Structovial

Instructions for use

1. Intended Use and Indication

The product is a medical device used in humans for injection into synovial joints (knee, hip, ankle and shoulder) in order to restore the natural viscoelastic properties of the synovial fluid (viscosupplementation). It is indicated for treatment of pain and restricted movement as a consequence of degenerative or traumatic changes to the synovial joint area (osteoarthritis).

2. Description

The product consists of a sterile, isotonic, viscoelastic solution for intra-articular use, supplied in a ready-to-use syringe. One ready-to-use syringe contains 2 ml of the viscoelastic solution. 1 ml of the product contains 10 mg (1 %) of sodium hyaluronate together with sodium chloride, sodium monohydrogen phosphate, citric acid and water for injection. The product is provided sterile and is intended for single use only. The product is sterilized using steam within the blister (sterile barrier). No materials of animal origin are used during manufacturing of the product or as raw materials. No pharmaceuticals are integrated into the product.

3. Method of Administration and Dosage

Take the ready-to-use syringe out of the blister, remove the rubber cap from the Luer-Lock adapter by turning it gently, attach an appropriate cannula and lock it into place by turning carefully. During administration, the syringe should be held as shown in figure 1. Depending on the size of the joint, up to 2 ml may be administered intra-articularly. In the knee, three to five injections of the product at weekly intervals are recommended. In hip, ankle and shoulder, the number of injections may range from one to five and should be chosen based on the clinical experience and the relief obtained by the patients. Several joints may be treated simultaneously and treatment cycles may be repeated. In order to avoid an intra-articular infection, a strict aseptic injection technique must be applied. After administration of the product, it is recommended that an ice-pack be placed on the treated joint for 5–10 minutes in order to prevent pain and swelling.

4. Performance and Mode of Action

In patients with degenerative joint disease (osteoarthritis), the viscoelasticity of the synovial fluid is significantly impaired. This causes mechanical stress on the joint and leads to the breakdown of the articular cartilage resulting in restricted and painful joint movement. The lubricating and shock-absorbing properties of this product help reduce pain and improve joint mobility. This effect may last for several months following a treatment cycle of three to five intra-articular injections.

5. Contraindications and Possible Interactions

The product must not be administered to patients who are known to be hypersensitive to one of the components. As this product is administered by intra-articular injection, patients with bacterial arthritis should be excluded from treatment in order to avoid possible complications. Currently there is no information of adverse interactions with other intra-articular treatments.

6. Adverse Reactions and Adverse Events

After administration, patients may experience local symptoms in the joint being treated (pain, sensation of heat, reddening and swelling). The following adverse events have been reported for similar products: mild or moderate arthralgia, in rare cases skin rash, aseptic joint effusions, pruritus and muscular cramps. Further adverse events that have been observed in very rare cases are: allergic reactions, anaphylactic shock, hemarthrosis, phlebitis, pseudosepsis, severe acute inflammatory reaction (SAIR), nasopharyngitis, joint stiffness, tendonitis, bursitis, fever and myalgia.

7. Warnings

The product must be administered only by a doctor trained to apply intra-articular injections. He or she should also be familiar with all the immunological and other potential risks associated with the use of biological material. The product has not been tested in pregnant women and in children under 18 years of age. Keep the product out of sight and reach of children. The product is intended for single use, the syringe must not be resterilized after use. The re-use of the product creates a potential infection risk for patients or users. Do not use if the sterile barrier (blister) has been opened and/or is damaged. Do not use a syringe with an open or shifted tip cap in the sterile barrier (blister). Do not administer after the expiry date. Patients should be advised to relative rest (but no immobilisation) for 24 hours after each injection in order to avoid strain on treated joints.

8. Storage

The product should be stored at room temperature (2–25 °C/36–77 °F) and protected from frost and moisture.
Available package sizes: 1, 3 ready-to-use syringes

9. Last revised

08/2012

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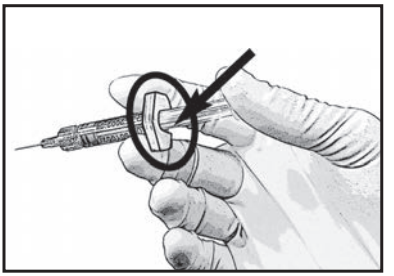
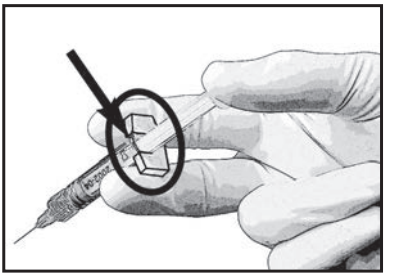
Figure 1



RIGHT! (because backstop opening at **back**)



WRONG! (because backstop opening at **front**)

Explanation of international symbols

- Do not re-use
- Consult instructions for use C
- Use by
- Batch number
- Sterilized using steam
- Keep away from sunlight Manter
- Keep dry
- Temperature limitation
- Do not use if package is damaged
- Manufacturer
- Does not contain any latex

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