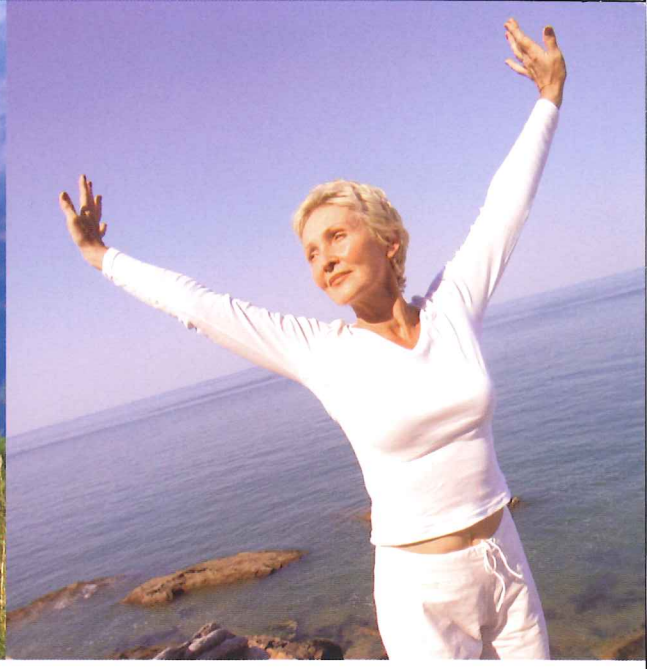
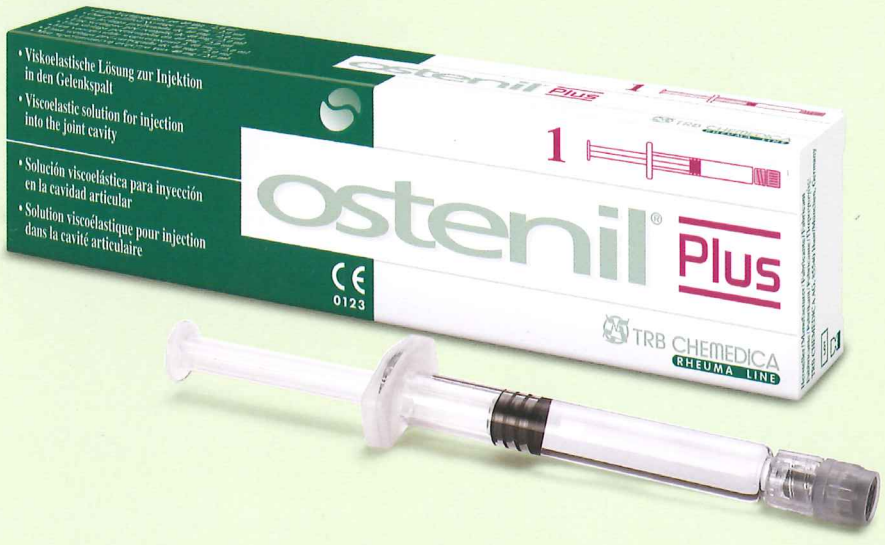


ostenil® Plus

Hyaluronic acid – protected by mannitol



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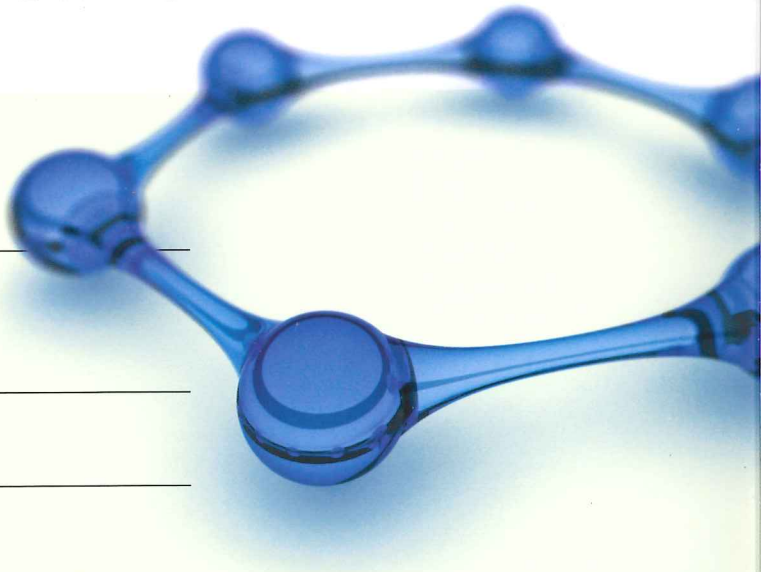
Product Information

OSTENIL® Plus

Short profile



+ 2 % Hyaluronic acid (40 mg/2 ml) from fermentative origin
+ 10 mg Mannitol
+ For all synovial joints
+ 1–3 injections in one week distance

High therapeutic efficacy with reduced frequency of applications – if indicated:

- ➔ when the time frame of patients is limited
- ➔ when it is difficult to meet the joint
- ➔ to minimize the risk of infection
- ➔ for a complete treatment range with hyaluronic acid

Hyaluronic acid – protected by mannitol

- Mannitol protects the hyaluronic acid molecule against "cracking attacks" from free radicals, the latter being generated in inflammatory processes, such as arthritis.
- The ROS (= reactive oxygen species) are negative oxygen derivates and playing a role in various diseases ("ageing of tissues").
- From this group the hydroxyl radical is the most aggressive free radical.
- ROS depolymerises hyaluronic acid.
- As a consequence, hyaluronic acid would show a decrease in viscosity and a shorter residence time at the site of action.

- **Mannitol is an effective antioxidant, protecting hyaluronic acid from depolymerisation *(Mendoza et al. 2007)*.**

INSTRUCTIONS FOR USE

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, sodium monohydrogenphosphate, sodium dihydrogenphosphate, mannitol and water for injection.

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.

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. 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 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.

Interactions with other products:
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.

Dosage and administration:
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 remains unbroken. Take the pre-filled syringe out of the sterile pack. Before usage of the pre-filled syringe the tamper-evident seal has to be tilt up. As a result the crosspieces of the tamper-evident seal break and the cap can be removed together with the tip cap (see pictures). Attach a suitable needle (for example 19 to 21 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, 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 and package size:
One pre-filled syringe of 40 mg / 2.0 ml OSTENIL® Plus in a sterile pack.

To be used by a physician only.

Last revision date: August 2008

TABLE OF PRODUCTS AND THEIR POSITION IN THE TREATMENT AND PROPHYLAXIS OF OSTEOARTHRITIS

Prophylaxis			**artilane®** for prophylaxis
Conservative treatment	**Big joint**	3–5 injections per treatment cycle	**ostenil®** 20 mg/2 ml
		1–3 injections per treatment cycle	**ostenil® Plus** 40 mg/2 ml + 10 mg Mannitol
	Small joint		**ostenil® mini** 10 mg/1 ml
Surgery			**viscoseal®** 50 mg/10 ml
			artilane® to support the treatment

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