL® was associated with reduced pain and improved function. [7]**

(5) Möller I et al. Presented at the 6th World Conference of the Osteoarthritis Research Society International 2001; poster PB22
(6) Tsvetkova E et al. Ann Rheum Dis 2010; 69(Suppl3): 281
(7) Funk L et al. Presented at the 9th World Conference of the Osteoarthritis Research Society International 2004; poster P338

OSTENIL®

OSTENIL® TENDON:
Reduce tendon pain

- HA obtained from bacterial fermentation
- HA 2% (40mg/2ml)
- Molecular weight: 1-2 million Daltons
- Mannitol 0.5% (10mg/2ml)
- 2ml pre-filled syringe
- Terminal sterilisation for optimal safety: the contents and the outer surface of the syringe are sterile.

- **Viscoelastic solution for peritendinous or intrasheath injection**
- **Enhances tendon gliding and prevents formation of adhesions**
- **Significantly reduces pain in Achilles, peroneal, and common wrist extensor tendons [8], and improves shoulder function. [9]**

(8) N. Lynen, Treatment of chronic tendinopathies with peritendinous hyaluronan injections under sonographic guidance 2012.
(9) Flores C et al. Sports Med Open. 2017; 3 (1):22.

OSTENIL® TENDON

OSTENIL® TENDON:

Clinically proven effectiveness

- **Patients with mid-portion Achilles or peroneal tendinopathy, or lateral epicondylitis, reported significant pain relief (VAS) following treatment with OSTENIL® TENDON. This symptomatic relief persisted for 3 months following treatment.** [8] (Fig.4)
- **Patients with supraspinatus tendinopathy who received treatment with OSTENIL® TENDON injections and physical therapy showed a faster recovery, leading to an earlier return to pre-injury activity and the need for fewer rehabilitation sessions.** [9]

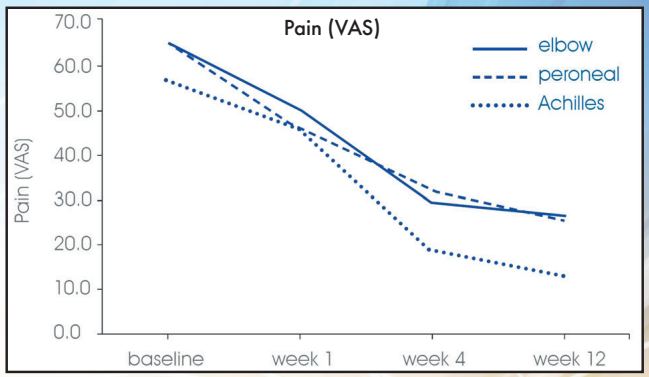


Fig.4

How does hyaluronic acid work in the treatment of tendinopathy?

The macro-molecular characteristics of hyaluronic acid, already proven in the effective treatment of symptomatic osteoarthritis, act to increase the gliding effect and reduce agglutinations in painful tendinosis, the tendon is fully lubricated and thus regains its functional capacity. This prevents any localised inflammatory process from worsening. [10-31]

General references for hyaluronic acid:

(10) K. Knobloch: Aus nach Sportverletzungen? Moderne Diagnostik
(11) Therapie und Präventionsmöglichkeiten. Balingen: Spitta; 2009
(12) B. K. Coombes et al., Lancet 2010; 376:Page 1751-67
(13) N. Scutt et al., J Orthop Res 2006; 24: 173-82
(14) J. D. Rees et al., Rheumatology 2006; 45: 508-21
(15) M. van Ark et al., Br J Sports Med 2011, bjsports78824 Published Online First: 3 May 2011
(16) 8 M. Özgen et al., Rheumatology International, Online First - 30. July 2010
(17) G. Mendoza et al., Carbohydr Res 2007; 342: Page 96-102
(18) 0 G. Lundborg et al., Scand J Plast Reconstr Surg 1977; 11: 195-203
(19) Boyer MI.: Flexor tendon biology. Hand Clin 2005; 21: 159-166
(20) R. St Onge et al., Clin Orthop Relat Res 1980; 146: 269-275
(21) T. Momose et al., Clin Anat 2002; 15: 199-205
(22) L. Hagberg et al., J Hand Surg [Br]. 1992; 17 (2): 167-71
(23) P. C. Amadio, J Hand Ther 2005; 18 (2): 112-9
(24) 7 R. D. Altman et al., J Rheumatol 1998; 25: 2203-12
(25) E. C. Huskisson et al., Rheumatology (Oxford) 1999; 38 (7): 602-7
(26) M. Dougados et al., Osteoarthritis Cartilage 1993; 1: 97-103
(27) P. W. Ackermann et al., J Orthop Res 2001; 19: 372-378
(28) L. Hagberg et al., J Orthop Res. 1991 Nov; 9 (6): 792-7
(29) L. Hagberg et al., J Hand Surg 1992c; 17: 935-941
(30) M. Özgen et al.; Rheumatol Int. 2010; 31. July (E-publication ahead of print)
(31) P. Kasten, Deutsche Zeitschrift für Sportmedizin Jahrgang 61, Nr. 4 (2010), Page 84-90

