SYFLEXX® M

Intra-articular visco-supplement



Syflexx M, due to its unique formulation, not only possesses lubricating properties and prevents joint surface wear but also has the highest adhesion to cell surface receptors. This adhesion stimulates fibroblasts biologically, leading to increased production of hyaluronans, collagen, and elastin, potentially contributing to the reconstruction of damaged joints. Additionally, its anti-inflammatory properties prevent the production of pro-inflammatory mediators, thereby reducing pain.

Product information

Instructions

Syflexx® M

(Sterile sodium hyaluronate for intra-articular injection containing lidocaine)

Syflexx® M is supplied in an autoclave-sterilized single-use prefilled glass syringe (PFS). Each package contains an instruction leaflet and a PFS syringe and a 21G needle tip.

Compounds

Sodium hyaluronate with average molecular weight: 62.5 mg

Lidocaine hydrochloride: 7.5 mg

Phosphate buffer (pH equal to 7): until reaching the volume of 2.5 ml

This product is a sterile, non-pyrogenic, transparent, viscoelastic, biocompatible and degradable gel for intra-articular injection that is biosynthetically produced and disposable. This product must be prescribed by a licensed physician.

This product is used in the following cases:

Symptomatic treatment of mild to moderate osteoarthritis (OA) of the knee or hip.

Symptomatic treatment of pain associated with mild to moderate osteoarthritis of the ankle, shoulder and elbow.

Treatment of pain after joint arthroscopy in the presence of osteoarthritis within three months after surgery is indicated.

Amount and method of consumption

This product is a single-dose injectable product that must be injected 3 times at one-week intervals during a six-month treatment period. The recommended dose is 2.5 ml (one syringe) for each knee, hip or shoulder joint. The amount of prescription for other joints is based on the diagnosis and opinion of a specialist doctor.

Mechanism of action

Hyaluronic acid is a natural part of synovial fluid in the body and acts as a lubricant for cartilage and ligaments and as a shock absorber in joints. It has been found that synovial fluid in arthritic joints has much lower viscosity and elasticity than healthy joints. Hence, injecting this product into the joint to restore viscosity and elasticity can reduce pain and improve joint range of motion. Also, in this product, by using hyaluronic acid with medium molecular weight, biological stimulation and increased proliferation of fibroblasts and collagen production are provided.

How to Use

Instructions

- Syflexx® should only be administered by a licensed physician (or in accordance with local regulations), familiar with the intra-articular injection method for the synovial joint being treated, and using appropriate intra-articular injection facilities.
- Syflexx® should be injected using a strict aseptic technique.
- The injection site should be swabbed with alcohol or other suitable antiseptic solution before injection.
- The route of Syflexx® injection should be chosen in such a way as to avoid damage to nearby vital structures.
- This product should only be injected into the joint cavity.
- If there is joint effusion, remove it first before injecting this product. The same needle tip should be used to remove the effusion and inject this product.
- The recommended needle size is 18 to 22 G and of appropriate length.
- Using smaller needles increases the pressure required to inject the product.
- Intra-articular injection in the hip joints should be done under fluoroscopic control (preferably with contrast material) or ultrasound control to ensure the correct placement of the needle in the joint cavity.
- The injection guide for other joints is determined by the attending physician.
- Injection discomfort can be minimized by applying a local cold compress or subcutaneous local anesthetics.
- Imaging-guided injections should only be performed by physicians experienced in this type of

injection.

Please inform your patient that:

- As with any joint injection procedure, it is recommended that you avoid vigorous physical activity (such as tennis, running, or prolonged walking) for the first two days after the injection.
- Some transient reactions related to the injection of this product, such as mild to moderate pain, swelling and stiffness in the first week after injection, can be expected. If the symptoms last more than a week, contact your doctor.

Maintenance

It should be stored in a dry and cool place at a temperature below 30 degrees Celsius, outside the refrigerator and away from frost and heat. Also keep out of reach of children.

Contraindications

Prohibited Usage

Syflexx® should not be injected in case of allergy to hyaluronic acid and similar compounds, as well as allergy to other components of the product.

Warnings

- Syflexx® should not be injected if the synovial joint is infected or severely inflamed.
- Syflexx® should not be injected if there is an active skin disease or infection at or near the injection site.
- This product should not be injected intravascularly, extra-articularly, in the synovial tissue or outside the joint capsule.
- Do not resterilize this product, as this may damage the product.
- Do not use disinfectants containing quaternary ammonium salts at the same time as skin preparation because hyaluronic acid can precipitate in their presence.

Precautions

- This product should be used with caution in patients with venous or lymphatic stasis in the legs.
- This product has not been tested on pregnant, lactating women or children.
- A separate needle head should be used for each joint to be treated.
- As with any joint injection procedure, there is a small risk of infection when injecting this product.
- If the patient is known to be allergic or sensitive to local anesthetics, local anesthetics should not be used.
- Injection under fluoroscopic control and using contrast material should not be done if the patient is known to be allergic or sensitive to contrast material.
- Increased injection pressure may indicate incorrect placement of the needle outside the joint or overfilling the joint.
- This product should be used with caution in patients with pre-existing chondrocalcinosis as the injection may lead to an acute attack of the disease.
- Do not use the product if the package is damaged.
- Do not use the product if the expiration date has passed.

Side Effects

Most of the side effects reported in clinical studies for the treatment of osteoarthritis of the knee, hip, shoulder, and ankle are described as transient pain, swelling, or local stiffness at the injection site.

These side effects were of mild or moderate severity and only occasionally required treatment with analgesics or NSAIDs.

Other side effects may include headache, local itching and skin reactions at the injection site.

Any other side effects should be reported to the treating physician and representative of this product or to the local distributor of the product

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