# Sostenil® mini

Sodium Hyaluronate

**Restoring Synovial Balance in the Hand**

Ostenil® *mini*
Sodium Hyaluronate

## Osteoarthritis of the hand

- Osteoarthritis (OA) of the hand is a common cause of pain and disability that limits hand strength and flexibility. It is highly prevalent in the elderly, and makes everyday activities such as holding small objects and opening jars very difficult.[1–3]
- In the hand, OA mainly affects the carpometacarpal (CMC), the metacarpophalangeal (MCP), the proximal interphalangeal (PIP) and the distal interphalangeal (DIP) joints.[4]
- Hand OA has received little clinical attention compared with OA of the knee or hip. More research is needed to evaluate the clinical impact of therapy on OA of the hand and to compare possible treatment options.[5]
- Intra-articular injections of sodium hyaluronate are an effective treatment for OA of large joints, such as the knee and hip.[6–8] In addition, they also show promise for the treatment of OA in small joints, such as those in the hand.[9,10]

## Ostenil® *mini*: designed for relief from OA in small joints

- Ostenil® *mini* is indicated for the treatment of pain and restricted mobility associated with degenerative and traumatic changes in small synovial joints, such as those in the hand.
- Ostenil® *mini* is an isotonic solution of highly purified hyaluronan (sodium hyaluronate 1%) produced by bacterial fermentation. It is presented in individually packaged, sterile, pre-filled syringes, each containing 1 ml hyaluronan solution.
- Ostenil® *mini* is administered intra-articularly as a course of 1–3 injections at weekly intervals. The beneficial effects of treatment with Ostenil® *mini* can last up to 6 months.[11,12]

## Significant pain reduction in OA of the first CMC following multiple injections of Ostenil® *mini*[13]

- After 2 to 3 weekly intra-articular injections, Ostenil® *mini* markedly reduced pain associated with OA of the CMC joint within 1 week of the first injection.
- Pain reduction became significant after the second injection ($p<0.001$ *vs* pre-injection) and lasted for at least 12 weeks after the third injection (Figure 1).
- Multiple injections of Ostenil® *mini* significantly increased lateral grip and pinch grip. These effects lasted for at least 12 weeks after the final injection ($p<0.001$ *vs* pre-injection; Figure 2).
- Joint mobility on radial and palmar abduction was markedly improved 12 weeks after the final injection.
- Treatment with Ostenil® *mini* was judged beneficial by 95% of patients.
- Weekly, intra-articular injections of Ostenil® *mini* in the CMC joint were well tolerated.

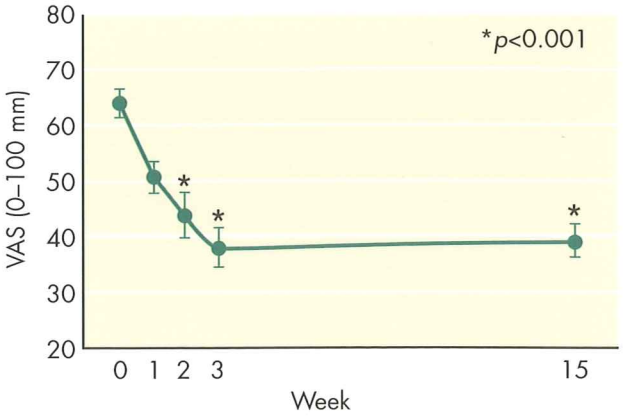


**Figure 1.** Ostenil® *mini* reduces OA-related pain (VAS=visual analogue scale).

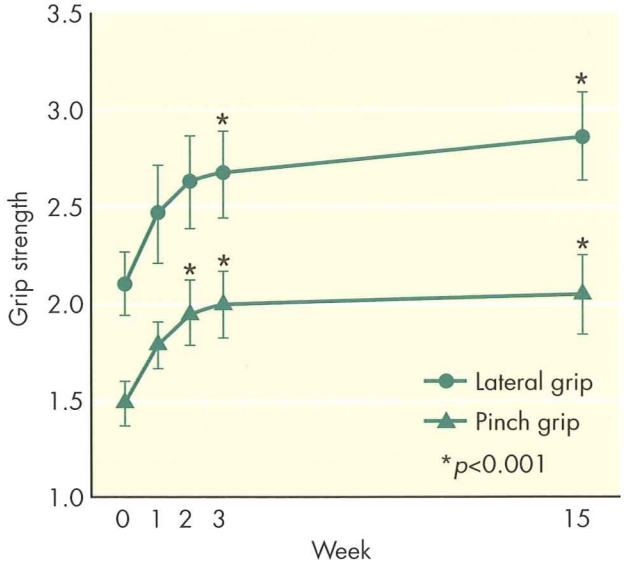


**Figure 2.** Ostenil® *mini* increases lateral and pinch grip.

## Multiple injections of Ostenil® *mini* give long-lasting benefits in OA of the first CMC compared with steroid injections[11]

