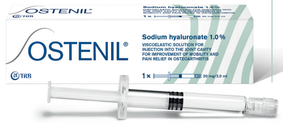
OSTENIL®

A range of formulations for a tailored approach to osteoarthritis treatment

OSTENIL®

For the treatment of pain and restricted mobility of large synovial joints*



2 ml pre-filled syringe, 1% sodium hyaluronate (20 mg/2.0 ml)

3-5 injections at one week interval

OSTENIL® PLUS

A more viscous formulation provides efficacy from as little as one injection for the treatment of pain and restricted mobility of large synovial joints*

2 ml pre-filled syringe, 2% sodium hyaluronate (40 mg/2.0 ml), 0.5% mannitol

1-3 injections at one week interval

OSTENIL® MINI

An optimal volume for the treatment of pain and restricted mobility in small synovial joints*

1 ml pre-filled syringe, 1% sodium hyaluronate (10 mg/1.0 ml)

1-3 injections at one week interval

New official packaging

Scan the QR code to learn more

MADE IN SWITZERLAND

With over 25 years of experience in producing injectables, TRB Chemedica's manufacturing processes are compliant to the highest possible pharmaceutical standards globally. **Manufactured in Vouvry, Valais, Switzerland.**

MDR APPROVED

The European Union Medical Device Regulation (MDR) was established to ensure a high standard of safety and quality of medical devices. All products in the OSTENIL® line have successfully passed the EU MDR review and clearance process and are available for use in the EU market. These products are medical devices. Please use them according to the Instructions for Use or label.

REFERENCES

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TRB Your experience Your expertise Your expectations

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OSTENIL®

REDISCOVER YOUR RHYTHM

EU MDR CERTIFIED

Swiss made

TRB Your experience Your expertise Your expectations

OSTENIL®

Hyaluronic acid restores the physiological function of the synovial fluid, improving joint function and reducing pain.

Degradation of the concentration and quality of hyaluronic acid in the synovial fluid of the joints plays a role in the progression of osteoarthritis. The lubricating, shock absorbing properties of the synovial fluid are impaired,[1] contributing to increased friction during movement and greater stress and damage to the cartilage.

Viscosupplementation with exogenous hyaluronic acid is an effective approach to restore the natural properties of the synovial fluid in patients with osteoarthritis.[2] This can provide long-lasting pain relief and improved mobility, and prolong the time until patients require joint replacement surgery.[3]

Harnessing the biomechanical properties of hyaluronic acid, the OSTENIL® range has been developed to relieve joint pain and improve mobility in patients suffering from osteoarthritis. The range of formulations provide safe, effective treatment for use in both large and small synovial joints.

OSTENIL®

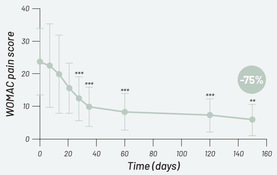
Pain relief and improved joint function

OSTENIL® is indicated for pain and restricted mobility of large synovial joints.

OSTENIL® has demonstrable efficacy in[4–12]:

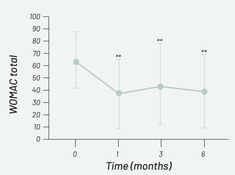
knee joints | **hip** joints | **shoulder** joints

OSTENIL® provided long-lasting pain relief from knee osteoarthritis, even 5 months after the first injection[4]



*Patients treated with intra-articular OSTENIL® injections for osteoarthritis knee pain showed gradual, sustained improvements in mean WOMAC pain scores compared to baseline. At 150 days following treatment initiation, patients showed a 75% reduction in pain. (n=26. ** p=0.0061, *** p<0.0001)*

OSTENIL® treatment resulted in 6-months of improved mobility in hip osteoarthritis[10]



Hip osteoarthritis patients receiving 3 weekly injections of OSTENIL showed improvements in hip functional activity (n=25, p<0.0001).

OSTENIL® delayed total knee replacement by up to 12 months, with just one treatment cycle[6]

In a group of patients with advanced osteoarthritis who were candidates for knee replacement, treatment with OSTENIL® delayed the time until surgery by a mean of 7.5 months (n=21). In 86% of patients, treatment delayed surgery by at least 12 months.

OSTENIL® PLUS

Effective joint pain relief from a single injection

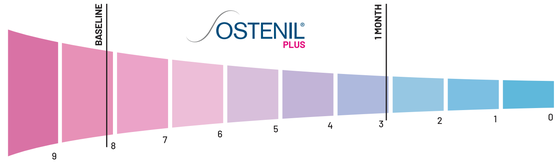
The more viscous formulation of OSTENIL® PLUS enables treatment of large synovial joints with a reduced number of injections compared with OSTENIL®.