OSTENIL® TENDON

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 [32]
- Enhances **tendon gliding** effect and **reduces adhesion** [33, 19]
- Promotes **tendon recovery** and **wound healing process** [34, 35]
- Acts as a **transport medium** for nutrients to reach the vascular portions of the tendon [21]
- Masks the nocieptors and thus provides **pain relief** [36, 37]
- **Prevents the free passage of inflammatory cells** [38, 39] and molecules through the tendon sheath due to its macromolecular meshwork

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

SHOULDER
Rotator cuff (supraspinatus) tendinopathy [9]
Bicipital tendinopathy

ELBOW
Lateral epicondylalgia [40]
Medial epicondylalgia

KNEE
Patellar tendinopathy

ANKLE and FOOT
Achilles tendinopathy [8]
Posterior tibial tendinopathy
Peroneal tendinopathy [8]

(32) Akaska T et al. Clin Biomech 2006; 21: 810-5
(33) Kumar N et al. Trends Biomater. Arif. Organs 2009; 23(1): 34-45
(34) Chen WY, Abatangelo G. Wound Repair Regen 1999; 7: 79-89
(35) Yagishita K el al. Anthroscopy 2005; 21: 1330-6
(36) Gotoh S et al. Ann Rheum Dis 1993; 52: 817-22
(37) Balazs EA. Clls Tissues Organs 2003; 174: 49-62
(38) Gaughan EM et al. Am J Vet Res 1991; 52(5): 764-72
(39) Amiel D et al. J Hand Surg 1989; 14A: 837-43
(40) Gorelick et al., Adv Tech Biol Med 2015, 3:2

OSTENIL® TENDON

OSTENIL® TENDON:

Statistically significantly superior to Extracorporeal Shockwave Therapy (ESWT) and Corticosteroid Injections

- **OSTENIL® TENDON provided a clinically relevant improvement in Achilles' midportion tendinopathy and had statistically significant superiority over ESWT application, also at 4 weeks and 6 months.** [41] (Fig.5)

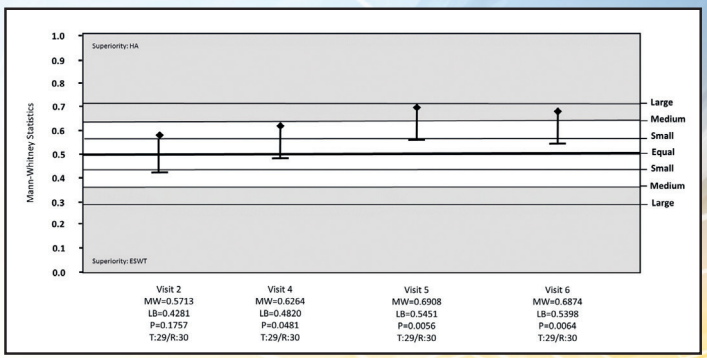


Fig.5

- **A single hyaluronate injection is efficacious for the treatment of insertional Achilles tendinopathy. The effect size is larger with hyaluronate injections and lasts longer than steroid therapy and non-invasive conservative treatment.** [42] (Fig.6)

