



TRB CHEMEDICA (UK) LTD

RHEUMA LINE

NAME OF PRODUCT:

OSTENIL® mini

INTENDED USE:

Viscoelastic solution for injection into small joints.

COMPOSITION:

Active substance:

Sodium hyaluronate

Excipients:

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 larger joints, for example the knee, hip or shoulder, OSTENIL® pre-filled syringes of 20 mg/2.0 ml should be used.

PRESENTATION:

Sterile pre-filled syringe containing 10 mg/1.0 ml sodium hyaluronate as an isotonic solution, in a sterile pack.

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 6 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 2–3 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, remove the Luer lock cap from the syringe, attach a suitable cannula (19 to 25 G) and secure it by turning slightly.

CHARACTERISTICS AND MODE OF ACTION:

OSTENIL® mini contains a highly purified specific fraction of sodium hyaluronate produced by fermentation from bacteria. The molecular weight range of OSTENIL® mini is designed to achieve optimum activity with additional benefits ancillary to the mechanical action and primarily related to the viscoelastic characteristics. The product is free from animal proteins and the narrow molecular weight range helps to ensure the absence of low weight pro-inflammatory fragments of hyaluronic acid.

Hyaluronic acid (HA) is a natural polymer, which provides viscoelastic properties to the synovial fluid. In a normal joint it is highly concentrated at the surface coating of articular cartilage as well as the superficial layers of the synovial membrane. In the synovial fluid, HA acts as a lubricant and a shock absorber, an



ostenil®
mini



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energy storing agent between opposing cartilages, a semi-permeable barrier regulating metabolic exchanges between the cartilage and the synovial fluid, a cell traffic controlling agent and a viscoelastic shield around the synoviocytes and adjacent nerve endings.¹

In degenerative joint disorders such as osteoarthritis the HA of the synovial fluid is fragmented and depolymerised² with a corresponding reduction in viscoelasticity. This increases the mechanical loading of the joint and results in cartilage breakdown and therefore pain and restricted mobility of the affected joint.

A treatment cycle with OSTENIL® mini helps restore the synovial homeostasis of the affected joint, thereby improving the viscoelastic properties of the synovial fluid³ and restoring the lubricating and shock-absorbing functions.

The net result is a decrease in pain and improvement in joint mobility, which can last for several months after a course of treatment. A course of two to three OSTENIL® mini injections into the saddle joint of the thumb has been shown to rapidly reduce pain and increase pinch and key grip strength measured using an intrinsicmeter.⁴ In chronic lower back pain of a non-radicular origin, injecting OSTENIL® mini into the facet joints of the lumbar vertebral column produces a decrease in pain and an improvement in performance of daily activities that can be demonstrated on validated scales. OSTENIL® mini had a slower onset of action than triamcinolone acetamide, the control medication, but demonstrated a longer lasting effect.⁵ Numerous publications describe the positive effects of intra-articular hyaluronic acid in locking of the temporomandibular joint: pain decreases, active mouth opening becomes easier and jaw-closing strength (bite force) increases.⁶⁻⁹

BIOCOMPATIBILITY:

Results of acute, sub-acute and chronic toxicity studies together with the results of the foetal toxicity, fertility, peri- and post-natal toxicity studies show that sodium hyaluronate is well tolerated.

INTERACTIONS:

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.

STORAGE:

Store below 25°C in original sterile pack, away from heat sources and light.
Do not freeze.

SHELF-LIFE:

3 years if stored in original unopened package at room temperature, ≤ 25°C.

PACKAGING:

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

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



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