OSTENIL®
Sodium Hyaluronate

Reducing Pain
Improving Function

- Long-lasting pain relief and improved function in knee OA patients with excellent tolerability[1]
- Among patients with advanced OA of the shoulder who were unsuitable for shoulder replacement surgery, OSTENIL® was associated with reduced pain and improved function[2]
- 12 months effective pain relief for patients suffering from hip OA[3]

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

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OSTENIL®

Viscoelastic solution for injection into the joint cavity

INSTRUCTIONS FOR USE

OSTENIL®
Sodium hyaluronate from fermentation 1.0 %. Viscoelastic solution for injection into the joint cavity. Sterile by moist heat.

Composition:
1 ml isotonic solution contains 10.0 mg sodium hyaluronate and sodium chloride, disodium phosphate, sodium dihydrogen phosphate, water for injections.

Indications:
Pain and restricted mobility in degenerative and traumatic changes of the knee joint and other synovial joints.

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

Interactions:
No information on the incompatibility of OSTENIL® 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.

Side effects:
Local secondary phenomena such as pain, feeling of heat, redness and swelling may occur in the joint treated with OSTENIL®. Application of an ice pack for five to ten minutes onto the treated joint will reduce the incidence of these events.

Directions for use:
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 will 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® can be started two to three days later.
The content and the outer surface of the OSTENIL® pre-filled syringe are sterile as long as the sterile pack is intact. Take the prefilled syringe out of the sterile pack, unscrew the Luer lock cap from the syringe, attach a suitable needle (for example 19 to 21 G) and secure it by turning slightly. Remove any air bubble, if present, before injection.

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® 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® is not recommended in these cases. 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. 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:
Synovial fluid, which is viscoelastic due to the presence of hyaluronic acid, is found in all synovial joints, particularly the large weight bearing 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 of five intra-articular injections.

Presentation:
One pre-filled syringe of 20 mg/2.0 ml OSTENIL® in a sterile pack.
OSTENIL® is a medical device. To be used by a clinician only.
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