- Three consecutive, weekly injections of Ostenil® *mini* provided greater pain relief compared with steroid injections at 26 weeks after the first injection.
- Although steroid acted more quickly, Ostenil® *mini* demonstrated a longer-lasting effect.
- Ostenil® *mini* improved lateral and pulp pinch strength compared with steroid at 26 weeks (Figure 3).
- Both radial and palmar abductions showed greater improvement with Ostenil® *mini* compared with steroid at 26 weeks.
- Of the patients treated with Ostenil® *mini*, 88% described a reduction in pain at 26 weeks compared with 79.1% of those treated with steroid.
- No adverse events occurred following injection with Ostenil® *mini*.

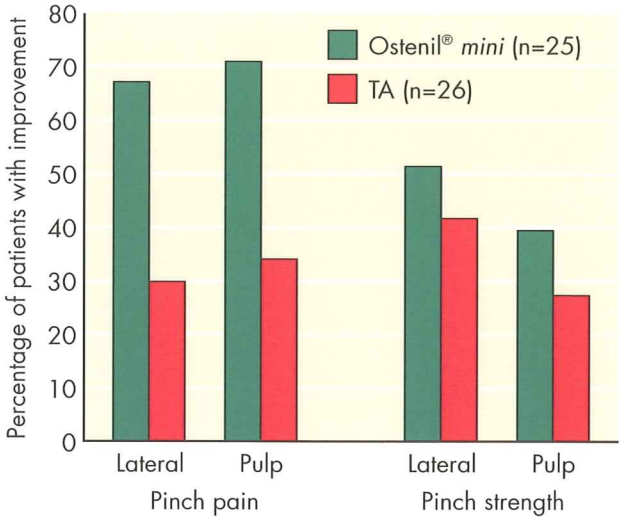


**Figure 3.** Ostenil® *mini* improved OA-related symptoms 26 weeks after the first injection (TA=triamcinolone acetonide).

## A single injection of Ostenil® *mini* is an effective, well-tolerated treatment for OA of the first CMC[12,14]

- A single injection of Ostenil® *mini* reduced OA-related pain within 1 week of injection, lasting for at least 24 weeks (Figure 4).[12]
- Although steroid acted more quickly, Ostenil® *mini* demonstrated a longer-lasting effect.[12]
- The reduction in pain on tip, key and palmar pinch favoured Ostenil® *mini* over steroid at 24 weeks after injection (Figure 5).[12]
- Pain on rotatory movement and joint shifting was further reduced with Ostenil® *mini* compared with steroid at 24 weeks.[12]
- In a separate study comparing the effectiveness of Ostenil® *mini* with a standard steroid injection for OA of the base of the thumb, efficacy was perceived as 'good' or 'excellent' by 62% of patients treated with Ostenil® *mini*, compared with 40% for steroid.[14]
- A single injection of Ostenil® *mini* was less painful and caused less post-injection discomfort than steroid.[14]
- In both studies, intra-articular injection of Ostenil® *mini* was well tolerated.[12,14]

