PRODUCT INFORMATION

# ARTHRUM 2,5% MONO INJECTION


SODIUM HYALURONATE (HA 75mg) 3 ml

ENGLISH

**DESCRIPTION :**

**ARTHRUM 2.5% MONO INJECTION** is a sterile viscoelastic device containing a natural derivative of hyaluronic acid, sodium hyaluronate, obtained by biofermentation, not chemically modified, with a very high molecular weight > 2,800,000 Daltons and a high concentration of 25mg/mL (75 mg per intra-articular injection).

**ARTHRUM 2.5% MONO INJECTION** does not contain any protein of avian origin and is not cross-linked by a chemical agent, eliminating any risk of allergy and potential cytotoxicity and ensuring perfect tolerability and safety during long-term use.

**ARTHRUM 2.5% MONO INJECTION** complies with the European Pharmacopoeia, ISO standards and EEC Directive 93/42, which guarantees the perfect safety and biocompatibility of the implantable device.

The high molecular weight combined with a high concentration of sodium hyaluronate in **ARTHRUM 2.5% MONO INJECTION** is a factor of efficacy in the symptomatic treatment of osteoarthritis by making up for the qualitative and quantitative insufficiency of sodium hyaluronate in the synovial fluid of osteoarthritic joints.

**DOSAGE FORM AND PRESENTATION :**

**ARTHRUM 2.5% MONO INJECTION** is a sterile, transparent, homogeneous viscoelastic preparation, not chemically modified, composed of highly purified sodium hyaluronate obtained by bacterial fermentation, containing 75 mg of sodium hyaluronate per 3-mL syringe.

**ARTHRUM 2.5% MONO INJECTION** is a sterile viscoelastic preparation supplied (3 mL) in pre-filled glass syringe with disposable needle, Luer lock.
A label mentioning the name of the product is placed on the syringe.
The syringe is supplied with an individual cover to provide sterility protection.
The syringe, package insert and disposable needle are included in a packaging that contains a list of the complete identification of the implantable viscoelastic device : **ARTHRUM 2.5% MONO INJECTION** Box of 1 syringe.

**COMPOSITION :**

Each syringe of **ARTHRUM 2.5% MONO INJECTION** contains :

| | |
|---|---|
| Sodium hyaluronate FB | 75 mg |
| Sodium chloride | 27 mg |
| Borate buffer | pH 7.2 ± 0.2 |
| Water for injection | to 3.0 ml |

Sterilization is done by steam autoclaving.
The content of every syringe is sterile and non-pyrogenic.

**PROPERTIES :**

Sodium hyaluronate exists naturally in human body and is a major constituent of intercellular matrix.
In joints, it is a structural component of cartilage and synovial fluid that acts as a lubricant, a shock absorber, a filter and a metabolic medium.
**ARTHRUM 2.5% MONO INJECTION** is biologically similar to the sodium hyaluronate of the human body.
The functions of **ARTHRUM 2.5% MONO INJECTION** are as follows :

• Protective effect on cartilage
- The lubricating properties of sodium hyaluronate molecules in synovial fluid allow the joint surfaces to slide against each other and protect them from mechanical damage.
- By reducing the stress on weight-bearing joints, the elastic properties protect cartilage from compressive forces.

• Metabolism interface
- Small molecules such as water, electrolytes and nutrients can diffuse readily in the direction of the cartilage and the synovial membrane.

• structure-modifying effect
- Sodium hyaluronate provides a protective barrier by masking the pain receptors of the synovial membrane.

The sodium hyaluronate is normally present in synovial fluid of healthy joints and is deteriorated both in terms of concentration and molecular weight in osteoarthritic joints. In the treatment of osteoarthritis, **ARTHRUM 2.5% MONO INJECTION** therefore has the effect of improving the deficient rheological characteristics of the synovial fluid (viscosity and elasticity). These characteristics are important for shocks absorption and lubrication and protection of cartilage surfaces. The rheological properties of 2.5 Hz of **ARTHRUM 2.5% MONO INJECTION** exceed those of healthy synovial fluid to anticipate dilution effect within joint. The use of a high molecular weight also increases the residence time in the joint.
In addition, different beneficial biological effects are attributed to hyaluronic acid in the joint, as have been expressed in journals that reviewed numerous scientific publications.

