Sostenil® mini

Sodium Hyaluronate

Restoring Synovial Balance in the Foot

Ostenil® *mini*
Sodium Hyaluronate

Osteoarthritis of the foot

- Osteoarthritis (OA) of the foot is a painful condition that impacts on daily living, and is commonly associated with increasing age or with sports-related injuries.[1–3]
- In general, OA of the foot is most common in the ankle, first tarsometatarsal and first metatarsophalangeal joints.[4]
- In particular, hallux rigidus or limitus, and hallux valgus severely reduce big toe flexibility causing pain when walking, running, dancing, etc.[1,2]
- OA of the foot 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 foot OA and to compare possible treatment options.
- Intra-articular injections of sodium hyaluronate are an effective treatment for OA of large joints, such as the knee and hip.[5–8] In addition, they show promise for the treatment of OA in small joints, such as those in the foot.[9–11]

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 foot.
- 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.[12,13]

A single injection of Ostenil® *mini* is an effective treatment for hallux limitus[14]

- The efficacy and tolerability of a single, intra-articular injection of Ostenil® *mini* were compared with those of steroid injections in a single-blind, randomized, 12-week study.
- A total of 37 patients with hallux limitus participated, and 40 joints were injected – 20 with Ostenil® *mini* and 20 with steroid.
- Within 2 weeks, Ostenil® *mini* significantly reduced pain on walking 20 m and the effects were maintained over 12 weeks ($p<0.01$ *vs* baseline; Figure 1).
- Pain on walking was significantly reduced with Ostenil® *mini* at 4 and 8 weeks after injection compared with steroid ($p<0.05$ *vs* steroid; Figure 1).
- Ostenil® *mini* and steroid significantly reduced pain on palpation or passive motion within 2 weeks of injection ($p<0.01$ *vs* baseline).
- Compared with steroid, Ostenil® *mini* caused significant improvement in total score and pain evaluated on the Hallux Metatarsophalangeal–Interphalangeal Scale of the American Orthopaedic Foot and Ankle Society (AOFAS; $p<0.05$; Figure 2).

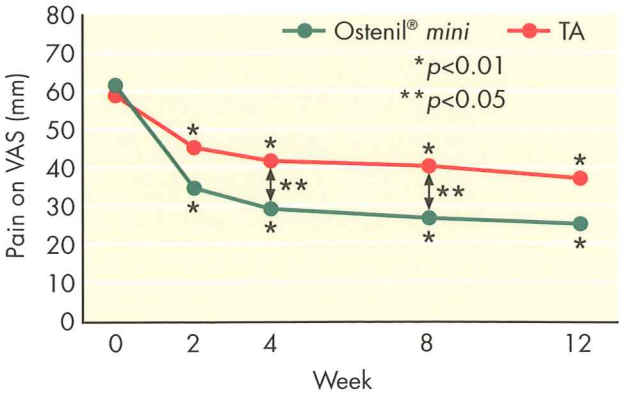

Figure 1. Ostenil® *mini* is significantly more effective than steroid at reducing pain on walking (TA=triamcinolone acetonide; VAS=visual analogue scale).

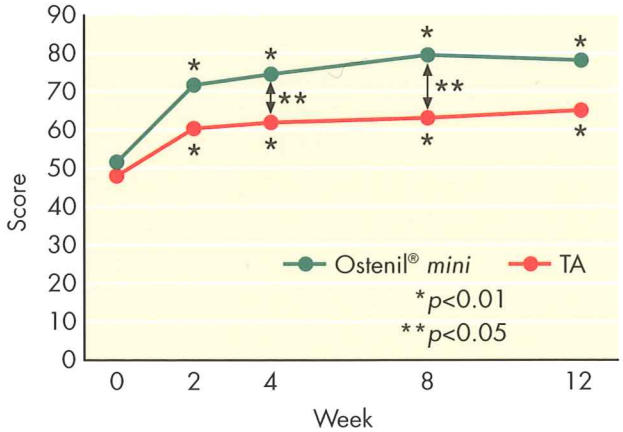

Figure 2. Ostenil® *mini* is significantly more effective than steroid at improving total score on the AOFAS scale.

Multiple injections of Ostenil® *mini* are an effective treatment in hallux rigidus and hallux valgus[15]

- The efficacy and tolerability of a course of three intra-articular injections of Ostenil® *mini* were evaluated in a single-centre, exploratory, prospective, 15-week study.
- Ostenil® *mini* injections were administered at weekly intervals to 22 patients with Kellgren grades I–III hallux rigidus (n=11) or hallux valgus (n=11) and continuous pain for at least 3 months.
- Ostenil® *mini* significantly reduced pain, as measured on a visual analogue scale (VAS), within 1 week of the first injection ($p<0.0001$ *vs* baseline). Pain reduction was maintained for at least 12 weeks after the last injection (Figure 3).
- Ostenil® *mini* reduced pain on walking and on load (Figure 4).
- Ostenil® *mini* significantly increased joint mobility ($p<0.001$ *vs* pre-treatment).
- Overall, these changes resulted in improved walking ability (Figure 5).
- A total of 85.7% of patients reported recovery from initial OA symptoms at 15 weeks.
- Ostenil® *mini* was equally effective in treating hallux rigidus or hallux valgus.