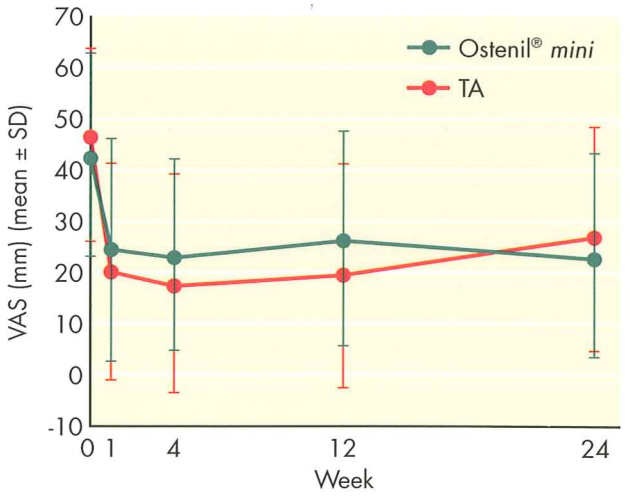


**Figure 4.** Ostenil® *mini* was as effective as steroid at reducing OA-related pain.

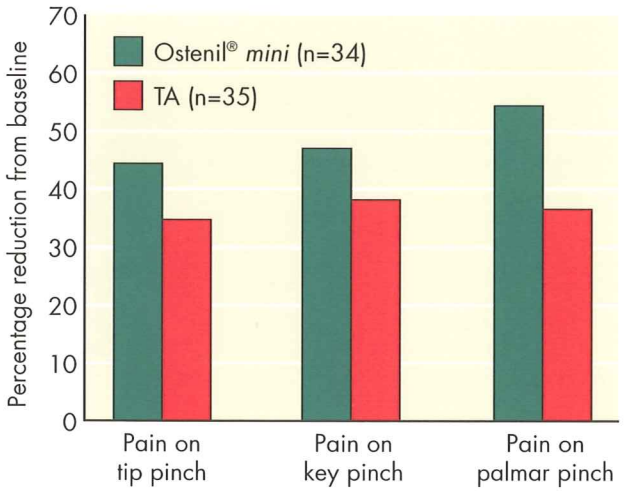


**Figure 5.** Improvements in pinch pain at 24 weeks after injection favoured Ostenil® *mini* over steroid.

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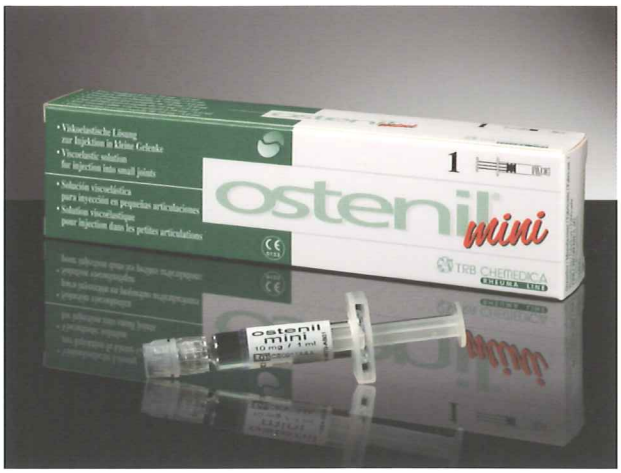


- Ostenil® *mini* reduces pain associated with OA within 1 week of injection.[13]
- A single injection of Ostenil® *mini* is effective for at least 6 months.[12]
- Ostenil® *mini* improves joint mobility and increases pain-free activity.[11–14]
- A single injection of Ostenil® *mini* is at least as effective as an injection of steroid.[14]
- Ostenil® *mini* is well tolerated.[11–14]

## References


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## Prescribing information

**OSTENIL® *mini***
Sodium hyaluronate 1.0 %. Viscoelastic solution for injection into small joints.
Sterile by moist heat.

**Composition:** 1 ml isotonic solution contains 10.0 mg sodium hyaluronate from fermentation and sodium chloride, sodium monohydrogenphosphate, sodium dihydrogenphosphate, water for injection.

**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 interphalangeal joints of the fingers and toes, the proximal joint of the big toe and the temporomandibular joint. In the treatment of bigger joints, for example the knee, hip or shoulder, OSTENIL® prefilled syringes of 20 mg/2.0 ml should be used.

**Contra-indications:** OSTENIL® *mini* should not be used in patients with ascertained hypersensitivity to one of the constituents.

**Precautions:** Caution should be exercised in patients with known hypersensitivity to drugs. The general precautions for intra-articular injections should be observed, including 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! As no clinical evidence is available on the use of hyaluronic acid in children, pregnant and lactating women or in inflammatory joint diseases such as rheumatoid arthritis or Bechterew disease, treatment with OSTENIL® *mini* is not recommended in these cases. Do not use if the pre-filled syringe or sterile pack are damaged. 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.

**Side effects:** Local secondary phenomena such as pain, feeling of heat, redness and swelling/joint effusion may occur in the joint treated with OSTENIL® *mini*. Application of an ice pack for five to ten minutes onto the treated joint will reduce the incidence of these events. In isolated cases the occurrence of side effects may be due to the intra-articular injection itself.

**Interactions with other products:** Avoid using OSTENIL® *mini* with instruments sterilised with quarternary ammonium salts solutions. No information on the incompatibility of OSTENIL® *mini* with other solutions for intra-articular use is available to date. The concomitant use of an oral analgesic or anti-inflammatory drug during the first few days of treatment may be helpful for the patient.

**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 may last at least six months. Repeat treatment cycles may be administered as required. In case of joint effusion it is advisable to reduce the effusion by aspiration, rest, application of an ice pack and/or intra-articular corticosteroid injection. Treatment with OSTENIL® *mini* can be started two to three days later.

The contents and outer surface of the OSTENIL® *mini* 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 from the syringe, attach a suitable needle (for example 19 to 25 G) and secure it by turning slightly. If present remove the air bubble from the syringe prior to injection.

**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. It is also responsible for the nutrition of the cartilage. 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. As a rule this results in a decrease in pain and an improvement in joint mobility which may last for several months after a treatment cycle.

**Presentation and package size:** One pre-filled syringe of 10 mg/1.0 ml OSTENIL® *mini* in a sterile pack.

**OSTENIL® *mini* is a medical device. To be used by a physician only.**

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**Manufacturer:** TRB Chemedica AG, D-85540 Haar/München


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