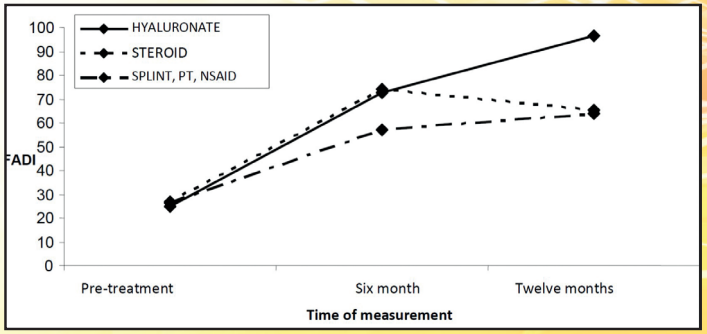


Fig.6

(41) N Lynen, et al. Arch Phys Med Rehabil. Jan 2017; 98(1): 64-71
(42) Gorelick L et al.; Scholars. Bull.; Vol-1, Iss-1 (Jul.2015): 16-20

OSTENIL® TENDON

OSTENIL® MINI:
Relief in OA for small joints

- HA obtained from bacterial fermentation
- HA 1% (10mg/1ml)
- Molecular weight: 1-2 million Daltons
- 1ml pre-filled syringe
- Terminal sterilisation for optimal safety: the contents and the outer surface of the syringe are sterile.

- **Specifically designed & licensed for small joints such as the hand, foot, facet joints and the temporomandibular joint, with 1-3 injections at weekly intervals.**
- **OSTENIL® MINI improves joint mobility and pain-free activity in the treatment of hallux rigidus. (43)**
- **A single injection of OSTENIL® MINI is as effective as an injection of steroid in patients with rhizarthrosis. (44)**
- **In temporomandibular joint disorders, an injection of OSTENIL® MINI reduces pain and improves joint function. (45)**

(43) Pons M et al. Foot Ankle Int 2007;28(1):38-42
(44) Tourret LJ et al. Presented at the 10th World Congress on Osteoarthritis. December 8-11, 2005; poster P157.
(45) Oliveras-Moreno JM et al. J Oral Maxillofac Surg 2008;66:2243-46

OSTENIL® MINI

GB

OSTENIL®

Viscoelastic solution for injection into the joint cavity

INSTRUCTIONS FOR USE

OSTENIL®

Sodium hyaluronate 1.0 %. Viscoelastic solution for injection into the joint cavity for improvement of mobility and pain relief in osteoarthritis. Transparent solution of natural, highly purified sodium hyaluronate obtained by fermentation. Devoid of animal proteins. Sterile by moist heat. The content and the outer surface of the OSTENIL® pre-filled syringe are sterile if the sterile barrier is intact. For single use only.

Composition:

1 ml isotonic solution (pH 7) contains 10.0 mg sodium hyaluronate, sodium chloride, disodium phosphate, sodium dihydrogen phosphate and water for injections.

Indications:

Pain and restricted mobility of the knee and other big synovial joints like hip and shoulder.

Contra-indications:

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

Precautions:

The treatment with OSTENIL® is not recommended in children, pregnant and lactating women or in inflammatory joint diseases such as rheumatoid arthritis or Bechterew disease. In case of joint effusion, the effusion should be reduced first.

The national guidelines for intra-articular injections must be observed, this includes thorough disinfection of the injection site and other measures to avoid joint infections. OSTENIL® should be injected accurately into the joint cavity, if necessary, under imaging control. Avoid injections into blood vessels or surrounding tissues.

Do not use if the pre-filled syringe or sterile pack 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. Do not resterilize as this may damage the product.

No information on the impairment of any diagnostic investigations, such as magnetic resonance imaging, clinical condition assessments or therapeutic treatments by OSTENIL® have been notified yet.

Interactions:

No information on the incompatibility of OSTENIL® with other medical devices and drugs for intra-articular use or oral analgesic or anti-inflammatory drugs have been notified yet.