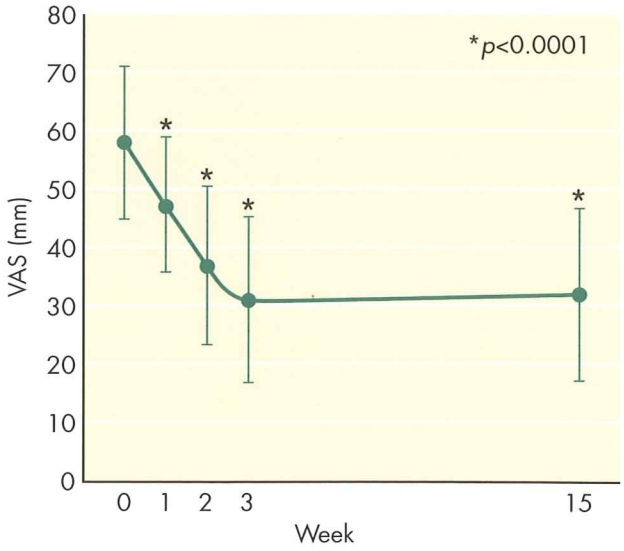

Figure 3. Ostenil® *mini* significantly reduced pain within 1 week of injection, lasting for at least 12 weeks.

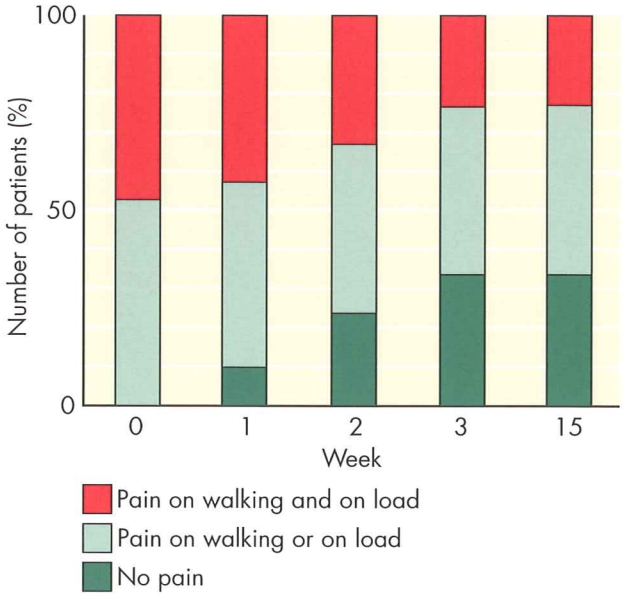

Figure 4. Ostenil® *mini* decreased pain on walking and on load.

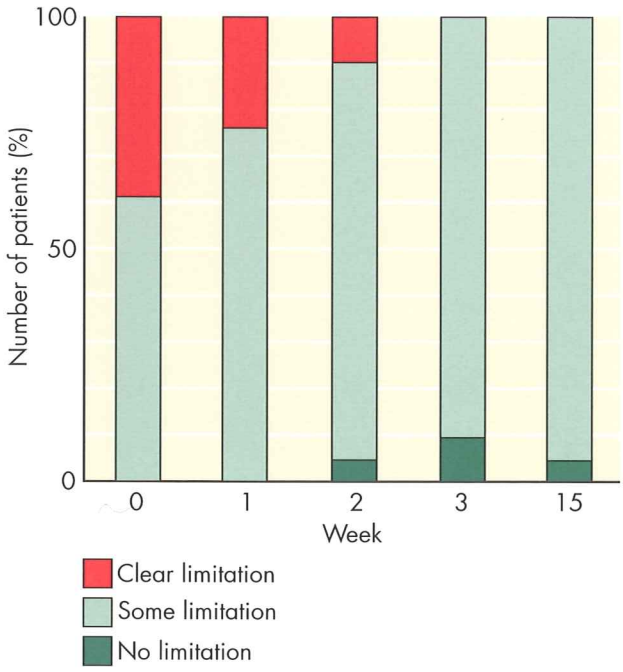

Figure 5. Ostenil® *mini* improved walking ability.

Ostenil® *mini* is well tolerated

- Single injections of Ostenil® *mini* or steroid were equally well tolerated.[14]
- A course of three injections of Ostenil® *mini* was well tolerated, and no significant local or systemic adverse events were experienced.[15]

Ostenil® *mini*

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- Ostenil® *mini* reduces pain associated with OA within 1 week of injection.[15]
- Ostenil® *mini* improves joint mobility and pain-free activity.[14,15]
- A single injection of Ostenil® *mini* reduces pain and eases walking for at least 3 months.[14]
- A single injection of Ostenil® *mini* is at least as effective as an intra-articular injection of steroid.[14]
- Ostenil® *mini* is well tolerated.[14,15]

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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