**INDICATIONS :**

**ARTHRUM 2.5% MONO INJECTION** viscoelastic devices are indicated in the symptomatic treatment of osteoarthritis of the knee, in particular for reducing pain and restoring joint mobility by replacing and supplementing the elastoviscosity of the synovial fluid in osteoarthritic joints.

The therapeutic indications are for all types of painful osteoarthritis of the knee :

- Primary osteoarthritis of the knee (Kellgren radiological stages I, II and III)
- Osteoarthritis of the knee and associated systemic factors :
  • Ineffectiveness of the usual treatments.
  • Intolerance and/or contraindication of NSAIDs or analgesics.
  • Use of anticoagulants, polymedication (hypertension, diabetes, obesity, cardiovascular and gastrointestinal problems).
  • Contraindications related to the placement of a prosthesis : young subjects and various contraindications related to the patient's condition.
- Incipient osteoarthritis of the knee of young subjects.
- Knee osteoarthritis secondary to traumas and sequelae of joint fractures.

**ADMINISTRATION :**

**ARTHRUM 2.5% MONO INJECTION** must be given by intra-articular injection by a suitably trained physician.

• Make sure that the individual sterility protection cap remains unopened and check the expiration date.
• Open the individual sterility protection cap aseptically.
• Remove the syringe aseptically.
• Screw the injection needle onto the Luer-Lock fitting after removing the cap without touching the tip of the syringe with your finger.
• Proceed with the intra-articular injection.
The content of the syringe is for a single use only.
• The syringe and needle must be discarded immediately after use.
They are to be disposed of in a waste receptacle specifically intended for single-use products.

**DOSAGE :**

**ARTHRUM 2.5% MONO INJECTION** is for adults only. The dosage schedule of **ARTHRUM 2.5% MONO INJECTION** is one intra-articular injection in the knee.
A second injection may be repeated between the first and third month if this is justified by the painful symptoms of the patient.

**PRECAUTIONS FOR USE :**

The following precautions for use are recommended :
• Make sure that the individual sterility protection cap of the product remains unopened before use.
• Aseptic procedures must be followed.
• Do not inject other products at the same time as **ARTHRUM 2.5% MONO INJECTION**.
• The precautions for use are the ones required by the protocol utilized for intra-articular injections in rheumatology and orthopedic surgery.
The specialist physicians are responsible for their own techniques and indications.
• It is recommended that, as with any intra-articular injection, the patients be advised to remain at rest for 24 hours and to avoid engaging in any sports or occupational activity.

Warnings :
Do not inject in a blood vessel
Do not inject outside of the articular cavity or in the synovial tissue or capsule and/or in the presence of a large effusion.
**ARTHRUM 2.5% MONO INJECTION** has not been studied in pregnant women.

**INCOMPATIBILITIES :**

Do not use quaternary ammonium (benzalkonium chloride) to disinfect the skin for the injection of **ARTHRUM 2.5% MONO INJECTION**.

**CONTRAINDICATIONS :**

• All inflammatory pathological joint conditions, which should be treated before administering a treatment by intra-articular injection of **ARTHRUM 2.5% MONO INJECTION**.
• Do not administer if the patient has a known hypersensitivity to sodium hyaluronate.

**ADVERSE EFFECTS :**

**ARTHRUM 2.5% MONO INJECTION** is well tolerated in man. Sometimes, pain may occur for 48 hours. It is recommended that an ice pack be applied for a few hours.

**STORAGE :**

Protect from light and frost. Store between +2°C and +30°C.
After opening, the **ARTHRUM 2.5% MONO INJECTION** viscoelastic device must be used immediately and discarded after use.

Year of CE Mark authorization : 2009.
Date of revision of the package insert : 2016-11.

For professional use only.

CE 0459 STERILE 2 2 STERILIZE 2°C 30°C

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