Undesirable effects:

In very rare cases (less than 1 in 10,000 patients) local secondary phenomena such as pain, feeling of heat, redness, swelling/joint effusion, pruritus and other local incompatibility reactions may occur during or after the injection of OSTENIL®. As with all invasive joint treatments, in very rare cases an infection may occur. It cannot be completely excluded that in very rare cases the intra-articular injection per se causes systemic side effects like tachycardia, hypotension, hypertension, palpitations, nausea and shortness of breath. Those reactions may occur independently from the solution applied. Before injecting OSTENIL®, the patient should be informed about contraindications and undesirable effects.

Reporting of side effects:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer TRB Chemedica AG and the local competent authority of the user.

Dosage and administration:

Inject OSTENIL® into the affected joint once a week for a total of 3 – 5 injections. Several joints may be treated at the same time. Depending on the severity of the joint disease the beneficial effects of a treatment cycle of five intra-articular injections may last for six months or longer. The sodium hyaluronate itself is degraded within a few days. Repeat treatment cycles may be administered as required. Take the pre-filled syringe out of the sterile pack, unscrew the Luer lock cap from the syringe, attach a suitable needle with Luer connector (for example 18 to 25 G) and secure it by turning slightly. Remove any air bubble, if present, before injection.

Disposal:

Put the used syringe in a sharps disposal container right away after use. Do not throw away the OSTENIL® prefilled syringe in the household trash. Follow your community guidelines for the right way to dispose of your sharps disposal container.

Characteristics and mode of action:

Synovial fluid, which is viscoelastic due to the presence of hyaluronic acid, is found in all synovial joints, where it ensures normal, painless movement due to its lubricating and shock-absorbing properties. In degenerative joint disorders such as osteoarthritis, the viscoelasticity of the synovial fluid is markedly reduced thereby decreasing its lubricating and shock-absorbing functions. This increases mechanical loading of the joint and cartilage destruction which ultimately results in pain and restricted mobility of the affected joint. Supplementing this synovial fluid with intra-articular injections of highly purified hyaluronic acid can ameliorate the viscoelastic properties of synovial fluid. This improves its lubricating and shock-absorbing functions and reduces mechanical overload of the joint. Clinical trials showed a pain decrease and improvement in joint mobility up to six months.

Storage:

Store between 2 °C and 25 °C in a dry place, protected from light! Do not use after the expiry date indicated on the box. Keep out of the reach of children.

Presentation:

1 pre-filled syringe of 20 mg/2.0 ml OSTENIL® in a sterile pack.

As long as the EUDAMED database is not fully functional, the SSCP is available to the public on the company's website www.trbchemedica.de.

OSTENIL® is a medical device. To be used by a clinician experienced and trained in intra-articular injections only.

Last revision date: 2022-01

GB

OSTENIL® MINI

Viscoelastic solution for injection into small joints

INSTRUCTIONS FOR USE

OSTENIL® MINI

Sodium hyaluronate 1.0 %. Viscoelastic solution for injection into small joints for improvement of mobility and pain relief in osteoarthritis. Transparent solution of natural, highly purified sodium hyaluronate obtained by fermentation. Devoid of animal proteins. Sterile by moist heat. The content and the outer surface of the OSTENIL® MINI pre filled syringe are sterile if the sterile barrier is intact. For single use only.

Composition:

1 ml isotonic solution (pH 7) contains 10.0 mg sodium hyaluronate, sodium chloride, disodium phosphate, sodium dihydrogen phosphate and water for injections.

Indications:

Pain and restricted mobility in degenerative and traumatic changes of small synovial joints, for example, the facet joints of the lumbar spine, the saddle joint of the thumb, the proximal joint of the big toe and the temporomandibular joint.

Contra-indications:

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

Precautions:

The treatment with OSTENIL® MINI is not recommended in children, pregnant and lactating women or in inflammatory joint diseases such as rheumatoid arthritis or Bechterew disease. In case of joint effusion, the effusion should be reduced first.

The national guidelines for intra-articular injections must be observed, this includes thorough disinfection of the injection site and other measures to avoid joint infections. OSTENIL® MINI should be injected accurately into the joint cavity, if necessary, under imaging control. Avoid injections into blood vessels or surrounding tissues.

