SUPLASYN®
STERILE SODIUM HYALURONATE SOLUTION
Synovial Fluid Replacement

HYALURONIC ACID (HA) is a normal component of the synovia and plays a central role in maintaining the physiological internal environment of the joint.

COMPOSITION: Viscoelastic solution of a defined molecular weight of purified hyaluronic acid, produced by fermentation.

Each syringe contains:
- Hyaluronic acid sodium salt ......................... 20 mg
- Excipients q.s ........................................... 2 ml

PROPERTIES: Hyaluronic acid is the prototype of a wide range of saccharide biopolymers (glycosaminoglycans or mucopolysaccharides), important components of all extracellular tissue structures, including cartilage and synovial fluid. The active substance of SUPLASYN is a hyaluronic acid of defined molecular chain length with a high degree of purity. The introduction of SUPLASYN into the synovial space will assist in the normalization of the joint following arthrocentesis.

INDICATIONS: As a replacement for synovial fluid following arthrocentesis. SUPLASYN has been shown to be beneficial in osteoarthritis for the management of pain and improvement in physical function of joints.

DOSEAGE AND ADMINISTRATION: Depending upon joint size, up to 2 ml may be administered intra-articularly. The recommended schedule is 1 injection per week for 3 weeks, but up to 6 may be given depending on patient’s condition.

Use strict aseptic technique. More than one joint may be treated at the same time. Discard any unused portion of the syringe. To use the pre-filled syringe, remove the Luer lock cap, attach a suitable cannula (recommended is 21 – 25 G depending on joint) and secure it by turning slightly. GRADUATION ON THE SYRINGE LABEL IS TO BE USED AS A GUIDE ONLY.

CONTRAINDICATIONS/PRECAUTIONS: Do not administer to patients with known hypersensitivity reactions. Respect usual precautions and contraindications for any intra-articular injection. Do not inject intra-vascularly. SUPLASYN should not be used in patients presenting an inflammation/irritation of the joint, since adverse events more commonly occur in patients with already existing joint inflammation/irritation. As no clinical evidence is available on the use of Hyaluronic Acid in children, pregnant and lactating women, treatment with SUPLASYN is not recommended in these patients. The patient should rest 24-48 hours after the injection and avoid any strenuous activity over the full course of the treatment.

Transient short duration pain may occur following intra-articular introduction. The affected joint may show a mild local reaction like pain, feeling of heat, hyperthermia, redness, effusion, irritation, and swelling/inflammation. If these symptoms occur, rest the affected joint and apply ice locally. Symptoms subside within days for most of the patients. In some cases, mild local reactions such as pain, irritation, swelling/joint inflammation and effusion may be significantly enhanced and much more severe as an expression of hypersensitivity. In such cases, a therapeutic intervention could be necessary, e.g. aspiration of joint fluid. Local adverse reactions could be accompanied by systemic reactions such as fever, chills, or cardiovascular reactions, and in rare cases anaphylactic reactions. In extremely rare circumstances, rash/itching, urticaria, synovitis, and a drop in blood pressure have been reported following the administration of SUPLASYN. Discontinue use if adverse reactions are experienced. Avoid using SUPLASYN with instruments sterilised with quaternary ammonium salts solutions.

WARNING: KEEP OUT OF REACH OF CHILDREN. DO NOT USE IF BLISTER IS DAMAGED. TO BE USED BY A PHYSICIAN ONLY.

PACKAGING: Available in 2 ml syringes; packages of 3.

STORAGE: Store between 4°C and 25°C. DO NOT FREEZE.

Date of preparation: December 2003.

Revised: November 2008.

Manufactured by: Bioniche Teo., Inverin, Co. Galway, Ireland

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Lot Number Expiry Date For single use only! Peel here Refer to instruction leaflet Sterile by filter sterilisation Store between 4°C and 25°C

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