



INSTRUCTIONS FOR USE

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OSTENIL® Plus

Sodium hyaluronate from fermentation 2.0%. Viscoelastic solution for injection into the joint cavity. Sterile by moist heat.

Composition:

1 ml isotonic solution (pH 7.3) contains 20.0 mg sodium hyaluronate from fermentation and sodium chloride, disodium phosphate, sodium dihydrogen-phosphate, mannitol and water for injections.

Indications:

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

Contra-indications:

OSTENIL® Plus should not be used in patients with ascertained hypersensitivity to one of the constituents.

Interactions:

No information on the incompatibility of OSTENIL® Plus 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, sensation of heat, redness and swelling may occur in the joint treated with OSTENIL® Plus. 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® Plus into the affected joint once a week for a total of 1–3 injections. Several joints may be treated at the same time. 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® Plus can be started two to three days later.

The content and the outer surface of the OSTENIL® Plus pre-filled syringe are sterile as long as the sterile pack is intact. Take the pre-filled syringe out of the sterile pack, unscrew the Luer lock cap from the syringe, attach a suitable needle (for example 18 to 25 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® Plus 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® Plus 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.

OSTENIL® Plus is a transparent solution of natural and highly purified sodium hyaluronate obtained by fermentation and is devoid of animal protein. OSTENIL® Plus also contains mannitol, a free radical scavenger, which helps to stabilise the chains of sodium hyaluronate. In biocompatibility studies, OSTENIL® Plus was found to be particularly safe.

Presentation:

One pre-filled syringe of 40 mg/2.0 ml OSTENIL® Plus in a sterile pack.

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

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