OSTENIL® PLUS has proven efficacy in the treatment of[13–18]:

knee joints | **hip** joints | **shoulder** joints

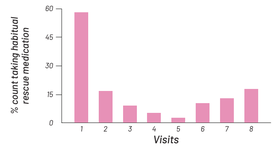
OSTENIL® PLUS also contains mannitol, a free radical scavenger, which helps to stabilise the chains of sodium hyaluronate[25]

A single injection of OSTENIL® PLUS reduces pain by over 60%[14]

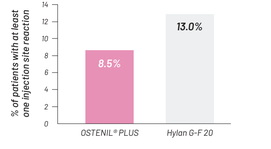


** Patients with knee osteoarthritis showed significant reductions in pain at 1-month following with OSTENIL® PLUS injection. VAS pain scores were reduced from 8.3 ± 0.5 at baseline to 3.2 ± 2.3 at 1-month (p<0.01, n=28).*

Ostenil Plus achieved considerable reduction in rescue medication usage[13] and also demonstrated an optimal safety profile[16]



This figure summarizes the data on the intake of rescue medication throughout the study. At the initial study visit, most patients (58.2%) regularly took analgesics and anti-inflammatory drugs and this intake decreased considerably as the study progressed such that at visit 5 (day 90) regular intake was lower (2.5%). Nevertheless, both regular and sporadic intake tended to increase from visits 6 and 7 reaching 17.7% of regular intake of paracetamol and/or ibuprofen at the final visit.



Only 8.5% of patients experienced injection site reactions in the OSTENIL® PLUS-treated group (n=12) compared with 13.0% in the Hylan G-F 20 group (n=19). In both groups, the most common injection site reactions included joint pain, localised inflammation, loin pain, and osteoarthritis flare-up.

OSTENIL® MINI

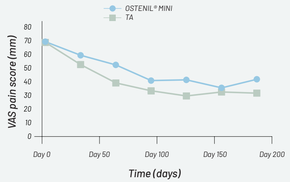
An optimal volume for small joints

OSTENIL® MINI has demonstrable efficacy in[19–23]:

temporomandibular joint | **facet** joints | **carpometacarpal** joint | **metatarsophalangeal** joint

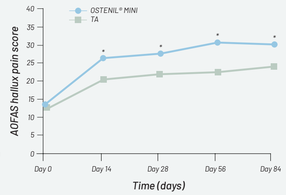
OSTENIL® MINI is a formulation developed for the treatment of pain and restricted mobility in small synovial joints.

OSTENIL® MINI relieved lumbar pain for up to 8 months[21]



In patients with chronic lumbar pain receiving three weekly injections of OSTENIL® MINI, pain was markedly reduced within 28 days of the first injection (n=29). Treatment resulted in sustained pain relief at 90 and 180 days after the final injection. OSTENIL® MINI was equivalent in efficacy to the standard-of-care intra-articular corticosteroid treatment, triamcinolone acetonide (TA, n=30).

OSTENIL® MINI outperformed corticosteroid treatment for pain relief in hallux rigidus osteoarthritis[20]



In patients with painful hallux rigidus (n=17), a single injection of OSTENIL® MINI resulted in significant reduction in pain, as measured by American Orthopaedic Foot & Ankle Society (AOFAS) hallux pain score. OSTENIL® MINI provided superior pain relief to TA (n=19) at all time points after baseline (p<0.05).

Safety

No known interactions to date. OSTENIL®, OSTENIL® PLUS, and OSTENIL® MINI can be safely used alongside other therapies and treatments for intra-articular use, oral analgesic, or anti-inflammatory drugs.

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

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

** Secondary phenomena such as discomfort, pain, feeling of heat, itching, bruising, redness and swelling are commonly observed injection-site reactions[24]*

OSTENIL®

COMPOSITION
sodium hyaluronate from biofermentation (OSTENIL® MINI: 10 mg; OSTENIL®: 20 mg; OSTENIL® PLUS: 40 mg) and sodium chloride, disodium phosphate, sodium dihydrogen phosphate, water for injections. In addition, OSTENIL® PLUS contains mannitol

INDICATION
*for improvement of mobility and pain relief in osteoarthritis. OSTENIL® and OSTENIL® PLUS are indicated for knee and other big synovial joints like hip and shoulder. OSTENIL® MINI is indicated for 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.

DOSAGE AND ADMINISTRATION
inject into the affected joint once a week for a total of 1-3 (OSTENIL® MINI, OSTENIL® PLUS) or 3-5 (OSTENIL®) injections.

CONTRA-INDICATIONS
OSTENIL®, OSTENIL® MINI and OSTENIL® PLUS should not be used in patients with hypersensitivity to any of their constituents.

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.

PRECAUTIONS
the treatment with OSTENIL®, OSTENIL® MINI and OSTENIL® PLUS is not recommended in children, pregnant and lactating individuals or in inflammatory joint diseases such as rheumatoid arthritis or ankylosing spondilitis. Do not use if the pre-filled syringe or sterile pack are damaged. Store between 2°C and 25°C. The instructions for use (IFU) may vary depending on the country where the product is authorised. Please refer to your local IFU for more information.