Do not use if the pre-filled syringe or sterile pack 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. Do not resterilize as this may damage the product.

No information on the impairment of any diagnostic investigations, such as magnetic resonance imaging, clinical condition assessments or therapeutic treatments by OSTENIL® MINI have been notified yet.

Interactions:

No information on the incompatibility of OSTENIL® MINI with other medical devices and drugs for intra-articular use or oral analgesic or anti-inflammatory drugs have been notified yet.

Undesirable effects:

In very rare cases (less than 1 in 10,000 patients) local secondary phenomena such as pain, feeling of heat, redness, swelling/joint effusion and tachycardia may occur during or after the injection of OSTENIL® MINI. As with all invasive joint treatments, in very rare cases an infection may occur. Before injecting OSTENIL® MINI, the patient should be informed about contraindications and undesirable effects.

Reporting of side effects:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer TRB Chemedica AG and the local competent authority of the user.

Dosage and administration:

Inject OSTENIL® MINI into the affected joint once a week for a total of 1 – 3 injections. Several joints may be treated at the same time. Depending on the severity of the joint disease the beneficial effects of a treatment cycle of three intra-articular injections may last for six months or longer. The sodium hyaluronate itself is degraded within a few days. Repeat treatment cycles may be administered as required. Take the pre-filled syringe out of the sterile pack, unscrew the Luer lock cap from the syringe, attach a suitable needle with Luer connector (for example 18 to 25 G) and secure it by turning slightly. Remove any air bubble, if present, before injection.

Disposal:

Put the used syringe in a sharps disposal container right away after use. Do not throw away the OSTENIL® MINI prefilled syringe in the household trash. Follow your community guidelines for the right way to dispose of your sharps disposal container.

Characteristics and mode of action:

Synovial fluid, which is viscoelastic due to the presence of hyaluronic acid, is found in all synovial joints, where it ensures normal, painless movement due to its lubricating and shock-absorbing properties. In degenerative joint disorders such as osteoarthritis, the viscoelasticity of the synovial fluid is markedly reduced thereby decreasing its lubricating and shock-absorbing functions. This increases mechanical loading of the joint and cartilage destruction which ultimately results in pain and restricted mobility of the affected joint. Supplementing this synovial fluid with intraarticular injections of highly purified hyaluronic acid can ameliorate the viscoelastic properties of synovial fluid. This improves its lubricating and shock-absorbing functions and reduces mechanical overload of the joint. Clinical trials showed a pain decrease and improvement in joint mobility up to six months.

Storage:

Store between 2 °C and 25 °C in a dry place, protected from light! Do not use after the expiry date indicated on the box. Keep out of the reach of children.

Presentation:

1 pre-filled syringe of 10 mg/1.0 ml OSTENIL® MINI in a sterile pack.

As long as the EUDAMED database is not fully functional, the SSCP is available to the public on the company's website www.trbchemedica.de.

OSTENIL® MINI is a medical device. To be used by a clinician experienced and trained in intra-articular injections only.

Last revision date: 2021-07

GB

OSTENIL® PLUS

Viscoelastic solution for injection into the joint cavity

INSTRUCTIONS FOR USE

OSTENIL® PLUS

Sodium hyaluronate 2.0 %. Viscoelastic solution for injection into the joint cavity for improvement of mobility and pain relief in osteoarthritis. Transparent solution of natural, highly purified sodium hyaluronate obtained by fermentation. Devoid of animal proteins. Sterile by moist heat. The content and the outer surface of the OSTENIL® PLUS pre-filled syringe are sterile if the sterile barrier is intact. For single use only.

Composition:

1 ml isotonic solution (pH 7) contains 20.0 mg sodium hyaluronate, sodium chloride, disodium phosphate, sodium dihydrogen phosphate, mannitol and water for injections.

Indications:

Pain and restricted mobility of the knee and other big synovial joints like hip and shoulder.

Contra-indications:

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

Precautions:

The treatment with OSTENIL® PLUS is not recommended in children, pregnant and lactating women or in inflammatory joint diseases such as rheumatoid arthritis or Bechterew disease. In case of joint effusion, the effusion should be reduced first.

The national guidelines for intra-articular injections must be observed, this includes thorough disinfection of the injection site and other measures to avoid joint infections. OSTENIL® PLUS should be injected accurately into the joint cavity, if necessary, under imaging control. Avoid injections into blood vessels or surrounding tissues. Do not use if the pre-filled syringe or sterile pack 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. Do not resterilize as this may damage the product. No information on the impairment of any diagnostic investigations, such as magnetic resonance imaging, clinical condition assessments or therapeutic treatments by OSTENIL® PLUS have been notified yet.

Interactions:

No information on the incompatibility of OSTENIL® PLUS with other medical devices and drugs for intra-articular use or oral analgesic or anti-inflammatory drugs have been notified yet.

Undesirable effects:

In very rare cases (less than 1 in 10,000 patients) local secondary phenomena such as pain, feeling of heat, redness, swelling/joint effusion, pruritus and other local incompatibility reactions may occur during or after the injection of OSTENIL® PLUS.

As with all invasive joint treatments, in very rare cases an infection may occur. It cannot be completely excluded that in very rare cases the intra-articular injection per se causes systemic side effects like tachycardia, hypotension, hypertension, palpitations, nausea and shortness of breath. Those reactions may occur independently from the solution applied. Before injecting OSTENIL® PLUS, the patient should be informed about contraindications and undesirable effects.

Reporting of side effects:

Any serious incident that has occurred in relation to the device should be reported to the manufacturer TRB Chemedica AG and the local competent authority of the user.

Dosage and administration:

Inject OSTENIL® PLUS into the affected joint once a week for a total of 1 – 3 injections. Several joints may be treated at the same time. Depending on the severity of the joint disease the beneficial effects may last for six months or longer. The sodium hyaluronate itself is degraded within a few days. Repeat treatment cycles may be administered as required. Take the pre-filled syringe out of the sterile pack, unscrew the Luer lock cap from the syringe, attach a suitable needle with Luer connector (for example 18 to 25 G) and secure it by turning slightly. Remove any air bubble, if present, before injection.

Disposal:

Put the used syringe in a sharps disposal container right away after use. Do not throw away the OSTENIL® PLUS prefilled syringe in the household trash. Follow your community guidelines for the right way to dispose of your sharps disposal container.

Characteristics and mode of action:

Synovial fluid, which is viscoelastic due to the presence of hyaluronic acid, is found in all synovial joints, where it ensures normal, painless movement due to its lubricating and shock-absorbing properties. In degenerative joint disorders such as osteoarthritis, the viscoelasticity of the synovial fluid is markedly reduced thereby decreasing its lubricating and shock absorbing functions. This increases mechanical loading of the joint and cartilage destruction which ultimately results in pain and restricted mobility of the affected joint. Supplementing this synovial fluid with intra-articular injections of highly purified hyaluronic acid can ameliorate the viscoelastic properties of synovial fluid. This improves its lubricating and shock-absorbing functions and reduces mechanical overload of the joint. Clinical trials showed a pain decrease and improvement in joint mobility up to six months.

OSTENIL® PLUS also contains mannitol, a free radical scavenger, which helps to stabilise the chains of sodium hyaluronate.

Storage:

Store between 2 °C and 25 °C in a dry place, protected from light! Do not use after the expiry date indicated on the box. Keep out of the reach of children.

Presentation:

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

As long as the EUDAMED database is not fully functional, the SSCP is available to the public on the company's website www.trbchemedica.de.

OSTENIL® PLUS is a medical device. To be used by a clinician experienced and trained in intra-articular injections only.

Last revision date: 2022-01

GB

OSTENIL® TENDON

Viscoelastic solution for injection for peritendinous or intrasheath injection

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-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

TRB Chemedica (UK) Ltd
9 Evolution, Lymedale Business Park, Hooters Hall Road, Newcastle-under-Lyme, Staffordshire ST5 9QF
Tel: 0845 330 7556 Email: info@trbchemedica.co.uk Web: ostenil.trbmedica.co.uk

TRB CHEMEDICA AG
Otto-Lilienthal-Ring 26
85622 Feldkirchen/Munich, Germany